UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

SCHEDULE 14A
(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934
(Amendment No.)

Filed by the Registrant ☒ Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☒ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material under § 240.14a-12

Ayala Pharmaceuticals, Inc.
(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

☐ Fee paid previously with preliminary materials.

☐ Fee computed on table in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11.

DATED DECEMBER 12, 2022

PROPOSED MERGER

YOUR VOTE IS VERY IMPORTANT

To the Stockholders of Ayala Pharmaceuticals, Inc.,

Ayala Pharmaceuticals, Inc., a Delaware corporation ("Ayala"), Advaxis, Inc., a Delaware corporation ("Advaxis"), and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis, entered into an Agreement and Plan of Merger (the "Merger Agreement"), on October 18, 2022, pursuant to which Merger Sub will merge with and into Ayala, with Ayala surviving as a wholly owned subsidiary of Advaxis, and the surviving company of the merger, which transaction is referred to herein as the Merger. Advaxis following the Merger is referred to herein as the combined company.

At the effective time of the Merger (the "Effective Time") each share of Ayala's Common Stock, par value $0.01 per share, (the "Ayala Common Stock"), issued and outstanding immediately prior to the Effective Time (other than shares held in treasury, if any) will be converted into the right to receive a number of shares of Advaxis' Common Stock, par value $0.001 per share (the "Advaxis Common Stock"), equal to the exchange ratio, which was initially 0.1874 shares as of October 18, 2022 and may be adjusted at the closing of the Merger based on the formula set forth in the Merger Agreement (the "Exchange Ratio") described in more detail in the section titled "*The Merger Agreement—Merger Consideration*" beginning on page 181 of the accompanying proxy statement/prospectus.

In addition, each outstanding option to purchase shares of the Ayala Common Stock (each, an "Ayala Option") unexercised immediately before the Effective Time, automatically and without any action on the part of the holder thereof, shall be assumed by Advaxis and converted into an option for Advaxis Common Stock (each, an "Advaxis Replacement Option") with the number of shares subject to, and the per share exercise price of, such option adjusted to reflect the Exchange Ratio. Each such substituted Advaxis Replacement Option shall continue to have, and shall be subject to, the same terms and conditions (including the applicable time-vesting and/or performance-vesting conditions) as applied to the Ayala Option immediately prior to the Effective Time. Further, each warrant to purchase shares of Ayala Common Stock (the "Ayala Common Warrants"), shall, upon the effective time of the Merger, become warrants to purchase Advaxis Common Stock (the "Advaxis Replacement Warrants"). The Holders of the Ayala Common Warrants shall have the right to receive, upon exercise of their Ayala Replacement Warrants, the number of shares subject to the warrant to be adjusted to reflect the Exchange Ratio. Ayala's pre-funded warrants to purchase common stock shall be automatically net exercised in accordance with their terms immediately prior to the Effective Time and the holders of the pre-funded warrants will hold Ayala Common Stock at the Effective Time as a result of such exercise. All other securities of Ayala shall be cancelled and shall be of no further force and effect from the Effective Time of the Merger and shall not be assumed or converted into a right to receive any shares of Advaxis Common Stock.

Each share of Advaxis Common Stock and option to purchase Advaxis Common Stock that is issued and outstanding at the Effective Time of the Merger will remain issued and outstanding, and such shares and options will be unaffected by the Merger. Immediately after the Merger, Advaxis stockholders as of immediately prior to the Merger are expected to own approximately 37.5% of the outstanding shares of the combined company and former Ayala stockholders are expected to own approximately 62.5% of the outstanding shares of the combined company.

Shares of Advaxis Common Stock are currently quoted on OTCQX under the symbol "ADXS." On December 9, 2022 the last trading day before the date of the accompanying proxy statement/prospectus, the closing sale price of Advaxis Common Stock on the OTCQX was $1.62 per share. After completion of the Merger, it is expected that the common stock of the combined company will be quoted on the OTCQX under the symbol "ADXS". Advaxis intends to file an initial listing application with The Nasdaq Stock Market LLC ("Nasdaq") prior to the closing of the Merger, and to undertake the actions necessary to allow the stock of the combined company to be listed on The Nasdaq Capital Market as of the closing of the Merger or promptly thereafter. However, because Advaxis is not currently listed on Nasdaq, the combined company will be required to meet the initial listing standards of The Nasdaq Capital Market applicable to companies seeking to uplist one or more securities from another U.S. market, such as the OTCQX. While Ayala and Advaxis intend to use their best commercially practicable efforts to have the stock of the combined company approved for listing on Nasdaq as of the closing of the Merger or promptly thereafter, no assurance can be made that these efforts will be successful.

Ayala stockholders are cordially invited to attend the special meeting of Ayala stockholders. Ayala is holding its special meeting of stockholders, or the Ayala Special Meeting, on January 13, 2023, at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date, in order to obtain the stockholder approvals necessary to complete the Merger and related matters. The Ayala Special Meeting will be held entirely as a virtual meeting. Ayala stockholders will be able to attend and participate in the Ayala Special Meeting online by visiting www.virtualshareholdermeeting.com/AYLA2023SM where they will be able to listen to the meeting live, submit questions and vote. At the Ayala Special Meeting, Ayala will ask its stockholders to:

- approve the adoption of the Merger Agreement, which is further described in the section titled "*The Merger Agreement*" and a copy of which is attached to this proxy statement/prospectus as Annex A (the "Ayala Merger Proposal"); and

- approve the adjournment of the Ayala Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes to approve the Ayala Merger Proposal.

As described in the accompanying proxy statement/prospectus, certain Ayala stockholders who in the aggregate own approximately 42.5% of the Ayala Common Stock as of October 31, 2022, are parties to voting and support agreements with Advaxis (the "Voting Agreements"), whereby such stockholders have agreed to vote in favor of, and to adopt and approve, the Merger Agreement, the Merger and the related transactions at any meeting of Ayala's stockholders, as applicable (or any adjournment or postponement thereof), subject to the terms of the Voting Agreements.

After careful consideration, the Ayala board of directors (the "Ayala Board") has approved the Merger Agreement and has determined that it is advisable to consummate the Merger. The Ayala Board has approved the proposals described in the accompanying proxy statement/prospectus and unanimously recommends that its stockholders vote "FOR" the proposals described in the accompanying proxy statement/prospectus.

More information about Advaxis, Ayala, the Merger Agreement and the transactions contemplated thereby (collectively the "Transactions"), and the foregoing proposals is contained in the accompanying proxy statement/prospectus. Ayala urges you to read the accompanying proxy statement/prospectus carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER "RISK FACTORS" BEGINNING ON PAGE 25 OF THE ACCOMPANYING PROXY STATEMENT/PROSPECTUS.

Ayala is excited about the opportunities the Merger brings to Ayala's stockholders and thanks you for your consideration and continued support.

Sincerely,

/s/ Roni Mamluk

Roni Mamluk, Ph.D.
President and Chief Executive Officer
Ayala Pharmaceuticals, Inc.

Neither the U.S. Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the accompanying proxy statement/prospectus. Any representation to the contrary is a criminal offense.

The accompanying proxy statement/prospectus is dated December 12, 2022 and is first being mailed to Ayala stockholders on or about December 13, 2022.

AYALA PHARMACEUTICALS, INC.
Oppenheimer 4
Rehovot 7670104, Israel

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS
TO BE HELD JANUARY 13, 2023

To the Stockholders of Ayala Pharmaceuticals, Inc.:

NOTICE IS HEREBY GIVEN that Ayala Pharmaceuticals, Inc. ("Ayala") will hold a virtual special meeting of stockholders (the "Ayala Special Meeting"), on January 13, 2023, at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date. The Ayala Special Meeting will be held entirely as a virtual meeting. You will be able to attend and participate in the Ayala Special Meeting online by visiting www.virtualshareholdermeeting.com/AYLA2023SM, where you will be able to listen to the meeting live, submit questions and vote.

The Ayala Special Meeting will be held for the following purposes:

1. To consider and vote upon the proposal to adopt the Agreement and Plan of Merger (the "Merger Agreement"), dated as of October 18, 2022, as amended or supplemented from time to time, by and among Ayala, Advaxis, Inc. ("Advaxis") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis, pursuant to which Merger Sub will merge with and into Ayala, with Ayala surviving as a wholly-owned subsidiary of Advaxis, as more fully described in the attached proxy statement/prospectus (the "Ayala Merger Proposal"); and

2. To consider and vote upon the proposal to approve the adjournment of the Ayala Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Ayala Merger Proposal (the "Ayala Adjournment Proposal").

Record Date: Ayala's board of directors has fixed December 7, 2022 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Ayala Special Meeting and any adjournment or postponement thereof (the "Record Date"). Only holders of record of shares of Ayala Common Stock at the close of business on the Record Date are entitled to notice of, and to vote at, the Ayala Special Meeting. At the close of business on the Record Date, Ayala had 14,820,727 shares of common stock outstanding and entitled to vote.

Your vote is important. The affirmative vote of the holders of a majority of the outstanding shares of Ayala Common Stock entitled to vote at the Ayala Special Meeting is required for approval of the Ayala Merger Proposal. Approval of the Ayala Merger Proposal is a condition to the completion of the Merger. Therefore, the Merger cannot be consummated without the approval of the Ayala Merger Proposal. The Ayala Merger Proposal is described in more detail in the section titled "*The Merger Agreement*" in the accompanying proxy statement/prospectus, which you should read carefully in its entirety before you vote. A copy of the Merger Agreement is attached as Annex A to the accompanying proxy statement/prospectus.

Even if you plan to virtually attend the Ayala Special Meeting, Ayala requests that you sign and return the enclosed proxy card or vote by mail or online to ensure that your shares will be represented at the Ayala Special Meeting if you are unable to virtually attend. You may change or revoke your proxy at any time before it is voted at the Ayala Special Meeting.

After careful consideration, the Ayala Board has approved the Merger Agreement and has determined that it is advisable to consummate the Merger. The Ayala Board has approved the proposals described in the accompanying proxy statement/prospectus and unanimously recommends that its stockholders vote "FOR" the proposals described in the accompanying proxy statement/prospectus.

By Order of Ayala's Board of Directors,

/s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Secretary and Treasurer
Rehovot, Israel
December 12, 2022

ABOUT THIS PROXY STATEMENT/PROSPECTUS

This document, which forms part of a registration statement on Form S-4 filed with the SEC by Advaxis, constitutes a prospectus of Advaxis under the Securities Act of 1933, as amended (the "Securities Act"), with respect to the shares of Advaxis Common Stock to be issued to Ayala stockholders pursuant to the Merger Agreement. This document also constitutes a proxy statement of Ayala under Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). It also constitutes a notice of meeting with respect to the special meeting, at which Ayala stockholders will be asked to consider and vote on the adoption of the Merger Agreement and certain related matters.

Advaxis has supplied all information contained in this proxy statement/prospectus relating to Advaxis, and Ayala has supplied all information contained in this proxy statement/prospectus relating to Ayala.

You should rely only on the information contained in this proxy statement/prospectus. Advaxis and Ayala have not authorized anyone to provide you with information that is different from that contained in this proxy statement/prospectus. This proxy statement/prospectus is dated December 12, 2022, and you should not assume that the information contained in this proxy statement/prospectus is accurate as of any date other than such date. Neither the mailing of this proxy statement/prospectus to Ayala stockholders nor the issuance by Advaxis of shares of Advaxis Common Stock pursuant to the Merger Agreement will create any implication to the contrary.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "design," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "seek," "should," "will" or the negative of these terms or other similar expressions.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- the plans, strategies and objectives of management for future operations, including the execution of integration and restructuring plans and the anticipated timing of filings;
- plans to develop and commercialize products;
- the plans, strategies and objectives of management with respect to the approval and consummation of the Merger;
- the expected benefits of and potential value created by the Merger for the stockholders of Advaxis and Ayala;
- the satisfaction of certain conditions to the completion of the Merger and whether and when the Merger will be consummated;
- Advaxis' ability to control and correctly estimate its operating expenses and its expenses associated with the Merger;
- the attraction and retention of highly qualified personnel;
- the ability to protect and enhance the combined organization's products, product candidates and intellectual property;
- expectations concerning Ayala's relationships and actions with third parties;
- the ability of the combined company to list on the Nasdaq; and
- future regulatory, judicial and legislative changes in Ayala's industry.

You should not rely upon forward-looking statements as predictions of future events. Neither Advaxis nor Ayala can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. In addition, statements that "we believe" and similar statements reflect the beliefs and opinions on the relevant subject of Advaxis, Ayala or the combined organization, as applicable. These statements are based upon information available as of the date of this prospectus, and while Advaxis, Ayala or the combined organization, as applicable, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation:

- the risk that the conditions to the closing are not satisfied, including the failure to timely, or at all, obtain stockholder approval for the Merger;
- uncertainties as to the timing of the consummation of the Merger; risks related to Advaxis' ability to correctly estimate its operating expenses and its expenses associated with the Merger;
- the ability of Advaxis, Ayala or the combined organization to protect its intellectual property rights; competitive responses to the Merger;
- unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Merger;
- legislative, regulatory, political and economic developments; and
- the risks set forth in the section titled "Risk Factors" in this proxy statement/prospectus.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Advaxis, Ayala or the combined organization could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus are current only as of the date on which the statements were made. Advaxis and Ayala do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as otherwise required by the federal securities laws.

QUESTIONS AND ANSWERS ABOUT THE MERGER

The following are answers to some questions that you, as a stockholder of Ayala, may have regarding the proposed Merger between Ayala and Advaxis and the proposals to be considered at the Ayala Special Meeting. This section does not provide all the information that might be important to you with respect to the proposed Merger between Ayala and Advaxis. Ayala and Advaxis urge you to carefully read the remainder of this proxy statement/prospectus, including the annexes.

Q: Why am I receiving this proxy statement/prospectus?

A: Ayala, Advaxis and Merger Sub have entered into the Merger Agreement. The Merger Agreement provides, among other things, that, upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Ayala, with Ayala surviving the Merger as a wholly owned subsidiary of Advaxis. A copy of the Merger Agreement is included in this proxy statement/prospectus as Annex A.

The Merger cannot be completed unless, among other things, Ayala's stockholders adopt the Merger Agreement. The approval of Advaxis' stockholders is not required for the Merger to be completed.

Ayala is using this document as a proxy statement to solicit proxies from Ayala's stockholders in connection with proposals relating to the Merger at the Ayala Special Meeting. Advaxis is using this document as a prospectus by which Advaxis will offer and issue Advaxis Common Stock in connection with the Merger.

This proxy statement/prospectus contains important information about the Merger and the other proposals being voted on at the Ayala Special Meeting. You should read it carefully and in its entirety. The enclosed materials allow you to have your shares voted by proxy without attending the Ayala Special Meeting, which will be held virtually. Your vote is important. We encourage you to submit your proxy as soon as possible.

Q: What am I being asked to vote on?

A: At the Ayala Special Meeting, Ayala stockholders will be asked to consider and vote on the following proposals:

1. To approve the adoption of the Merger Agreement, pursuant to which Merger Sub will merge with and into Ayala, with Ayala surviving as a wholly-owned subsidiary of Advaxis (the "Ayala Merger Proposal"); and

2. To approve the adjournment of the Ayala Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Ayala Merger Proposal (the "Ayala Adjournment Proposal").

The approval of Advaxis' stockholders is not required for the Merger to be completed.

Q: Why are Ayala and Advaxis proposing the Merger?

A: The boards of directors of Advaxis and Ayala believe that the Merger will provide substantial strategic and financial benefits to the companies, Advaxis' stockholders and Ayala's stockholders. To review the reasons for the Merger, see "*The Merger—Advaxis Reasons for the Merger*" and "*The Merger—Ayala's Reasons for the Merger; Recommendation of the Ayala Board*" for more information.

Q: What will I receive in the Merger?

A: At the Effective Time, each share of Ayala Common Stock outstanding at that time (other than certain shares of Ayala Common Stock that may be cancelled pursuant to the terms and conditions of the Merger Agreement) will be converted into the right to receive a number of shares of Advaxis Common Stock equal to the Exchange Ratio, provided, however that such stock merger consideration is subject to further adjustment as described in this proxy statement/prospectus.

Q: What is the Exchange Ratio and how is it calculated?

A: The Exchange Ratio is 0.1874 as of the date of the Merger Agreement and is subject to adjustment at the Effective Time to reflect the following ratio (rounded to four decimal places): the quotient obtained by dividing (a) (i) $14,859,960 divided by (ii) the total number of shares of Ayala capital stock outstanding at that time on an as-exercised basis and using the treasury stock method by (b) (i) $8,915,976 divided by (ii) the total number of shares of Advaxis Common Stock outstanding at that time on an as-exercised basis and using the treasury stock method.

Q: Are Ayala stockholders guaranteed to receive exactly 0.1874 shares of Advaxis Common Stock for each share of Ayala Common Stock exchanged in the Merger?

A: No. For the reasons discussed in this proxy statement/prospectus, the overall value of the merger consideration you receive is subject to change and could vary from these numbers. As a result, you may receive more or less overall value in total merger consideration. See "*Risk Factors*" and "*The Merger Agreement—Merger Consideration*."

Q: What equity stake will Ayala stockholders hold in Advaxis immediately following the Merger?

A: Upon the closing of the Merger, based upon the number of shares of Advaxis Common Stock expected to be issued in the Merger and an unadjusted Exchange Ratio, pre-merger Advaxis stockholders will own approximately 37.5% of the combined company and pre-merger Ayala stockholders will own approximately 62.5% of the combined company.

Q: How will the Merger affect the Ayala equity awards?

A: ***Stock Options.*** Pursuant to the Merger Agreement, at the Effective Time, each option to purchase Ayala Common Stock (each, an "Ayala Option") granted under Ayala's 2017 Stock Incentive Plan, as amended, that is outstanding and unexercised immediately prior to the Effective Time, will be converted into an option to purchase Advaxis Common Stock (each, an "Adjusted Option") equal to the product obtained by multiplying (i) the number of shares of Ayala Common Stock subject to the Ayala Option immediately prior to the Effective Time, by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share. Each Adjusted Option shall have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the Effective Time, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent. Each Adjusted Option shall otherwise be subject to the same terms and conditions applicable to the corresponding Ayala Option under Ayala's 2017 Stock Incentive Plan, as amended, and the agreements evidencing grants thereunder, including vesting terms and provisions.

Restricted Stock Units. Pursuant to the Merger Agreement, at the Effective Time, each restricted stock unit with respect to a number of shares of Ayala Common Stock (each, an "Ayala RSU") that is outstanding immediately prior to the Effective Time, whether or not vested, will be converted into a restricted stock unit with respect to a number of shares of Advaxis Common Stock (each, an "Adjusted RSU") equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the Effective Time by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share. Each Adjusted RSU shall otherwise be subject to the same terms and conditions applicable to the corresponding Ayala RSU under, as applicable, Ayala's 2017 Stock Incentive Plan, as amended, and the agreements evidencing grants thereunder, including vesting terms.

Restricted Stock. As outstanding shares of Ayala Common Stock, all restricted stock awards ("Ayala Restricted Stock") that are outstanding will be substituted and converted automatically into the right to receive a number of shares of Advaxis Common Stock equal to the Exchange Ratio, provided, however that such stock merger consideration is subject to further adjustment as described in this proxy statement/prospectus. In accordance with the terms of the applicable restricted stock award agreement, these shares of Advaxis Common Stock shall be subject to the terms and conditions applicable to the corresponding Ayala Restricted Stock under, as applicable, Ayala's 2017 Stock Incentive Plan, as amended, and the agreements evidencing grants thereunder, including vesting terms.

Q: When and where is the Ayala Special Meeting?

A: The Ayala Special Meeting will be held on January 13, 2023, at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date. The Ayala Special Meeting will be held entirely online. You will be able to attend and participate in the Ayala Special Meeting online by visiting *www.virtualshareholdermeeting.com/AYLA2023SM*, where you will be able to listen to the meeting live, submit questions and vote.

Q: What do I need to do now?

A: After you have carefully read this proxy statement/prospectus and have decided how you wish to vote your shares, please vote your shares promptly so that your shares are represented and voted at the Ayala Special Meeting, even if you plan on attending. If you hold your shares in your name as a stockholder of record, you must complete, sign, date and mail your proxy card in the enclosed postage-paid return envelope as soon as possible or vote by Internet or phone, following the instructions on your proxy card. If you hold your shares in "street name" through a bank, broker or other nominee, you must direct your bank, broker or other nominee how to vote in accordance with the instructions you have received from your bank, broker or other nominee.

Q: What constitutes a quorum for the Ayala Special Meeting?

A: A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present at the Ayala Special Meeting if the holders of a majority in voting power of all issued and outstanding shares of Ayala Common Stock entitled to vote as of the close of business on December 7, 2022, which is the Record Date of the Ayala Special Meeting, are present virtually at the Ayala Special Meeting or represented by proxy. As of the close of business on the Record Date, there were 14,820,727 shares of Ayala Common Stock issued and outstanding and entitled to vote. This means that at least 7,410,364 shares must be represented by stockholders present virtually at the Ayala Special Meeting or represented by proxy to have a quorum. Your shares will be counted towards the quorum if you submit a valid proxy or attend the Ayala Special Meeting. Abstentions and broker non-votes, if any, will be included in determining the number of shares present at the meeting for the purpose of determining the presence of a quorum.

Q: What is the vote required to approve each proposal?

A: Approval of the Ayala Merger Proposal requires the affirmative vote of a majority of the outstanding shares of Ayala Common Stock entitled to vote on the proposal. **If you mark "ABSTAIN" on your proxy card or when voting by Internet or phone, fail to submit a proxy, fail to vote at the Ayala Special Meeting or fail to instruct your bank, broker or other nominee with respect to the Ayala Merger Proposal, it will have the same effect as a vote "AGAINST" the proposal.** Approval of the Ayala Adjournment Proposal requires the affirmative vote of a majority in voting power of the votes cast affirmatively or negatively at the Ayala Special Meeting. If you mark "**ABSTAIN**" on your proxy card or when voting by Internet or phone, fail to submit a proxy, fail to vote at the Ayala Special meeting or fail to instruct your bank, broker or other nominee with respect to the Ayala Adjournment Proposal, it will have no effect on the proposal.

Q: How does the Ayala Board recommend that I vote at the Ayala Special Meeting?

A: The Ayala Board recommends that Ayala's stockholders vote "**FOR**" the Ayala Merger Proposal and "**FOR**" the Ayala Adjournment Proposal.

Q: Why is my vote important?

A: The Merger will not be completed unless Ayala stockholders holding at least a majority of the shares of Ayala Common Stock outstanding as of the close of business on the Record Date vote to approve the Ayala Merger Proposal. If you do not return your proxy, it will be more difficult for Ayala to obtain the necessary quorum to hold the Ayala Special Meeting. In addition, your failure to submit a proxy or vote electronically at the Ayala Special Meeting, your failure to instruct your bank, broker or other nominee how to vote, or if you mark "**ABSTAIN**" on your proxy card or when voting by Internet or phone, will have the same effect as a vote "**AGAINST**" the Ayala Merger Proposal.

The approval of Advaxis' stockholders is not required for the Merger to be completed.

Q: Who can vote at the Ayala Special Meeting?

A: Holders of outstanding shares of Ayala Common Stock as of the close of business on the Record Date are eligible to vote at the Ayala Special Meeting.

Q: Am I a stockholder of record or a beneficial owner? Why does this matter?

A: If on the Record Date your shares were registered directly in your name with Ayala's transfer agent, American Stock Transfer & Trust Company, LLC, then you are a stockholder of record with respect to those shares.

If on the Record Date your shares were held in an account at a broker, bank or other similar organization as your nominee, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Ayala Special Meeting.

The form in which you own your shares affects how you vote your shares and how you can change your vote.

Q: How do I attend the Ayala Special Meeting and how can I vote my shares?

A: Ayala is conducting a virtual Special Meeting so its stockholders can participate from any geographic location with internet connectivity. Ayala has designed the format of the virtual online Ayala Special Meeting to provide stockholders the same ability to participate that they would have at an in-person meeting.

To attend, you must go to the meeting website at *www.virtualshareholdermeeting.com/AYLA2023SM* and enter the 16-digit control number found on your proxy card or voting instruction form sent to you by your bank, broker or other nominee. Once admitted, during the Ayala Special Meeting, you may vote, submit questions and view the list of stockholders entitled to vote at the Ayala Special Meeting by following the instructions available on the meeting website.

Access to the meeting platform will begin at 9:45 a.m. Eastern Time on January 13, 2023. If you encounter any difficulties accessing the virtual meeting during check-in or during the meeting, please call the technical support number that will be posted on the meeting website login page at *www.virtualshareholdermeeting.com/AYLA2023SM*. Technical support will be available beginning at 9:45 a.m. Eastern Time on January 13, 2023 and will remain available until the meeting has ended.

Rules for the conduct of the Ayala Special Meeting will be available on the meeting website. To obtain a copy of the rules of conduct for the Ayala Special Meeting in advance of the Ayala Special Meeting, please submit an email to oren.e@ayalapharma.com.

Regardless of whether you plan to participate in the Ayala Special Meeting, it is important that your shares be represented and voted at the Ayala Special Meeting. Accordingly, Ayala encourages you to vote in advance of the Ayala Special Meeting.

Q: How can I vote my shares of Ayala Common Stock?

A: For each proposal, you may vote "**FOR"** or **"AGAINST"** each proposal, or **"ABSTAIN"** from voting on such proposal.

If you are a stockholder of record, you may vote by proxy via telephone, over the Internet or by returning a proxy card, or you may vote online at the Ayala Special Meeting. Regardless of whether you plan to participate in the Ayala Special Meeting, we urge you to vote by proxy to ensure your vote is counted. You may still participate in the Ayala Special Meeting and vote online during the Ayala Special Meeting if you have already voted by proxy.

- You may vote your shares by proxy over the Internet, by telephone or by returning your proxy card by mail in the envelope provided. Instructions to vote over the Internet or by telephone are printed on your proxy card. To vote using the proxy card, please complete, sign and date the enclosed proxy card and return it promptly to Broadridge as provided on the proxy card. If you vote by proxy via telephone, over the Internet or by returning your signed proxy card to Broadridge before the Ayala Special Meeting, we will vote your shares as you direct.

- To vote online during the Ayala Special Meeting, you must go to the meeting website at *www.virtualshareholdermeeting.com/AYLA2023SM*. Once admitted, during the Ayala Special Meeting, you may vote by following the instructions available on the meeting website.

The deadline for receipt of a completed proxy card returned by mail at the address stated on the proxy card is 6:00 p.m. Eastern Time on January 12, 2023. The deadline for voting via the Internet or by telephone is 11:59 p.m. Eastern Time on January 12, 2023.

If you sign and return your proxy card but do not mark your card to instruct the proxies how to vote your shares of Ayala Common Stock on each proposal, your shares of Ayala Common Stock will be voted "**FOR**" the Ayala Merger Proposal and "**FOR**" the Ayala Adjournment Proposal, in accordance with the recommendation of the Ayala Board.

If you are a beneficial owner, you may vote your shares by directing the broker, bank or other similar organization that holds your shares as your nominee on how to vote the shares in your account. Please refer to the voting instructions provided by your broker, bank or other nominee. Many organizations allow beneficial owners to give voting instructions via telephone or the Internet, as well as in writing. If you are a beneficial owner and would like to vote your shares at the Ayala Special Meeting, please contact your broker, bank or other nominee for instructions and documents that may be required in order to do so.

Q: What if I return a proxy card but do not make specific choices?

A: You will only receive a proxy card if you are the record holder of your shares of Ayala Common Stock. If you return a signed and dated proxy card without marking any voting selections, your shares will be voted "**FOR**" the Ayala Merger Proposal and "**FOR**" the Ayala Adjournment Proposal, in accordance with the recommendation of the Ayala Board. If any other matter is properly presented at the meeting, your proxy (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

Q: If my shares of Ayala Common Stock are held in "street name" by my bank, broker or other nominee, will my bank, broker or other nominee automatically vote my shares for me?

A: No. If your shares of Ayala Common Stock are held in "street name," your bank, broker or other nominee will vote your shares of Ayala Common Stock only if you provide instructions on how to vote to your bank, broker or other nominee. Under stock exchange rules, banks, brokers and other nominees who hold shares of Ayala Common Stock in "street name" for a beneficial owner of those shares typically have the authority to vote in their discretion on "routine" proposals when they have not received instructions from beneficial owners. However, banks, brokers and other nominees are not allowed to exercise their voting discretion with respect to the approval of matters determined to be "non-routine," without specific instructions from the beneficial owner. Broker non-votes are shares held by a bank, broker or other nominee that are represented at the Ayala Special Meeting, but with respect to which the bank, broker or other nominee is not instructed by the beneficial owner of such shares to vote on the particular proposal and the bank, broker or other nominee does not have discretionary voting power on such proposal. Ayala believes that the Ayala Merger Proposal and the Ayala Adjournment Proposal are "non-routine" proposals and therefore your bank, broker or other nominee cannot vote your shares of Ayala Common Stock without your specific voting instructions. Because the only proposals for consideration at the Ayala Special Meeting are non-routine proposals, it is not expected that there will be any broker non-votes at the Ayala Special Meeting. However, if there are any broker non-votes, they will have (i) the same effect as a vote "**AGAINST**" the Ayala Merger Proposal and (ii) no effect on the outcome of the Ayala Adjournment Proposal.

Q: Can I change my vote?

A: Yes. If you are a record holder of Ayala Common Stock, you can revoke your proxy and change your vote at any time before the final vote at the meeting.

- You may return by mail another properly completed proxy card with a later date, which must be received at the address stated on the proxy card no later than 6:00 p.m., Eastern Time on January 12, 2023.
- You may submit another properly completed proxy with a later date via the Internet or by telephone before the closing of those voting facilities at 11:59 p.m., Eastern Time on January 12, 2023.
- You may participate in the virtual online Ayala Special Meeting and vote at the meeting. Simply participating in the virtual online meeting will not, by itself, revoke your proxy.
- You may send a written notice that you are revoking your proxy to our Corporate Secretary at Ayala Pharmaceuticals, Inc., Oppenheimer 4, Rehovot 7670104, Israel, Attn: Corporate Secretary.

A revocation or later-dated proxy received by Ayala after the vote will not affect the vote.

If you are a beneficial holder (and hold your shares in "street name" through a bank, broker or other nominee), you should contact your bank, broker or other nominee to revoke your proxy or change your vote in accordance with their instructions.

Q: What happens if I fail to submit a proxy or I abstain from voting?

A: If you fail to submit a proxy or fail to instruct your bank, broker or other nominee to vote, assuming a quorum is present at the Ayala Special Meeting, it will have no effect on the outcome of the Ayala Adjournment Proposal, but it will have the same effect as a vote "**AGAINST**" the Ayala Merger Proposal. An abstention occurs when an Ayala stockholder returns a proxy with an "**ABSTAIN**" instruction or virtually attends the Ayala Special Meeting and votes to abstain from voting.

Q: What are the material U.S. federal income tax consequences of the Merger to Ayala stockholders?

A: The Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"). The completion of the Merger is, however, not conditioned on the Merger qualifying as a "reorganization" within the meaning of Section 368(a) of the Code or upon the receipt of an opinion of counsel to that effect. No assurance can be given that the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

Neither Advaxis nor Ayala has sought or intends to seek a ruling from the Internal Revenue Service (the "IRS") as to the U.S. federal income tax consequences of the Merger. If the IRS were to successfully challenge whether the Merger qualifies as a "reorganization," the tax consequences would differ materially from those described in this proxy statement/prospectus as discussed below under "*Material U.S. Federal Income Tax Consequences of the Merger—Tax Consequences if the Merger Fails to Qualify as a Reorganization*." This discussion neither binds the IRS nor precludes it from adopting a contrary position, and there can be no assurance that the IRS or a court would not disagree with or challenge any of the conclusions described in this proxy statement/prospectus.

Provided that the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code, subject to the limitations and qualifications described below under "*Material U.S. Federal Income Tax Consequences of the Merger*," a U.S. Holder (as defined in the section titled "*Material U.S. Federal Income Tax Consequences of the Merger*") of Ayala Common Stock will generally (i) not recognize any gain or loss upon the exchange of Ayala Common Stock for Advaxis Common Stock in the Merger (other than with respect to cash received in lieu of a fractional share of Advaxis Common Stock), (ii) have a tax basis in the Advaxis Common Stock received in the Merger (including fractional shares of Advaxis Common Stock for which cash is received) equal to the tax basis of the Ayala Common Stock surrendered in exchange therefor, and (iii) have a holding period for the Advaxis Common Stock received in the Merger (including fractional shares of Advaxis Common Stock for which cash is received) that includes its holding period for its Ayala Common Stock surrendered in exchange therefor.

For further information, see "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger.*"

The U.S. federal income tax consequences described above may not apply to all holders of Ayala Common Stock. Your tax consequences will depend on your individual situation. Accordingly, we strongly urge you to consult your independent tax advisor for a full understanding of the particular tax consequences of the Merger to you.

Q: Are Ayala stockholders entitled to appraisal or dissenters' rights?

A: Yes. Pursuant to Section 262 of the Delaware General Corporation Law (the "DGCL"), Ayala stockholders who do not vote in favor of adoption of the Merger Agreement, who continuously hold their shares of Ayala Common Stock through the Effective Time and who otherwise comply in all respects with the applicable requirements of Section 262 of the DGCL have the right to seek appraisal of the fair value of their shares of Ayala Common Stock, as determined by the Delaware Court of Chancery, if the Merger is consummated. See "*The Merger— Appraisal Rights and Dissenters' Rights*."

Q: Should I send in my Ayala stock certificates now?

A: No. Please do not send in your Ayala stock certificates with your proxy. After the completion of the Merger, an exchange agent mutually acceptable to Advaxis and Ayala will send you instructions for exchanging Ayala stock certificates for the merger consideration.

Q: Whom may I contact if I cannot locate my Ayala stock certificate(s)?

A: If you are unable to locate your original Ayala stock certificate(s), you should contact Ayala's transfer agent, American Stock Transfer & Trust Company, LLC, at (800) 937-5449 (toll-free) or (718) 921-8124 (international).

Q: What should I do if I hold my shares of Ayala Common Stock in book-entry form directly with Ayala's transfer agent, as opposed to a physical stock certificate?

A: You are not required to take any special additional actions if your shares of Ayala Common Stock are not represented by a certificate and are instead held in book-entry form with Ayala's transfer agent. After the completion of the Merger, an exchange agent mutually acceptable to Advaxis and Ayala will contact you to provide you with details regarding the merger consideration, including shares of Advaxis Common Stock in book-entry form and any cash to be paid instead of fractional shares in the Merger.

Q: What should I do if I receive more than one set of voting materials?

A: Ayala stockholders may receive more than one set of voting materials, including multiple copies of this proxy statement/prospectus and multiple proxy cards. For example, if you hold shares of Ayala Common Stock in more than one brokerage account, you will receive a separate voting instruction card for each brokerage account in which you hold such shares. If you are a holder of record of Ayala Common Stock and your shares are registered in more than one name, you will receive more than one proxy card. Please complete, sign, date and return each proxy card that you receive or otherwise follow the voting instructions set forth in this proxy statement/prospectus to ensure that you vote every share of Ayala Common Stock that you own.

Q: When do you expect to complete the Merger?

A: Advaxis and Ayala expect to complete the Merger during the first quarter of 2023, subject to any potential regulatory review or approval. However, neither Advaxis nor Ayala can assure you of when or if the Merger will be completed. Ayala must obtain the approval of Ayala's stockholders for the Ayala Merger Proposal and both parties must satisfy certain closing conditions. See "*The Merger Agreement—Conditions to the Completion of the Merger*" for more information regarding conditions to the completion of the Merger.

Q: What happens if the Merger is not completed?

A: If the Merger is not completed, Ayala stockholders will not receive any consideration for their shares of Ayala Common Stock in connection with the Merger. Instead, Ayala will remain an independent, public company and, assuming that Ayala is able to comply with the required listing standards, Ayala Common Stock will continue to be traded on an exchange of The Nasdaq Stock Market LLC. In addition, if the Merger Agreement is terminated in certain circumstances, Advaxis or Ayala may be required to pay a termination fee. See "*The Merger Agreement—Termination*" for a complete discussion of the circumstances under which a termination fee will be required to be paid.

Q: Where can I find the voting results of the Ayala Special Meeting?

A: The preliminary voting results will be announced at the Ayala Special Meeting. In addition, within four business days following the Ayala Special Meeting, Ayala will disclose the preliminary or, if available, final voting results of the Ayala Special Meeting on a Current Report on Form 8-K filed with the SEC. If preliminary voting results are disclosed, Ayala will file an amended Current Report on Form 8-K with the SEC to disclose final voting results within four business days following certification of the final voting results.

Q: Is the completion of the Merger subject to a financing condition?

A: No. The completion of the Merger is not subject to any financing condition.

Q: How will I know when the other conditions to completion of the Merger have been satisfied?

A: As of the date of this proxy statement/prospectus, the parties have not satisfied the closing conditions to the Merger. If the closing conditions are satisfied, Ayala will announce the closing of the Merger via the filing of a Current Report on Form 8-K with the SEC. There is also a possibility that the closing conditions to the Merger will not be satisfied prior to the outside date of April 18, 2023, after which date either party may elect to terminate the Merger Agreement, subject to certain caveats. As a result, it is possible that factors outside the control of both companies could result in the Merger being completed at a different time or not at all.

Ayala stockholders will not know the actual Exchange Ratio or the value of the Advaxis Common Stock to be received as merger consideration until after the date of the Ayala Special Meeting. See *"Risk Factors."*

Q: Are there any risks that I should consider in deciding whether to vote for the adoption of the Merger Agreement?

A: Yes. You should read and carefully consider the risk factors set forth in the "*Risk Factors*" section.

Q: Who can answer any questions I may have about the Merger or the Transactions contemplated by the Merger Agreement?

A: If you have any questions about the Merger or the other Transactions, or if you need additional copies of this proxy statement/prospectus, you should contact:

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104, Israel
Attn: Secretary
Tel: (857) 444-0553

PROSPECTUS SUMMARY

This summary highlights selected information from this proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the Merger and the proposals being considered at the Ayala Special Meeting, you should read this entire proxy statement/prospectus carefully, including the Merger Agreement and the other annexes to which you are referred in this proxy statement/prospectus. For more information, please see the section titled "Where You Can Find More Information" beginning on page 344 of this proxy statement/prospectus.

Overview of the Companies

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
Telephone: (609) 452-9813

Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary antigen delivery products, or L*m* Technology™, based on a platform technology that utilizes live attenuated Listeria monocytogenes, or Lm, bioengineered to secrete antigen/adjuvant fusion proteins. These Lm-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable the T cells to attack tumor cells.

Advaxis believes that *Lm* Technology™ immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates ADXS-PSA and ADXS-504 have the potential to enhance performance of other oncology treatments, while having a generally well-tolerated safety profile. Advaxis is currently winding down or has wound down clinical studies of *Lm* Technology™ immunotherapies in four program areas:

- Non-small cell lung cancer ("ADXS-503")
- Human Papilloma Virus ("HPV")-associated cancers ("AXAL")
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 ("HER-2") associated cancers

All these clinical program areas are anchored in Advaxis' *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. While we are currently winding down clinical studies of *Lm* Technology™ immunotherapies in these four program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104
Israel
Telephone: (857) 444-0553

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers. Ayala's approach is focused on predicating, identifying and addressing tumorigenic drivers of cancer to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors including adenoid cystic carcinoma ("ACC") and desmoid tumors. AL102 has received a designation from the U.S. Food and Drug Administration (the "FDA") to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need (the "Fast Track" designation) and is currently in the Phase 2 portion of a pivotal study for patients with desmoid tumors (RINGSIDE). AL101 has received Fast Track designation and Orphan Drug Designation, or ODD, a designation from the FDA under the Orphan Drug Act, or ODA, intended to treat a rare disease or condition, and is currently in a Phase 2 clinical trial for patients with ACC ("ACCURACY") bearing Notch activating mutations. For more information, visit www.ayalapharma.com.

Doe Merger Sub, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
(609) 452-9813

Merger Sub is a direct, wholly owned subsidiary of Advaxis. Merger Sub was incorporated in the State of Delaware on October 14, 2022 solely for the purpose of carrying out the Merger. Merger Sub has not carried on any activities to date, except for activities incidental to its formation and activities undertaken in connection with the Merger.

The Merger (see page 140)

On October 18, 2022, Ayala entered into the Merger Agreement with Advaxis and Merger Sub, pursuant to which Merger Sub will merge with and into Ayala, with Ayala as the surviving corporation and becoming a wholly-owned subsidiary of Advaxis. If the Merger is completed, Merger Sub will merge with and into Ayala, with Ayala being the surviving entity as a wholly-owned subsidiary of Advaxis (collectively with the other transactions contemplated by the Merger Agreement, the "Transactions").

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (i) each share of the common stock, par value $0.01 per share, of Ayala (the "Ayala Common Stock") issued and outstanding immediately prior to the Merger (including restricted stock issued by Ayala under its 2017 Stock Incentive Plan) shall be automatically converted into the right to receive 0.1874 shares (as such amount may be adjusted as provided in the Merger Agreement, the "Exchange Ratio") of the common stock, par value $0.001 per share, of Advaxis (the "Advaxis Common Stock"); (ii) each outstanding option to purchase shares of Ayala Common Stock (each, an "Ayala Option") will be substituted and converted automatically into an option (each, a "Advaxis Replacement Option") to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the Effective Time, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the Effective Time, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iii) each restricted stock unit of Ayala (each, an "Ayala RSU") outstanding immediately prior to the Effective Time, whether or not vested, will be substituted and converted automatically into a restricted stock unit award of Advaxis (each, an "Adjusted RSU") with respect to a number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the Effective Time of the Merger by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

Under the Exchange Ratio formula in the Merger Agreement, upon the closing of the Merger, on a pro forma basis and based upon the number of shares of Advaxis Common Stock expected to be issued in the Merger, pre-merger Advaxis stockholders will own approximately 37.5% of the combined company and pre-merger Ayala stockholders will own approximately 62.5% of the combined company.

Each share of Advaxis Common Stock and option to purchase Advaxis Common Stock that is issued and outstanding at the Effective Time of the Merger will remain issued and outstanding, and such shares will be unaffected by the Merger.

For a more complete description of the Merger and the Exchange Ratio, please see the section titled "*The Merger Agreement*" in this proxy statement/prospectus.

The Merger will be completed as promptly as practicable, but in no event later than the three (3) business days after all of the conditions to consummation of the Merger set forth in the Merger Agreement are satisfied or waived (save and except for those conditions that by their nature are to be satisfied at the closing, but subject to the satisfaction or waiver of each of such conditions), including the adoption of the Merger Agreement by the Ayala stockholders and the approval by the Advaxis stockholders of the issuance of Advaxis Common Stock in the Merger. The Merger is anticipated to close promptly after the Ayala Special Meeting scheduled to be held on January 13, 2023. However, Advaxis and Ayala cannot predict the exact timing of the completion of the Merger because it is subject to the satisfaction or waiver of various conditions.

Reasons for the Merger (see pages 151 and 153)

Advaxis Reasons for the Merger

After consideration and consultation with its senior management and its financial and legal advisors, the Advaxis board of directors unanimously determined that the Merger Agreement, the Merger and other transactions contemplated thereby are advisable, fair to and in the best interests of Advaxis and its stockholders. The Advaxis board of directors considered various reasons to reach its determination. For example:

- During its evaluation of the Merger Agreement and other Transactions, the Advaxis Board considered several factors in its decision to approve the Merger Agreement with Ayala.
- The Advaxis Board assessed the financial condition and prospects of Advaxis and risks associated with continued operations; considered the expected cash resources of the combined company and the likelihood the combined company would possess sufficient cash resources to fund future product development; and analyzed the potential strategic alternatives of other merger partner candidates. Further, Advaxis management conducted scientific, regulatory, and technical due diligence of the regulatory pathway for, and market opportunity of, Ayala's product candidates. The current financial market conditions and historical market prices, volatility, and trading information for Advaxis Common Stock was considered by the Advaxis Board as well.
- The Advaxis Board considered that the combined company would be led by a board of directors with representation from each of the current boards of directors of Advaxis and Ayala.
- The Advaxis Board's consideration of the financial analyses of Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), including its opinion to the Advaxis Board, to the effect that, as of such date and based on and subject to various assumptions, matters considered and limitations, conditions and qualifications described in its opinion, the Exchange Ratio was fair, from a financial point of view, to Advaxis, as more fully described below under the caption "*The Merger—Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald.*"

- The Advaxis Board also considered, in its deliberations, the variety of risks and other countervailing factors related to entering into the Merger Agreement, including the potential effect of the termination fee; substantial expense incurred in connection with the Merger; the scientific, technical, regulatory and other risks and uncertainties associated with the development and commercialization of Ayala's product candidates; the risk of a lack of available sources of financing necessary to fund product development; and various other risks.

- The Advaxis Board considers the factors overall to be favorable to, and to support, its determination of approval of the Merger Agreement.

Ayala's Reasons for the Merger

After consideration the Ayala board of directors (the "Ayala Board"), by a unanimous vote of all directors at its meeting on October 18, 2022, approved and declared advisable the Merger Agreement and the Merger, and recommended that Ayala stockholders vote to approve the Merger Agreement.

In the course of evaluating the Merger Agreement and the Transactions, the Ayala Board held numerous meetings and consulted with Ayala management and Ayala's legal and financial advisors and considered a number of factors in reaching its decision to approve the Merger Agreement, the Merger and the other Transactions, which included the following (not in order of relative importance):

- *Consideration of Alternatives*. The Ayala Board pursued several strategic and financing transactions for Ayala in 2022 and considered alternatives to the Merger and determined that entering into the Merger Agreement was more favorable to Ayala stockholders than other alternatives available to Ayala.

- *Challenges that Ayala Would Face on a Standalone Basis.* The challenges facing Ayala if it were to continue on a standalone basis, including Ayala's financial condition and prospects, including Ayala's limited cash runway and the fact that Ayala's management believed that Ayala's cash and cash equivalents would not be sufficient to meet its obligations past the middle of the first quarter of 2023 (in contrast to Ayala's pro forma cash runway through the fourth quarter of 2023 upon completion of the Merger), and Ayala's inability to raise additional capital on reasonable terms;

- *Advaxis Net Cash.* The expected cash resources of the combined company as of the closing of the Merger, resulting from the approximately $20 million of net cash expected to be held by Advaxis upon completion of the Merger that would be available to be invested in the combined company's programs;

- *Participation in Potential Appreciation*. After giving effect to the Merger, Ayala stockholders will own approximately 62.5% of the combined company's outstanding common stock, and as a result, Ayala stockholders would participate in the future growth of the combined company after the consummation of the Merger;

- *Voting Agreements*. The Voting and Support Agreements (the "Voting Agreements"), pursuant to which Israel Biotech Fund I, L.P. ("IBF I"), which owned approximately 22.24% of the outstanding shares of Ayala Common Stock as of the date of the Merger Agreement, and aMoon 2 Fund Limited Partnership ("aMoon"), which owned approximately 20.3% of the outstanding shares of Ayala Common Stock as of the date of the Merger Agreement, agreed to support the transaction and vote in favor of the adoption of the Merger Agreement, demonstrating strong support for a combination with Advaxis;

- *Financial Analyses of Torreya; Receipt of Fairness Opinion*. The financial analyses of Torreya Capital, LLC ("Torreya") and its oral opinion (which was subsequently confirmed in its written opinion, dated October 16, 2022) (the "Torreya Opinion") to the Ayala Board to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications, set forth in the Torreya Opinion, the Exchange Ratio was fair, from a financial point of view, to Ayala.

- *Terms of the Merger Agreement*. The terms and conditions of the Merger Agreement, including:
  - *Ownership Split*. The determination that the expected relative percentage ownership of Ayala's stockholders (62.5%) and Advaxis' stockholders (37.5%) in the combined company was appropriate, based on the Ayala Board's judgment and assessment of the approximate valuations of Advaxis (including the value of the net cash Advaxis is expected to provide to the combined company) and Ayala;
  - *Tax Treatment*. The expectation that the Merger will be treated as a "reorganization" within the meaning of Section 368(a) of the Code for U.S. federal income tax purposes, with the result that in the Merger the holders of Ayala Common Stock will generally not recognize taxable gain or loss for U.S. federal income tax purposes (other than with respect to cash received in lieu of a fractional share of Advaxis Common Stock);
  - *Reciprocity*. The review by the Ayala Board, in consultation with Ayala's advisors, of the structure of the Merger and the terms and conditions of the Merger Agreement, including certain reciprocal provisions that may have the effect of discouraging alternative Acquisition Proposals involving Ayala or Advaxis and their ability to terminate the Merger Agreement;
  - *Conditions to Consummation of the Merger*. The limited number and nature of the conditions to the parties' obligations to complete the Merger and the belief of the Ayala Board of the likelihood of satisfying such conditions;
  - *Right to Withdraw Recommendation to Ayala Stockholders*. The right of Ayala under the Merger Agreement to consider certain unsolicited Acquisition Proposals should Ayala receive a superior proposal, and the right of the Ayala Board under certain circumstances to withdraw its recommendation to Ayala stockholders that they adopt the Merger Agreement;
  - *Opportunity to Vote*. The opportunity of the Ayala stockholders to vote on the adoption of the Merger Agreement; and
  - *Termination Fee*. The conclusion of the Ayala Board that the potential termination fees payable by Ayala or Advaxis to the other party, and the circumstances when such fee may be payable, were reasonable.
- The Ayala Board also considered various risks and other potentially negative factors concerning the Merger Agreement, the Merger and the other Transactions, which included the following factors:
  - the challenges inherent in combining the businesses, operations and regulatory compliance systems of Ayala and Advaxis;
  - the expectation that the combined company will need to raise substantial additional capital in the future, which could result in further dilution to stockholders;
  - the fact that forecasts of future results of operations and synergies are necessarily estimates based on assumptions;

- the possibility that the Merger might not be completed, or that completion might be unduly delayed, including as a result of Ayala's stockholders failing to grant the requisite approvals to consummate the Merger, and the potential negative impact that may have on Ayala's business and stockholders;
- the risk to Ayala's business, operations and financial results in the event that the Merger is not consummated, including the diminution of Ayala's cash and the significant challenges associated with the need to raise additional capital through the public or private sale of equity securities;
- the substantial costs to be incurred in connection with the Merger, including the cash and other costs of integrating the businesses of Ayala and Advaxis, as well as the transaction expenses arising from the Merger;
- the terms of the Merger Agreement, including generally reciprocal covenants relating to (i) the two companies' conduct of their respective businesses during the period between the signing of the Merger Agreement and the completion of the Merger, and (ii) the restrictions on the two companies' ability to solicit alternative transaction proposals;
- the likely detrimental effect on Ayala's cash position, stock price and ability to initiate another process and to successfully complete an alternative transaction should the Merger not be completed;
- the likelihood of disruptive stockholder litigation following announcement of the Merger;
- the strategic direction of the combined company following the completion of the Merger; and
- various other risks associated with the combined organization and the Merger, including those described in the section entitled "*Risk Factors*", the matters described under "*Cautionary Statement Concerning Forward-Looking Statements*" and the matters described under "*Certain Prospective Financial Information for Ayala*" beginning on pages 25, 1 and 168, respectively, of this proxy statement/prospectus.

For a more complete description of the reasons for the Merger, please see the sections titled "*The Merger—Advaxis Reasons for the Merger*" and "*The Merger—Ayala's Reasons for the Merger; Recommendation of the Ayala Board*" beginning on pages 151 and 153, respectively, of this proxy statement/prospectus.

Opinion of Advaxis' Financial Advisor (see page 156)

Advaxis retained Cantor Fitzgerald & Co. ("Cantor Fitzgerald") to act as its financial advisor in connection with the Merger. In connection with the Merger, Cantor Fitzgerald rendered its opinion to the Advaxis Board on October 18, 2022, to the effect that, as of that date and based on and subject to various assumptions, matters considered and limitations, conditions and qualifications described in its opinion, the Exchange Ratio was fair, from a financial point of view, to Advaxis.

The full text of Cantor Fitzgerald's opinion describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken by Cantor Fitzgerald. This opinion is attached as Annex C and is incorporated herein by reference. Cantor Fitzgerald's opinion was provided for the benefit and use of the Advaxis Board (in its capacity as such) in connection with its consideration of the Merger. Cantor Fitzgerald's opinion did not constitute a recommendation to the Advaxis Board in connection with the Merger, nor did the opinion constitute a recommendation to any holders of common stock of Advaxis or Ayala as to how they should vote or act with respect to the Merger or any related matter. Cantor Fitzgerald's opinion did not address Advaxis' underlying business decision to pursue the Merger, the relative merits of the Merger as compared to any alternative business or financial strategies that might exist for Advaxis or the effects of any other transaction in which Advaxis might engage. For a description of the opinion that the Advaxis Board received from Cantor Fitzgerald, see the section entitled "*The Merger—Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald*."

Opinion of Ayala's Financial Advisor (see page 162)

Torreya rendered the Torreya Opinion to the Ayala Board that, as of October 16, 2022, based on and subject to the factors and assumptions set forth in the Torreya Opinion, the Exchange Ratio was fair, from a financial point of view to the holders of shares of Ayala. For a more complete description of the Torreya Opinion, please see the section titled "*The Merger—Opinion of Ayala's Financial Advisor—Torreya Capital, LLC* " beginning on page 162.

Interests of Certain Directors, Officers and Affiliates of Advaxis and Ayala (see page 169)

Interests of Advaxis Directors and Executive Officers in the Merger

In considering the recommendation of the Advaxis Board with respect to issuing shares of Advaxis Common Stock pursuant to the Merger Agreement and the other matters to be acted upon by Ayala stockholders at the Ayala Special Meeting, Ayala stockholders should be aware that certain members of the Advaxis Board and executive officers of Advaxis have interests in the Merger that may be different from, or in addition to, interests they have as Ayala stockholders.

Under the terms of Advaxis' President and Chief Executive Officer's employment agreement, Mr. Kenneth Berlin is entitled to severance payments if his employment were terminated without Just Cause or he terminated his employment for Good Reason during the period three months prior and 18 months following a Change of Control (such period, the "CIC Protection Period") (as such terms are defined in Mr. Berlin's employment agreement). Mr. Berlin would receive a cash severance payment equal to 2.0 times his base salary and target bonus, payable in a single lump sum within 60 days of the termination, as well as an amount equal to his target bonus for the year in which his employment is terminated, prorated for the portion of the year prior to the termination, payable within 45 days of the termination. Mr. Berlin would receive 24 months of continued health and welfare benefits. In the event Mr. Berlin's employment were terminated without Just Cause, or he has terminated his employment for Good Reason, other than during the CIC Protection Period, he would receive equal monthly installments of 1.25 times his applicable base salary for 15 months, plus a one-time target bonus. Additionally, Mr. Berlin would receive continued health and welfare benefits in this circumstance for 15 months. In addition, Mr. Berlin is also entitled to full accelerated vesting of all outstanding equity awards upon a Change in Control regardless of whether he is terminated.

Mr. Andres Gutierrez, Advaxis' Chief Medical Officer, is also contractually entitled to severance payments, including a cash severance payment equal to 1.0 times the base salary paid in equal monthly installments of 12 months, plus a target bonus for the fiscal year in which the termination occurs, along with health and welfare benefits up to 12 months if terminated by the Company without Just Cause or by Mr. Gutierrez for Good Reason or by reason of disability.

Based on the terms of their respective employment agreements, Advaxis' current executive officers would be entitled to receive a total value of approximately $3.4 million (collectively, not individually) in connection with the consummation of the Merger (under certain conditions) which includes the value associated with the acceleration of outstanding equity awards.

Additionally:

- Kenneth A. Berlin, Dr. David Sidransky, Dr. Samir Khleif, and Ronni Appel, members of the Advaxis Board, will continue as directors after the Merger, and, following the closing of the Merger, Dr. Sidransky, Dr. Khleif and Mr. Appel will be eligible to be compensated as directors of Advaxis pursuant to the Advaxis compensation policy that is expected to remain in place following the Merger. Under the Merger Agreement, Ayala's directors and executive officers are entitled to continued indemnification, expense advancement and insurance coverage.

- Kenneth A. Berlin, Andres Gutierrez, and Igor Gitelman will continue as executive officers of the combined company after the Merger.

As of November 16, 2022, the directors and executive officers of Advaxis owned, in the aggregate, less than 1% of the outstanding voting shares of Advaxis Common Stock. The Advaxis Board was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement. For more information, please see the section titled "*The Merger—Interests of the Advaxis Directors and Executive Officers in the Merger*" of this proxy statement/prospectus.

Dr. Sidransky's Interests in the Merger

Dr. David Sidransky, a member of the Advaxis Board and the Ayala Board, is a co-founder and owner of IBF I. IBF I is an owner of Ayala Common Stock. IBF I owns an aggregate of 3,315,119 of Ayala's Common Stock, which represent, in the aggregate, ownership of approximately 22.37% of Ayala's outstanding shares. Additionally, Dr. Sidransky introduced the parties of the Merger. "Certain Relationships and Related-Party Transactions of the Combined Company" of this proxy statement/prospectus.

Interests of Ayala Directors and Executive Officers in the Merger

In considering the recommendation of the Ayala Board with respect to the proposal for the adoption of the Merger Agreement (the "Ayala Merger Proposal"), Ayala stockholders should be aware that the executive officers and directors of Ayala have certain interests in the Merger that may be different from, or in addition to, the interests of Ayala stockholders generally. The Ayala Board was aware of these interests and considered them, among other matters, in approving the Merger Agreement and the other Transactions and making its recommendation that Ayala stockholders vote in favor of the Ayala Merger Proposal.

These interests include, among others:

- As of October 31, 2022, all current directors and executive officers of Ayala, together with their affiliates, owned approximately 68.75% of Ayala's outstanding stock capital which will, at the Effective Time, be automatically converted into the right to receive an amount of registered shares of Advaxis Common Stock equal to the Exchange Ratio; certain Ayala affiliates have also entered into support agreements in connection with the Merger. The support agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger — Support Agreements*" in this proxy statement/prospectus;

- Ayala's current executive officers and directors are entitled to certain liability insurance coverage pursuant to the terms of the tail insurance policy of Advaxis; and

- Each of Ayala's executive officers has entered into an employment agreement under which the executive officer is entitled to severance benefits upon a qualifying termination of employment as further described in the section title "*Interests of Ayala Directors and Executive Officers in the Merger—Executive Officer Employment Agreements*" in this proxy statement/prospectus beginning on page 172.

Management Following the Merger (see page 306)

Effective as of the closing of the Merger, the combined company's executive officers are expected to be:

Name	Title
Kenneth Berlin	President and Chief Executive Officer
Igor Gitelman	Interim Chief Financial Officer
Andres Gutierrez, M.D., Ph.D.	Chief Medical Officer

The Merger Agreement and Agreements Related to the Merger Agreement (see page 181)

The terms and conditions of the Merger Agreement are contained in the Merger Agreement, which is attached to this proxy statement/prospectus as Annex A and is incorporated by reference herein in its entirety. Ayala encourages you to read the Merger Agreement carefully, as it is the legal document that governs the business combination. For more information on the Merger Agreement, see the section entitled "*The Merger Agreement*."

Ancillary Agreements Related to the Merger (see page 201)

In connection with execution of the Merger Agreement, Advaxis entered into the Voting Agreements with each of (a) IBF I, and (b) aMoon, pursuant to which each such party agreed, among other things, to vote their respective beneficially owned shares of Ayala Common Stock (i) in favor of (1) the adoption of the Merger Agreement and the approval of the Merger and the other Transactions, and (2) any proposal to adjourn or postpone the stockholders meeting of Ayala called to approve such matters (the "Ayala Adjournment Proposal") to the extent permitted or required under the Merger Agreement; and (ii) against (1) any Advaxis Acquisition Proposal (as defined in the Merger Agreement), except as expressly permitted by the Merger Agreement, (2) any merger agreement or merger (other than the Merger Agreement and the Merger), consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by Advaxis, in each case except as expressly permitted by the Merger Agreement and (3) any proposal, action or agreement that would reasonably be expected to (1) materially delay or postpone, prevent or otherwise impair the Merger or the other Transactions, (2) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of Ayala under the Merger Agreement, (3) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of such party under the Voting Agreements, (4) result in any of the conditions set forth in Section 6 of the Merger Agreement not being fulfilled or (5) except as expressly contemplated by the Merger Agreement, change in any manner the dividend policy or capitalization of, including the voting rights of any class of capital stock of Ayala. The Voting Agreements will terminate upon the earliest to occur of (a) the mutual agreement of Advaxis and the stockholder party to such Voting Agreement; (b) Ayala Special Meeting at which a vote upon the Ayala Merger Proposal and the other Transactions is taken; and (c) the date on which the Merger Agreement is terminated in accordance with its terms. The Voting Agreements provide that, in the event of an Advaxis Change in Recommendation (as defined in the Merger Agreement), the number of shares of capital stock of Ayala subject to the Voting Agreements shall only be 30% of the total current outstanding voting power of Ayala, and the number of shares of capital stock of Ayala of each of IBF I and aMoon subject to the Voting Agreements shall be reduced proportionately based on the number of shares of capital stock of Ayala subject thereto.

Voting by Ayala's Directors and Executive Officers (see page 133)

As of the Record Date for the Ayala Special Meeting, directors and executive officers of Ayala and their affiliates owned and were entitled to vote 3,709,106 shares of Ayala Common Stock, representing approximately 25% of the shares of Ayala Common Stock outstanding on that date. Ayala currently expects that Ayala's directors and executive officers will vote their shares of Ayala Common Stock in favor of the Ayala Merger Proposal and the Ayala Adjournment Proposal, although none of them has entered into any agreement obligating them to do so. Approval of the Ayala Merger Proposal requires the affirmative vote of a majority of the outstanding shares of Ayala Common Stock entitled to vote on the proposal. Approval of the Ayala Adjournment Proposal requires the affirmative vote of a majority in voting power of the votes cast affirmatively or negatively at the Ayala Special Meeting.

Conditions to the Completion of the Merger (see page 185)

The consummation of the Merger is subject to, and will take place within three business days of, the satisfaction or waiver of certain customary closing conditions, including, without limitation: (i) the registration statement on Form S-4 (which will include a prospectus of Advaxis and a proxy statement of Ayala) (the "Registration Statement"), to be filed by Advaxis with the U.S. Securities and Exchange Commission ("SEC") to register the public offering and sale of Advaxis' Common Stock to some or all holders of the shares of Ayala Common Stock in connection with the Merger, must have become effective and not subject to any stop order or proceeding seeking a stop order; (ii) Ayala must have obtained the approval of its stockholders for the Merger and the other Transactions (the "Ayala Stockholder Approval"); (iii) receipt of all required state securities or "blue sky" authorizations for the issuance of such shares of Advaxis' Common Stock, except for such authorizations the lack of receipt of which would not reasonably be expected to have a material adverse impact on any of the parties to the Merger Agreement or their respective affiliates; (iv) the absence of any law or judgment of a governmental entity of competent jurisdiction that is in effect and restrains, enjoins, or otherwise prohibits consummation of the Merger; (v) the absence of a material adverse effect on the business, financial condition or results of operations of, respectively, (a) Ayala and its subsidiaries, taken as a whole or (b) Advaxis and its subsidiaries, taken as a whole; (vi) the accuracy of Ayala's and Advaxis' representations and warranties, subject to specified materiality qualifications; (vii) compliance by Ayala and Advaxis with its respective covenants in the Merger Agreement in all material respects; and (viii) delivery of customary closing documents, including a customary officer certificate from Ayala and Advaxis.

No Solicitation (see page 188)

Each of Advaxis and Ayala agreed that, subject to limited exceptions, Advaxis and Ayala and any of their respective subsidiaries will not, and each party will not authorize or permit any of its officers, directors, employees, investment bankers, attorneys, accountants, representatives, consultants or other agents retained by it or any of its subsidiaries to, directly or indirectly:

- solicit, initiate, induce, encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (as defined below);
- participate in any discussions or negotiations or cooperate in any way with any person regarding any proposal or offer the consummation of which would constitute an Acquisition Proposal;
- provide any non-public information or data concerning it or any of its subsidiaries to any person in connection with any proposal, the consummation of which would constitute an Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating an Acquisition Proposal;
- enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to an Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to an Acquisition Proposal;
- adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (including by approving any transaction, or approving any person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any person (other than the other party and its subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or its organizational or other governing documents; or
- resolve, publicly propose or agree to do any of the foregoing actions.

Termination (see page 199)

The Merger Agreement may be terminated under certain customary and limited circumstances at any time prior to the closing, including without limitation: (i) by mutual written consent of Advaxis and Ayala; (ii) by either Advaxis or Ayala, if (a) if a governmental authority shall have issued a final and non-appealable permanent restraining order, permanent injunction or other similar permanent order which has the effect of enjoining or otherwise prohibiting consummation of the Transactions, (b) the closing has not occurred on or before April 18, 2023, or (c) the Ayala Stockholder Approval has not been obtained at the Ayala Special Meeting, in each of (a), (b) and (c) where the terminating party's material breach of the Merger Agreement is not the cause of, or has resulted in, the failure of such condition; (iii) by Ayala if (a) Advaxis breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of Ayala's conditions to closing the Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the Merger Agreement, (b) Advaxis has materially breached or failed to perform its non-solicitation covenant, or entered into a Parent Acquisition Proposal (as defined in the Merger Agreement), (c) the Ayala's board of directors authorizes Ayala to enter into a Parent Acquisition Proposal constituting a Parent Superior Proposal (as such terms are defined in the Merger Agreement); and (iv) by Advaxis if (a) Ayala breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of Advaxis' conditions to closing the Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the Merger Agreement, (b) Ayala has materially breached or failed to perform its non-solicitation covenant, or entered into a Company Acquisition Proposal (as defined in the Merger Agreement), (c) Advaxis' board of directors authorizes Advaxis to enter into a Company Acquisition Proposal constituting a Company Superior Proposal (as such terms are defined in the Merger Agreement).

Termination Fee (see page 200)

If the Merger Agreement is terminated under certain circumstances, Advaxis or Ayala, as applicable, will be required to pay the other party a termination fee equal to $600,000.

Material U.S. Federal Income Tax Consequences of the Merger (see page 178)

It is intended that, subject to customary assumptions, caveats, exceptions and exclusions, the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder. In general, and subject to the exceptions, qualifications and limitations set forth in the section titled "Material U.S. Federal Income Tax Consequences of the Merger," assuming the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, the material U.S. federal income tax consequences to a U.S. Holder (as defined in the section titled "Material U.S. Federal Income Tax Consequences of the Merger") of Ayala Common Stock will be as follows:

- each such U.S. Holder will not recognize gain or loss upon the exchange of Ayala Common Stock for Advaxis Common Stock pursuant to the Merger (other than with respect to cash received in lieu of a fractional share of Advaxis Common Stock);
- such U.S. Holder's aggregate tax basis for the shares of Advaxis Common Stock received in the Merger will equal the U.S. Holder's aggregate tax basis in the shares of Ayala Common Stock surrendered in the Merger; and
- the holding period of the shares of Advaxis Common Stock received by such U.S. Holder in the Merger will include the holding period of the shares of Ayala Common Stock surrendered in exchange therefor.

Determining the actual U.S. federal income tax consequences of the Merger to you may be complex and will depend on the facts of your own situation. You should consult your tax advisors to fully understand the tax consequences to you of the Merger, including the estate, gift, state, local or non-U.S. tax consequences of the Merger.

Potential Listing of Common Stock of Combined Company (see page 175)

Shares of Advaxis Common Stock are currently quoted on OTCQX under the symbol "ADXS." Advaxis intends to file an initial listing application with Nasdaq prior to the closing of the Merger, and to undertake the actions necessary to allow the stock of the combined company to be listed on The Nasdaq Capital Market as of the closing of the Merger or promptly thereafter. However, because Advaxis is not currently listed on Nasdaq, the combined company will be required to meet the initial listing standards of The Nasdaq Capital Market applicable to companies seeking to uplist one or more securities from another U.S. market, such as the OTCQX. While Ayala and Advaxis intend to use their best commercially practicable efforts to have the stock of the combined company approved for listing on Nasdaq as of the closing of the Merger or promptly thereafter, no assurance can be made that these efforts will be successful. If the listing application is accepted, Advaxis anticipates that the common stock of the combined company will be listed on The Nasdaq Capital Market following the closing of the Merger under the trading symbol "AYRX." There can be no assurance that these efforts to uplist will be successful.

Anticipated Accounting Treatment (see page 314)

The Merger will be accounted for as a reverse acquisition in accordance with U.S. GAAP. Under this method of accounting, Ayala will be deemed to be the accounting acquirer for financial reporting purposes. As a result of the Merger, the net assets of Advaxis will be recorded at their acquisition-date fair value in the financial statements of Ayala and the reported operating results prior to the Merger will be those of Ayala.

Appraisal Rights and Dissenters' Rights (see page 175)

Under the Delaware General Corporation Law (the "DGCL"), Ayala stockholders are entitled to appraisal rights in connection with the Merger.

Comparison of Rights of Holders of Shares (see page 329)

Advaxis and Ayala, respectively, are incorporated under the laws of the State of Delaware. If the Merger is completed, Ayala stockholders will become holders of Advaxis Common Stock and will have different rights as holders of Advaxis Common Stock than they had as holders of Ayala Common Stock. The differences between the rights of these respective holders result from the differences of the respective governing documents of Ayala and Advaxis, as the same may be amended in connection with the Merger. For additional information, see the section titled "*Comparison of Rights of Holders of Advaxis Capital Stock and Ayala Capital Stock*" beginning on page 330 of this proxy statement/prospectus.

Risk Factors of the Combined Company (see page 26)

Both Advaxis and Ayala are subject to various risks associated with their businesses and their industries. In addition, the Merger, including the possibility that the Merger may not be completed, poses a number of risks to each company and its respective securityholders, including, without limitation, the following risks:

- The Exchange Ratio will not be adjusted based on the market price of Advaxis Common Stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed;
- Failure to complete the Merger may result in Advaxis or Ayala paying a termination fee Advaxis or Ayala, as applicable, which could harm the price of Advaxis Common Stock and the future business and operations of each company;
- If the conditions to the Merger are not satisfied or waived, the Merger will not occur;
- The Merger may be completed even though material adverse effects may result from the announcement of the Merger, changes in or affecting the industries in which Advaxis or Ayala operate and other causes;
- If Advaxis and Ayala complete the Merger, the combined company will need to raise additional capital by issuing equity securities or incurring additional debt or by entering into licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations;
- Some Advaxis and Ayala executive officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests;
- Advaxis' stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger;
- Efforts to have the common stock of the combined company listed on The Nasdaq Capital Market may not be successful; and
- If the Merger is not completed, Advaxis' stock price may fluctuate significantly.

These risks and other risks are discussed in greater detail under the section titled "Risk Factors" beginning on page 25 of this proxy statement/prospectus. Advaxis and Ayala both encourage you to read and consider all of these risks carefully.

Risks Related to the Merger (see page 26)

- The exchange ratio will not be adjusted based on the market price of Advaxis Common Stock, so the Merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.
- If the conditions to the Merger are not satisfied or waived, the Merger may not occur.
- The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry wide changes or other causes.
- If Advaxis and Ayala complete the Merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.
- Advaxis and Ayala directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.
- Advaxis and Ayala stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.
- If the Merger is not completed, Advaxis' and Ayala's stock price may fluctuate significantly.
- Advaxis stockholders and Ayala stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.
- If Advaxis does not successfully consummate the transaction with Ayala, Advaxis' and Ayala's, as applicable, board of directors may dissolve or liquidate its assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to Advaxis' and Ayala's stockholders will depend heavily on the timing of such transaction or liquidation.
- Efforts to have the common stock of the combined company listed on The Nasdaq Capital Market may not be successful.

Advaxis' Summary of Risk Factors (see page 34)

Below is a summary of the principal factors that make an investment in Advaxis' Common Stock speculative or risky. This summary does not address all of the risks that Advaxis faces. Additional discussion of the risks summarized in this risk factor summary, and other risks that Advaxis faces, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this proxy statement/prospectus and Advaxis' other filings with the SEC, before making an investment decision regarding Advaxis' Common Stock.

- Advaxis has incurred significant losses since its inception and anticipate that it will continue to incur losses for the foreseeable future.
- Advaxis will require additional capital to fund its operations and if it fails to obtain necessary financing, it will not be able to complete the development and commercialization of its product candidates.
- Advaxis is significantly dependent on the success of its L*m* Technology™ platform and its product candidates based on this platform.
- If Advaxis is unable to establish, manage or maintain strategic collaborations in the future, its revenue and drug development may be limited.
- Advaxis is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations ("Trade Laws"). Advaxis can face serious consequences for violations.
- Advaxis depends upon its senior management and key consultants and their loss or unavailability could put it at a competitive disadvantage.
- The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. Advaxis may be unable to compete with more substantial enterprises.
- Advaxis can provide no assurance that its clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.
- Advaxis may face legal claims; legal disputes are expensive and Advaxis may not be able to afford the costs.
- Advaxis can provide no assurance of the successful and timely development of new products.
- Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on Advaxis' business and results of operations.
- Advaxis relies on patents to protect its technology. Advaxis may be unable to protect its intellectual property rights and it may be liable for infringing the intellectual property rights of others.
- The price of Advaxis' Common Stock and warrants may be volatile.

Ayala's Summary of Risk Factors (see page 64)

Below is a summary of the principal factors that make an investment in Ayala's Common Stock speculative or risky. This summary does not address all of the risks that Ayala faces. Additional discussion of the risks summarized in this risk factor summary, and other risks that Ayala faces, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this proxy statement/prospectus and Ayala's other filings with the SEC, before making an investment decision regarding Ayala's Common Stock.

- Ayala will require additional capital to fund its operations, and if Ayala fails to obtain necessary financing, it may not be able to complete the development and commercialization of AL101 and AL102;
- Ayala's recurring losses from operations raise substantial doubt regarding its ability to continue as a going concern;
- Ayala has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability;
- Ayala is heavily dependent on the success of AL101 and AL102, its most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, Ayala's business may be harmed;
- Due to Ayala's limited resources and access to capital, it must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect Ayala's business;
- The outbreak of COVID-19, may adversely affect Ayala's business, including its clinical trials;
- Ayala's ability to use its net operating loss carryforwards to offset future taxable income may be subject to certain limitations;
- Ayala's product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach Ayala is taking to discover and develop product candidates is novel and may never lead to marketable products;
- Ayala was not involved in the early development of its lead product candidates; therefore, Ayala is dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for its product candidates;
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Ayala's control;
- If Ayala does not achieve its projected development and commercialization goals in the timeframes it announces and expects, the commercialization of Ayala's product candidates may be delayed and Ayala's business will be harmed;
- Ayala's product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- The market opportunities for AL101 and AL102, if approved, may be smaller than Ayala anticipates;
- Ayala may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations;
- Ayala has never obtained marketing approval for a product candidate and Ayala may be unable to obtain, or may be delayed in obtaining, marketing approval for any of its product candidates;
- Even if Ayala obtains approval from the FDA for its product candidates in the United States, Ayala may never obtain approval for or commercialize them in any other jurisdiction, which would limit Ayala's ability to realize their full market potential;
- Ayala has been granted ODD for AL101 for the treatment of ACC and may seek ODD for other indications or product candidates, and Ayala may be unable to maintain the benefits associated with ODD, including the potential for market exclusivity, and may not receive ODD for other indications or for its other product candidates;
- Although Ayala has received Fast Track designation for AL101, and may seek Fast Track designation for our other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process;
- Ayala faces significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if Ayala fails to compete effectively;
- Ayala is dependent on a small number of suppliers for some of the materials used to manufacture its product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of its product candidates;
- Enacted and future healthcare legislation may increase the difficulty and cost for Ayala to obtain marketing approval of and commercialize its product candidates, if approved, and may affect the prices Ayala may set;
- If Ayala is unable to obtain, maintain, protect and enforce patent and other intellectual property protection for its technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, Ayala's competitors could develop and commercialize products and technology similar or identical to Ayala's, and Ayala may not be able to compete effectively in its markets;
- Ayala may engage in acquisitions or in-licensing transactions that could disrupt its business, cause dilution to its stockholders or reduce its financial resources; and
- Risks related to Ayala's operations in Israel could materially adversely impact its business, financial condition and results of operations.

RISK FACTORS

The combined company (for the purpose of this "Risk Factors" section, "we," "us" and "our") will be faced with a market environment that cannot be predicted and that involves significant risks and uncertainties, many of which will be beyond our control. You should carefully consider all of the information set forth in this proxy statement/prospectus. The combined company's business, financial condition and results of operations could be materially and adversely affected by any of these risks. In that event, the trading price of our common stock would likely decline and you might lose all or part of your investment. In addition to the other information contained in this proxy statement/prospectus, you should carefully consider the material risks described below before deciding how to vote your shares of Ayala Common Stock. You should also read and consider the other information in this proxy statement/prospectus and additional information about Ayala set forth in its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which is filed with the SEC as updated by its Quarterly Reports on Form 10-Q. Please see the section titled "*Where You Can Find More Information*" beginning on page 343 of this proxy statement/prospectus for further information. This proxy statement/prospectus also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See also "*Cautionary Statement Concerning Forward-Looking Statements"* on page 1 of this proxy statement/prospectus.

- Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the Transactions.
- The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of Advaxis' Common Stock, Ayala's Common Stock, and their respective business prospects.
- Failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations.
- If Advaxis does not successfully consummate the transaction with Ayala, the Advaxis Board and the Ayala Board, as applicable, may dissolve or liquidate its assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to Advaxis' and Ayala's stockholders will depend heavily on the timing of such transaction or liquidation.
- Efforts to have the common stock of the combined company listed on The Nasdaq Capital Market may not be successful.

Risks Related to the Merger

The Exchange Ratio will not be adjusted based on the market price of Advaxis Common Stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

At the Effective Time, outstanding Ayala Common Stock will be converted into shares of Advaxis Common Stock. Applying the Exchange Ratio, the former Ayala stockholders immediately before the Merger are expected to own approximately 62.5% of the aggregate number of shares of the combined company's common stock following the Merger, and Advaxis stockholders immediately before the Merger are expected to own approximately 37.5% of the aggregate number of shares of the combined company's common stock following the Merger, subject to certain assumptions.

Any changes in the market price of Advaxis' Common Stock before the completion of the Merger will not affect the number of shares Ayala stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger, the market price of Advaxis Common Stock increases from the market price on the date of the Merger Agreement, then Ayala stockholders could receive merger consideration with substantially more value for their Ayala Common Stock than the parties had negotiated when they established the Exchange Ratio. Similarly, if before the completion of the Merger the market price of Advaxis Common Stock declines from the market price on the date of the Merger Agreement, then Ayala stockholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

If the conditions to the Merger are not satisfied or waived, the Merger may not occur.

Even if the Merger Agreement is adopted by the stockholders of Ayala and the Ayala Merger Proposal is approved by the Ayala stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled "The Merger Agreement—Conditions to the Completion of the Merger" beginning on page 181 of this proxy statement/prospectus. Advaxis and Ayala cannot assure you that all of the conditions to the consummation of the Merger will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or the closing may be delayed, and Advaxis and Ayala each may lose some or all of the intended benefits of the Merger.

The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry wide changes or other causes.

In general, neither Advaxis nor Ayla is obligated to complete the Merger if there is a material adverse effect affecting the other party between October 18, 2022, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or market conditions, industry wide changes, changes in U.S. GAAP, changes in laws, rules or regulations of general applicability or interpretations thereof, natural disasters, pandemics (including the COVID-19 pandemic), outbreaks of hostilities or acts of terrorism, changes resulting from the announcement, performance or pendency of the Merger, changes in the price or trading volume of Advaxis Common Stock, and failures to meet internal or third-party guidance or forecasts. Therefore, if any of these events were to occur, impacting Advaxis or Ayala, the other party would still be obliged to consummate the closing of the Merger. If any such adverse changes occur and Advaxis and Ayala consummate the closing of the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger to the stockholders of Advaxis, Ayala or both. For a more complete discussion of what constitutes a material adverse effect on Advaxis or Ayala, see the section titled "*The Merger Agreement—Representations and Warranties*" beginning on page 187 of this proxy statement/prospectus.

If Advaxis and Ayala complete the Merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including Advaxis' pre-merger stockholders and Ayala's former stockholders. It is also possible that the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company. Alternatively, in connection with the Merger, Advaxis may seek investments from outside sources to provide capital for the combined company.

Advaxis and Ayala directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Directors and executive officers of Advaxis and Ayala have interests in the Merger that are different from, or in addition to, the interests of other Advaxis stockholders generally. These interests with respect to Advaxis' directors and executive officers may include, among others, acceleration of equity award vesting and severance payments if employment is terminated in a qualifying termination in connection with the Merger. Four current member of the Advaxis Board will continue as directors of the combined company after the Effective Time, and, following the closing of the Merger, three will be eligible to be compensated as non-employee directors of the combined company pursuant to the Advaxis non-employee director compensation policy that is expected to remain in place following the Effective Time, and current members of the Advaxis executive management team will continue with the combined company. These interests with respect to Ayala's directors and executive officers may include, among others, that certain of Ayala's directors and executive officers have options, subject to vesting, to purchase shares of Ayala Common Stock which, at the Effective Time, will be converted into and become fully vested options to purchase shares of the common stock of the combined company; and all of Ayala's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Further, certain current members of Ayala's board of directors will continue as directors of the combined company after the Effective Time, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to the Advaxis non-employee director compensation policy that is expected to remain in place following the Effective Time. Certain directors and executive officers own options to purchase the shares of their respective companies.

The Advaxis and Ayala boards of directors were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the Merger, in the case of the Ayala board of directors, recommend the approval of the Merger Agreement to Ayala Stockholders. These interests, among other factors, may have influenced the directors and executive officers of Advaxis and Ayala to support or approve the Merger.

For more information regarding the interests of Advaxis and Ayala directors and executive officers in the Merger, please see the sections titled "*The Merger—Interests of Advaxis Directors and Executive Officers in the Merger*" beginning on page 169 and "*The Merger—Interests of Ayala Directors and Executive Officers in the Merger*" beginning on page 172 of this proxy statement/prospectus.

Advaxis stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

During the period of 2020-2022, Advaxis undertook a confidential, strategic review process, which was intended to result in an actionable plan that leverages its assets, capital and capabilities to maximize stockholder value. Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on October 18, 2022, Advaxis entered into a Merger Agreement with Ayala, under which the publicly traded Ayala will merge with a wholly-owned subsidiary of Advaxis. Pre-merger Ayala stockholders will own approximately 62.5% of the combined company and pre-merger Advaxis stockholders will own approximately 37.5% of the combined company. Both Advaxis and Ayala are devoting substantially all of their time and resources to consummating this transaction; however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance stockholder value. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, Advaxis stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

If the Merger is not completed, Advaxis' and Ayala's stock price may fluctuate significantly.

The market price of Advaxis' Common Stock is subject to significant fluctuations. During the 12-month period ended November 28, 2022, the closing sales price of Advaxis' Common Stock on The Nasdaq Capital Market and the OTCQX, as applicable, ranged from a high of $32.02 on November 29, 2021, to a low of $1.58 on November 17, 2022 (accounting for the June 2022 reverse stock split).

The market price of Ayala's Common Stock is subject to significant fluctuations. During the 12-month period ended November 28, 2022, the closing sales price of Ayala's Common Stock on The Nasdaq Capital Market ranged from a high of $9.75 on November 10, 2021, to a low of $0.53 on November 21, 2022.

Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of Advaxis' Common Stock and Ayala's Common Stock will likely be volatile based on whether stockholders and other investors believe that Advaxis and Ayala can complete the Merger or otherwise raise additional capital to support the combined company's operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of Advaxis' Common Stock and Ayala's Common Stock are exacerbated by low trading volume. Additional factors that may cause the market price of Advaxis' common stock and Ayala's Common Stock, respectively, to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend its intellectual property rights or defend against claims involving the intellectual property rights of others;

- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with its future products;
- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have at times experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of Advaxis Common Stock and Ayala Common Stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Advaxis stockholders and Ayala stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.

After the completion of the Merger, the current stockholders of Advaxis and stockholders of Ayala will own a smaller percentage of the combined company than their ownership of their respective companies prior to the Merger. Immediately after the Merger, Advaxis stockholders as of immediately prior to the Merger are expected to own approximately 37.5% of the outstanding shares of the combined company and former Ayala stockholders are expected to own approximately 62.5% of the outstanding shares of the combined company.

During the pendency of the Merger, Advaxis and Ayala may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.

Covenants in the Merger Agreement impede the ability of Advaxis and Ayala to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, proposing, seeking or knowingly encouraging, facilitating or supporting any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them. For more information, see the section titled "*The Merger Agreement—No Solicitation*."

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the Transactions.

The terms of the Merger Agreement prohibit each of Advaxis and Ayala from soliciting or engaging in discussions with third parties regarding alternative Acquisition Proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited Acquisition Proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law, as described in further detail in the section titled "The Merger Agreement—No Solicitation." In addition, if the Merger Agreement is terminated by Advaxis or Ayala under certain circumstances, including because of a decision by either company's board of directors to accept a superior proposal, such company would be required to pay the other a termination fee of $600,000. This termination fee may discourage third parties from submitting alternative takeover proposals to either company or its stockholders and may cause such company's board of directors to be less inclined to recommend an alternative proposal.

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of Advaxis' Common Stock, Ayala's Common Stock, and their business prospects.

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of Advaxis' Common Stock, Ayala's Common Stock, and their business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of Advaxis' Common Stock, Ayala's Common Stock, and their business prospects.

Our efforts to have the common stock of the combined company listed on Nasdaq may not be successful.

While Advaxis intends to file an initial listing application with Nasdaq prior to the closing of the Merger, and to undertake the actions necessary to allow the stock of the combined company to be listed on The Nasdaq Capital Market as of the closing of the Merger or promptly thereafter, we may not be successful in those efforts. Because Advaxis is not currently listed on Nasdaq, the combined company will be required to meet the initial listing standards of The Nasdaq Capital Market applicable to companies seeking to uplist one or more securities from another U.S. market, such as the OTCQX. We believe that in order to achieve compliance with those listing standards, Advaxis and the combined company will need to undertake certain actions, including Advaxis obtaining the approval of its stockholders, at a special meeting, to undertake a reverse split of the Advaxis Common Stock, and the combined company raising additional capital. Any or all of these efforts may fail.

Failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations.

The Merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the Merger is not consummated, Advaxis and Ayala, as applicable, are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, the terminating party will be required to pay the non-terminating party a termination fee of $600,000; and
- the price of the terminating party's common stock may decline and remain volatile.

If the Merger does not close for any reason, either party's board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of such company's various assets, dissolve or liquidate its assets, declare bankruptcy or seek to continue to operate its business. If either company seeks another strategic transaction or attempts to sell or otherwise dispose of its various assets, there is no assurance that it will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If either company decides to dissolve and liquidates its assets, such company would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

If either party were to seek to continue its business, such company would need to determine whether to acquire one or more other product candidates. Such company would also need to raise funds to support continued operations and re-assess its workforce requirements in consideration of its reduced workforce.

If the Merger is not consummated, Advaxis and Ayala, as applicable, may be unable to retain the services of key remaining members of its management teams and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate its assets or continue its business.

If Advaxis does not successfully consummate the transaction with Ayala, Advaxis' and Ayala's, as applicable, board of directors may dissolve or liquidate its assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to Advaxis' and Ayala's stockholders will depend heavily on the timing of such transaction or liquidation.

If the Merger does not close for any reason, Advaxis' and Ayala's, as applicable, board of directors may elect to, among other things, dissolve or liquidate its assets, which may include seeking protection from creditors in a bankruptcy proceeding. If Advaxis and Ayala, as applicable, decides to dissolve and liquidate its assets, such company would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to Advaxis' and Ayala's, as applicable, stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as Advaxis and Ayala, as applicable, funds its operations in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, either party may be required to pay the other a termination fee of $600,000, which would further decrease such company's' available cash resources. If either party board of directors were to approve and recommend, and its stockholders were to approve, a dissolution and liquidation, such company would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. Advaxis' and Ayala's, as applicable, commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under its clinical trials; (ii) obligations under its employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a Change in Control; and (iii) potential litigation against such company, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of Advaxis' and Ayala's, as applicable, assets may need to be reserved pending the resolution of such obligations. In addition, either company may be subject to litigation or other claims related to a dissolution and liquidation of such company. If a dissolution and liquidation were pursued, such company's board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Advaxis and Ayala, as applicable, common stock could lose all or a significant portion of their investment in the event of its liquidation, dissolution or winding up.

Risk Factors of the Combined Company

The failure to successfully integrate the businesses and operations of Ayala and Advaxis in the expected time frame may adversely affect the combined company's future results.

We and Advaxis have operated independently and there can be no assurances that the businesses can be integrated successfully. It is possible that the integration process could result in the loss of key Ayala or Advaxis employees, independent contractors, principal investigators, Clinical Research Organizations ("CROs"), consultants, vendors, and any other third parties, the disruption of our ongoing businesses, inconsistencies in standards, controls, procedures and policies, unexpected integration issues, higher than expected integration costs and an overall integration process that takes longer than originally anticipated. Specifically, the following issues, among others, must be addressed in integrating the operations of Ayala and Advaxis in order to realize the anticipated benefits of the Merger so the combined company performs as expected:

- combining the companies' operations and corporate functions;
- combining the businesses of Ayala and Advaxis and meeting the capital requirements of the combined company, in a manner that permits the combined company to achieve any cost savings or other synergies anticipated to result from the Merger, the failure of which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all;
- integrating personnel from the two companies, especially in the COVID-19 environment which has required many people to work remotely in many locations;
- integrating and unifying Ayala's and Advaxis' pipeline of product candidates in development;
- identifying and eliminating redundant and underperforming functions and assets;
- harmonizing the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;
- maintaining existing agreements with employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, avoiding delays in entering into new agreements with prospective employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, and leveraging relationships with such third parties for the benefit of the combined company;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
- consolidating the companies' administrative and information technology infrastructure;
- coordinating research, commercialization, and marketing efforts;
- coordinating geographically dispersed organizations; and
- effecting actions that may be required in connection with obtaining regulatory or other governmental approvals.

In addition, at times the attention our management may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations or other opportunities that may have been beneficial to us, which may disrupt our ongoing business.

Advaxis and Ayala will incur substantial direct and indirect costs as a result of the Merger and the combined company will incur substantial direct and indirect costs in connection with combining the business of Advaxis and Ayala following the Merger.

Advaxis and Ayala will incur substantial expenses in connection with and as a result of consummating the Merger, and over a period of time following the consummation of the Merger, the combined company also expects to incur substantial expenses in connection with coordinating and, in certain cases, combining the businesses, operations, policies and procedures of Advaxis and Ayala. A portion of the transaction costs related to the Merger will be incurred regardless of whether the Merger is consummated. While Advaxis and Ayala have assumed that a certain level of transaction expenses will be incurred, factors beyond Advaxis' and Ayala's control could affect the total amount or the timing of these expenses. These expenses may exceed the costs historically borne by Advaxis and Ayala. These expenses could adversely affect the financial condition, results of operations and cash flows of the combined company following the consummation of the Merger.

The actual financial position and results of operations of the combined company after the Merger may differ materially from the unaudited pro forma financial information included in this joint proxy statement/prospectus.

The unaudited pro forma financial information included in this joint proxy statement/prospectus is presented for informational purposes only and may not be an indication of what Ayala's financial position or results of operations would have been had the Merger been consummated on the dates indicated. The unaudited pro forma financial information has been derived from the audited and unaudited historical financial statements of Ayala and Advaxis and certain adjustments and assumptions regarding Ayala after giving effect to the Merger. The assets and liabilities of Advaxis have been measured at fair value based on various preliminary estimates using assumptions that Ayala and Advaxis management believes are reasonable, utilizing information currently available. These fair value measurements can be highly subjective and the reasonable application of measurement principles may result in a range of alternative estimates using the same facts and circumstances. These estimates, which require extensive use of accounting estimates and management judgment, may be revised as additional information becomes available and as additional analyses are performed. Differences between preliminary estimates in the unaudited pro forma financial information and the final acquisition accounting will occur and could have a material impact on the unaudited pro forma financial information and the combined company's financial position and future results of operations.

In addition, the assumptions used in preparing the unaudited pro forma financial information may not prove to be accurate, and other factors may affect the combined company's financial condition or results of operations following the consummation of the Merger. Any material variance from the pro forma financial information may cause significant variations in the market price of the Advaxis Common Stock. See "*Unaudited Pro Forma Condensed Combined Financial Information*" beginning on page 315 of this proxy statement/prospectus.

Sales of shares of Advaxis Common Stock after the completion of the Merger may cause the market price of Advaxis Common Stock to fall.

Ayala stockholders may decide not to hold the shares of Advaxis Common Stock they receive in the Merger and other Ayala stockholders, such as funds with limitations on the amount of stock they are permitted hold in individual issuers, may be required to sell shares of Advaxis Common Stock that they receive in the Merger. Such sales, or market perception of such sales, of Advaxis Common Stock could result in higher than average trading volume following the closing of the Merger and may cause the market price for Advaxis Common Stock to decline. Such sales may take place promptly following the Merger or at other times in the future. There is no lock-up in place that would prevent institutional or larger stockholders from selling some or all of their Advaxis Common Stock after the close of the transaction.

If third parties threaten to terminate, terminate or alter existing contracts or relationships with Advaxis or Ayala, Advaxis' and Ayala's respective businesses may be materially harmed.

Ayala has contracts with customers, suppliers, vendors, landlords, licensors and other business partners which may require Ayala to obtain consents from these other parties in connection with the Merger. If these consents cannot be obtained, the combined company may suffer a loss of potential future revenues and may lose rights that are material to the business of the combined company. In addition, third parties with whom Ayala or Advaxis currently have relationships may terminate or otherwise reduce the scope of their relationship with either party in anticipation of the Merger. Any such disruptions could limit the combined company's ability to achieve the anticipated benefits of the Merger. The adverse effect of such disruptions could also be exacerbated by a delay in the completion of the Merger or the termination of the Merger Agreement.

Both Ayala and Advaxis have operated with a loss and negative cash flows for the entirety of their existence and it is expected the combined company will have to raise significant capital in the future that could be dilutive to stockholders of the combined company.

Both Ayala and Advaxis have operated with a loss and negative cash flows for the entirety of their existence. Ayala and Advaxis have incurred significant net operating losses in every year since inception and expect to continue to incur significant expenses and operating losses for the foreseeable future. Ayala's net losses were approximately $40.3 million for the year ended December 31, 2021 and $28.4 million for the nine months ended September 30, 2022. Advaxis' net losses were approximately $17.9 million for the year ended October 31, 2021 and $10.8 million for the nine months ended July 31, 2022. Based on the combined company's anticipated cash balances and recurring losses, there is substantial doubt about the combined company's ability to continue as a going concern as a standalone company.

The combined company may not be able to raise capital to continue operations in the future which could result in bankruptcy or liquidation of the combined company. As a result, adequate funding may not be available to the combined company on acceptable terms, or at all.

Risks Related to the Business of Advaxis

You should carefully consider the risks described below as well as other information provided to you in this proxy statement/prospectus, including information in the section of this document entitled "Forward-Looking Statements." The risks and uncertainties described below are not the only ones facing Advaxis. Additional risks and uncertainties not presently known to Advaxis or that it currently believes are immaterial may also impair its business operations. If any of the following risks actually occur, Advaxis' business, financial condition or results of operations could be materially adversely affected, the value of its common stock could decline, and you may lose all or part of your investment.

Risks Related to Advaxis' Financial Position, Capital Needs and Strategic Considerations

Advaxis has incurred significant losses since its inception and anticipate that it will continue to incur losses for the foreseeable future.

Advaxis is a clinical-stage biotechnology company. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Advaxis has not generated any revenue from product sales to date, and it continues to incur significant development and other expenses related to its ongoing operations. As a result, Advaxis is not profitable and have incurred losses in each period since its inception.

Advaxis expects to continue to incur losses for the foreseeable future, and it expects these losses to increase as it continues its development of, and seek regulatory approvals for, Advaxis' product candidates, and begin to commercialize any approved products. Advaxis may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of Advaxis' future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues. If any of Advaxis' product candidates fail in clinical studies or do not gain regulatory approval, or if approved, fails to achieve market acceptance, Advaxis may never become profitable. Even if Advaxis achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. Advaxis' prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' (deficit) equity and working capital.

Advaxis will require additional capital to fund its operations and if it fails to obtain necessary financing, it will not be able to complete the development and commercialization of its product candidates.

The research and development of Advaxis' products have consumed substantial amounts of cash since inception. Advaxis expects to continue to invest in advancing the clinical development of its product candidates and to commercialize any product candidates for which it receives regulatory approval. As of July 31, 2022, Advaxis had cash and cash equivalents of approximately $28.15 million. Advaxis will require additional capital for the further development of its product candidates. Advaxis is pursuing various ways to support its development efforts including debt and/or equity financing as well as targeting potential collaborators of its products.

Advaxis cannot be certain that additional funding will be available on acceptable terms, or at all. If Advaxis is unable to raise additional capital in sufficient amounts or on terms acceptable to it, Advaxis may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its products or product candidates or one or more of its other research and development initiatives. Advaxis' forecast of the period of time through which its financial resources will be adequate to support its operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. Advaxis has based this estimate on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than it currently expects. Advaxis' future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- The progress, timing, costs and results of the clinical studies underway;
- future clinical development plans it establishes for Advaxis' product candidates;
- the number and characteristics of product candidates that Advaxis develops or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that Advaxis performs more studies than those that it currently expects;
- the cost of filing, prosecuting, defending and enforcing Advaxis' patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against Advaxis or its product candidates;
- the effect of competing technological and market developments;

- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and

- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Advaxis may receive regulatory approval in regions where it chooses to commercialize its products on its own.

Risks Related to Advaxis' Business, Industry and Strategy

Advaxis is currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, an ongoing military conflict between Russia and Ukraine, and record inflation. Advaxis' business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine, geopolitical tensions, or record inflation.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has caused record inflation globally. Advaxis is continuing to monitor the situation in Ukraine and globally and assessing its potential impact on Advaxis' business.

Although, to date, Advaxis' business has not been materially impacted by the ongoing military conflict between Russian and Ukraine, geopolitical tensions, or record inflation, it is impossible to predict the extent to which its operations will be impacted in the short and long term, or the ways in which the conflict in Ukraine, geopolitical tensions, or record inflation may impact Advaxis' business. The extent and duration of the conflict in Ukraine, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict, but could be substantial.

Advaxis is a clinical stage company.

Advaxis is a clinical stage biotechnology company with a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout Advaxis' clinical stage, it may exhaust its financial resources and be unable to complete the development of its products. Advaxis anticipates that it will continue to incur significant operational costs as Advaxis executes its clinical development strategy. Advaxis' deficit will continue to grow during its drug development period.

Advaxis has sustained losses from operations in each fiscal year since its inception, and it expects losses to continue for the foreseeable future due to its substantial investment in research and development. As of July 31, 2022, Advaxis had an accumulated deficit of approximately $438.4 million and stockholders' equity of approximately $28.2 million. Advaxis expects to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that its immunotherapies will become commercially viable or profitable as a result of these expenditures. If Advaxis fails to raise a significant amount of capital, it may need to significantly curtail operations or cease operations in the near future. If any of Advaxis' product candidates fail in clinical trials or does not gain regulatory approval, Advaxis may never become profitable. Even if Advaxis achieves profitability in the future, it may not be able to sustain profitability in subsequent periods.

Advaxis is significantly dependent on the success of its Lm Technology platform and its product candidates based on this platform.

Advaxis is invested, and it expects to continue to invest, significant efforts and financial resources in the development of product candidates based on its *Lm* Technology. Advaxis' ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates, and such regulatory approval and commercialization may never occur.

The successful development of immunotherapies is highly uncertain.

Successful development of immunotherapies is highly uncertain and is dependent on numerous factors, many of which are beyond Advaxis' control. Immunotherapies that appear promising in the early phases of development may fail to reach, or be delayed in reaching, the market for several reasons including:

- preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, delays in receiving the necessary products or supplies for the conduct of clinical or pre-clinical trials, additional time requirements for data analysis, or Biologics License Application ("BLA") preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, FDA delays in inspecting manufacturing establishments, failure to receive FDA approval for manufacturing processes or facilities, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

Even if Advaxis' product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of risk evaluation and mitigation strategies, or REMS, to monitor the safety or efficacy of the products. If Advaxis does not receive FDA approval for, and successfully commercialize its product candidates, it will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing Advaxis' product candidates will have a material adverse impact on its business and financial condition.

Advaxis must rely upon third parties for manufacturing.

Advaxis currently has agreements with third party manufacturing facilities for production of many of its immunotherapies for research and development and testing purposes. Advaxis depends on third-party manufacturers to supply all of its clinical materials, but it does not have direct control over their personnel or operations. Third-party manufacturers must be able to meet Advaxis' deadlines as well as adhere to quality standards and specifications. Advaxis' reliance on third parties for the manufacturing of its drug substance, investigational new drugs and, in the future, any approved products, creates a dependency that could severely disrupt Advaxis' research and development, its clinical testing, and ultimately its sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. For instance, manufacturers may experience unforeseen problems, such as material or personnel shortages, temporary or permanent facility closures, or scale up challenges. If any contracted manufacturing operation is unreliable or unavailable, Advaxis may not be able to manufacture clinical drug supplies of its immunotherapies, and its preclinical and clinical testing programs may not be able to move forward and its entire business plan could fail. If Advaxis is able to commercialize its products in the future, there is no assurance that any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner.

There is also no guarantee that Advaxis' third-party manufacturers will be able to manufacture its product candidates in accordance with current Good Manufacturing Practices, or cGMPs. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If these third-party manufacturers are not able to comply with cGMPs, Advaxis may not be able to conduct clinical trials, may need to conduct additional studies, and may not, eventually, receive and maintain FDA approval for those products. Deviations from manufacturing requirements may also require remedial measures that may be costly and/or time-consuming for a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon or by third parties with whom Advaxis contracts could materially harm its business. A failure to comply with the applicable regulatory requirements may also result in regulatory enforcement actions against Advaxis' manufacturers.

While Advaxis is ultimately responsible for the manufacturing of its product candidates, other than through its contractual arrangements, Advaxis has little control over its manufacturers' compliance with these regulations and standards. If Advaxis' manufacturers encounter manufacturing difficulties, including cGMP compliance, it may need to find alternative manufacturing facilities, which it may not be able to on favorable terms or at all, and which would significantly impact Advaxis' ability to develop, obtain and maintain regulatory approval for or market its product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. Advaxis must also receive FDA approval for the use of any new manufacturers for commercial supply.

If Advaxis is unable to establish, manage or maintain strategic collaborations in the future, its revenue and drug development may be limited.

Advaxis' strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of its clinical product candidates, and it may rely even more on strategic collaborations for research, development, marketing and commercialization for some of Advaxis' immunotherapies. To date, Advaxis has been heavily reliant upon third party outsourcing for its clinical trials execution and production of drug supplies for use in clinical trials. Establishing strategic collaborations is difficult and time-consuming. Advaxis' discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of Advaxis' financial, clinical, regulatory or intellectual property position. Advaxis' current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of its immunotherapies or the generation of sales revenue. To the extent that Advaxis has entered or will enter into co-promotion or other collaborative arrangements, its product revenues are likely to be lower than if it directly marketed and sold any products that Advaxis may develop.

Management of Advaxis' relationships with its collaborators will require:

- significant time and effort from Advaxis' management team;
- financial funding to support said collaboration;
- coordination of Advaxis' research and development programs with the research and development priorities of its collaborators; and
- effective allocation of Advaxis' resources to multiple projects.

If Advaxis continues to enter into research and development collaborations at the early phases of drug development, its success will in part depend on the performance of its corporate collaborators. Advaxis will not directly control the amount or timing of resources devoted by its corporate collaborators to activities related to its immunotherapies and its collaborations may terminate at any time. Advaxis' corporate collaborators may not commit sufficient resources to its research and development programs or the commercialization, marketing or distribution of its immunotherapies. If any corporate collaborator fails to commit sufficient resources or terminate their collaborations with Advaxis, its preclinical or clinical development programs related to this collaboration could be delayed or terminated.

Further, Advaxis' collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with Advaxis. Collaborators may also fail to comply with the applicable regulatory requirements, which may subject them or Advaxis to regulatory enforcement actions. Finally, if Advaxis fails to make required milestone or royalty payments to its collaborators or to observe other obligations in its agreements with them, Advaxis' collaborators may have the right to terminate those agreements.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

In an effort to optimize processes and results, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered as product candidates are developed from preclinical studies to late-stage clinical trials toward approval and commercialization. Any of these changes could cause Advaxis' product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, regulatory disclosure, or prior approval from the FDA. For instance, the FDA may require that Advaxis conducts a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude Advaxis' development and commercialization plans, and the regulatory approval of its product candidates. It may also require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Advaxis' product candidates and jeopardize its ability to commence product sales and generate revenue. Any of the foregoing could limit Advaxis' future revenues and growth. Any changes would also require that Advaxis devotes time and resources to manufacturing development, including with third-party manufacturers, and would also likely require additional testing and regulatory actions on its part, which may delay the development of its product candidates.

Advaxis may incur significant costs complying with environmental laws and regulations.

Advaxis and its contracted third parties use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, Advaxis stores these materials and wastes resulting from their use at Advaxis or its outsourced laboratory facility pending their ultimate use or disposal. Advaxis contract with a third party to properly dispose of these materials and wastes. Advaxis is subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with such laws and regulations may be costly.

Additional laws and regulations governing international operations could negatively impact or restrict Advaxis' operations.

If Advaxis further expands its operations outside of the United States, it must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring Advaxis to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If Advaxis expands its presence outside of the United States, it will require Advaxis to dedicate additional resources to comply with these laws, and these laws may preclude it from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit its growth potential and increase Advaxis' development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Advaxis is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. Advaxis can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, exclusion from public tenders, reputational harm and other consequences. Advaxis has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Advaxis plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and it can be held liable for the corrupt or other illegal activities of its personnel, agents or partners, even if Advaxis does not explicitly authorize or have prior knowledge of such activities.

If Advaxis uses biological materials in a manner that causes injury, it may be liable for damages.

Advaxis' research and development activities involve the use of biological and hazardous materials. Although Advaxis believes its safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, it cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. Advaxis does not carry specific biological waste or pollution liability or remediation insurance coverage, nor do its workers' compensation, general liability, and property and casualty insurance policies provide coverage for damages and fines/penalties arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, Advaxis could be held liable for damages or penalized with fines in an amount exceeding its resources, and its clinical trials or regulatory approvals could be suspended or terminated.

Advaxis needs to attract and retain highly skilled personnel; it may be unable to effectively manage growth with its limited resources.

As of October 31, 2022 Advaxis had 15 employees, 14 of which were full time employees. Advaxis' ability to attract and retain highly skilled personnel is critical to its operations and expansion. Advaxis faces competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than it has. Advaxis may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If Advaxis is not successful in attracting and retaining these personnel, or integrating them into its operations, business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances Advaxis may be unable to conduct certain research and development programs, unable to adequately manage its clinical trials and other products, unable to commercialize any products, and unable to adequately address its management needs.

Advaxis depends upon its senior management and key consultants and their loss or unavailability could put it at a competitive disadvantage.

Advaxis depends upon the efforts and abilities of its senior executives, as well as the services of several key consultants. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on Advaxis' business, prospects, financial condition and results of operations. Advaxis has not obtained, does not own, nor is it the beneficiary of, key-person life insurance.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. Advaxis may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, Advaxis' actual or proposed immunotherapies could become obsolete before it recoups any portion of its related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. Advaxis competes with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with Advaxis in recruiting and retaining highly qualified scientific personnel and consultants. Advaxis' ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to Advaxis.

Advaxis is aware of certain investigational new products under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases it has targeted for product development. Various companies are developing biopharmaceutical products that have the potential to directly compete with Advaxis' immunotherapies even though their approach may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and major pharmaceutical companies, including companies like: Gritstone, Moderna, Bristol-Myers Squibb Company ("BMS"), Merck and Neon Therapeutics, among others, each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than Advaxis does (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). Advaxis also experiences competition in the development of its immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions.

In addition, certain of Advaxis' immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

Risks Related to the Development and Regulatory Approval of Advaxis Product Candidates

Advaxis can provide no assurance that its clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.

Advaxis is currently evaluating the safety and efficacy of its product candidates in clinical trials. However, even though the initiation and conduct of the clinical trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an Investigational New Drug Application, or IND, in the United States, or the equivalent in countries outside of the United States), Advaxis is at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining FDA and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on Advaxis' business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of Advaxis' clinical trials or study endpoints; or it may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with Advaxis' interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of its product candidates may not be sufficient to support the submission of a BLA or New Drug Application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which Advaxis contracts for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering Advaxis' clinical data insufficient for approval.

In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Advaxis has not submitted for nor obtained regulatory approval for any product candidate in-humans (US & EU) and it is possible that none of its existing product candidates or any product candidates Advaxis may seek to develop in the future will ever obtain regulatory approval.

Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.

Product candidates are subject to extensive pre-clinical testing and clinical trials to demonstrate their safety and efficacy in humans. Conducting pre-clinical testing and clinical trials is a lengthy, time-consuming and expensive process that takes many years. Advaxis cannot be sure that pre-clinical testing or clinical trials of any of its product candidates will demonstrate the safety, efficacy and benefit-to-risk profile necessary to obtain marketing approvals. In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in larger or late-stage clinical trials, which are required for marketing approval.

Even if Advaxis is successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, it must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. There are a number of additional factors that may cause Advaxis' clinical trials to be delayed, prematurely terminated or deemed inadequate to support regulatory approval, such as:

- safety issues up to and including patient death (whether arising with respect to trials by third parties for compounds in a similar class as tour product or product candidate), inadequate efficacy, or an unacceptable risk-benefit profile observed at any point during or after completion of the trials;

- slower than expected rates of patient enrollment, which could be due to any number of factors, including failure of Advaxis' third-party vendors, including its CROs, to effectively perform their obligations to Advaxis, a lack of patients who meet the enrollment criteria or competition from clinical trials in similar product classes or patient populations, or onerous treatment administration requirements;

- subjects may drop out of Advaxis' clinical trials, be lost to follow-up at a higher rate than it anticipates, or not comply with the required clinical trial procedures;

- Advaxis may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and its CROs;

- the cost of clinical trials may be greater than Advaxis anticipates or it may have insufficient funds for a clinical trial or to pay the substantial FDA user fees;

- the FDA or comparable foreign regulatory authorities may disagree with Advaxis' study design, including endpoints, its intended indications, or its interpretation of data;

- the risk of failure of Advaxis' clinical investigational sites and related facilities, including its suppliers and CROs, to maintain compliance with the FDA's cGMP and Good Clinical Practices, or GCP, regulations or similar regulations in countries outside of the U.S., including the risk that these sites fail to pass inspections by the appropriate governmental authority, which could invalidate the data collected at that site or place the entire clinical trial at risk;

- any inability to reach agreement or lengthy discussions with the FDA, equivalent regulatory authorities, or ethical review committees on trial design that Advaxis is able to execute or it may be required to modify its trial design such that studies are impracticable;

- regulators may require Advaxis to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- FDA refusal to accept the data from foreign clinical trial sites to the extent Advaxis uses such sites;
- changes in laws, regulations, regulatory policy or clinical practices, especially if they occur during ongoing clinical trials or shortly after completion of such trials; and
- clinical trial record keeping or data quality and accuracy issues.

Any deficiency in the design, implementation or oversight of Advaxis' development programs could cause it to incur significant additional costs, conduct additional trials, experience significant delays, prevent it from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm its business and cause its stock price to decline.

Advaxis may face legal claims; legal disputes are expensive and it may not be able to afford the costs.

Advaxis may face legal claims involving stockholders, consumers, clinical trial subjects, competitors, regulators and other parties. Advaxis is engaged in legal proceedings. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping Advaxis from engaging in business practices, or requiring other remedies, including, but not limited to, compulsory licensing of patents.

The costs of litigation or any proceeding, including, but not limited to, those relating to Advaxis' intellectual property or contractual rights, could be substantial, even if resolved in its favor. Some of Advaxis' competitors or financial funding sources have far greater resources than it does and may be better able to afford the costs of complex litigation. Also, a lawsuit, even if frivolous, will require considerable time commitments on the part of management, Advaxis' attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect Advaxis' financial results. Legal claims may also adversely impact Advaxis in other ways, such as the withdrawal or slower enrollment in or from its clinical trials, regulatory enforcement actions, and negative media attention, any of which could materially and negatively harm Advaxis and its operations.

Advaxis can provide no assurance of the successful and timely development of new products.

Advaxis immunotherapies are at various stages of development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Advaxis will need to complete significant additional clinical trials demonstrating that its product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Advaxis' success will depend on its ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, Advaxis may invest substantial amounts of time and money without developing revenue-producing products. As Advaxis enters a more extensive clinical program for its product candidates, the data generated in these studies may not be as compelling as the earlier results.

The proposed development schedules for Advaxis immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, clinical holds, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within its control. Any delay in the development, introduction or marketing of Advaxis products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of Advaxis' projects, the unproven technology involved, and the other factors described elsewhere in this section, there can be no assurance that Advaxis will be able to successfully complete the development or marketing of any new products which could materially harm its business, results of operations and prospects.

Advaxis research and development expenses are subject to uncertainty.

Factors affecting Advaxis research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than Advaxis has;
- need for market acceptance of Advaxis' immunotherapies if it receives regulatory approval;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- ability to raise sufficient capital to fund Advaxis research and development activities;
- amount and timing of operating costs and capital expenditures relating to expansion of Advaxis business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that Advaxis research and development expenses will be consistent from period to period. Advaxis may be required to accelerate or delay incurring certain expenses depending on the results of its studies and the availability of adequate funding.

Advaxis may be required to suspend or discontinue clinical trials for a number of reasons, which could preclude approval of any of its product candidates.

Advaxis clinical trials may be suspended at any time for a number of reasons. A clinical trial may be suspended or terminated by Advaxis, an Institutional Review Board ("IRB"), the FDA or other regulatory authorities due to a failure to conduct the clinical trial in accordance with regulatory requirements or its clinical protocols, presentation or identification of unforeseen safety signals or issues, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or for other business-related reasons. For example, in June 2019, Advaxis announced that it was closing its AIM2CERV Phase 3 clinical trial with AXAL in cervical cancer due to the delays Advaxis incurred as a result of the recent FDA partial clinical hold on the trial, as well as the estimated cost and time to completion of the trial. Furthermore, Advaxis has completed the clinical study report from Part A of the ADXS-NEO study and plans to close its ADXS-NEO program IND as next step. In addition, clinical trials for Advaxis' product candidates could be suspended due to adverse side effects. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Advaxis may also voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable risk to patients or do not demonstrate clinical benefit. If Advaxis elects or is forced to suspend or terminate any clinical trial of any product candidates that it develops, the commercial prospects of such product candidates will be harmed and its ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may significantly harm Advaxis' business, financial condition, results of operations and prospects.

Preliminary or interim results of a clinical trial are not necessarily predictive of future or final results.

Interim or preliminary data from clinical trials that Advaxis may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. Even if Advaxis' clinical trials are completed as planned, it cannot be certain that their results will support its proposed indications.

Advaxis is subject to numerous risks inherent in conducting clinical trials.

Advaxis outsources the management of its clinical trials to third parties. Agreements with CROs, clinical investigators and medical institutions for clinical testing and data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, Advaxis' clinical trials. For example, if any of Advaxis' clinical trial sites or CROs fail to comply with FDA-approved good clinical practices, Advaxis may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to Advaxis' clinical protocols or for other reasons, its clinical trials may be extended, delayed or terminated, and Advaxis may be unable to obtain regulatory approval for, or successfully commercialize, its agents. Advaxis is not certain that it will successfully recruit enough patients to complete its clinical trials nor that it will reach its primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of future development of Advaxis' agents.

While Advaxis has agreements governing the activities of such third parties and are responsible for its third-party service provider's activities and regulatory compliance, it has limited influence and control over their actual performance and activities and cannot control whether or not they devote sufficient time and resources to Advaxis' ongoing clinical, non-clinical, and preclinical programs and cannot control whether they maintain regulatory compliance. Advaxis' third-party service providers may also have relationships with other entities, some of which may be its competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm Advaxis' competitive position.

Agreements with third parties conducting or otherwise assisting with Advaxis' clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of Advaxis' relationships with these third parties terminate, it may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involve additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if Advaxis needs to enter into alternative arrangements, it could delay its product development activities and adversely affect its business. Though Advaxis carefully manages its relationships with third parties, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on Advaxis' business, financial condition and prospects, and results of operations.

Advaxis or its regulators may suspend or terminate its clinical trials for a number of reasons. Advaxis may voluntarily suspend or terminate its clinical trials if at any time it believes they present an unacceptable risk to the patients enrolled in its clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of Advaxis' clinical trials, or place its products on temporary or permanent hold, at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in Advaxis' clinical trials.

Advaxis' clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that Advaxis or its clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, it may receive reports of observations or warning letters detailing deficiencies, and it will be required to implement corrective actions. If regulatory agencies deem Advaxis' responses to be inadequate or are dissatisfied with the corrective actions it or its clinical trial sites have implemented, Advaxis' clinical trials may be temporarily or permanently discontinued, may be fined, Advaxis or its investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve its marketing applications or allow it to manufacture or market its products, and Advaxis may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in Advaxis failing to obtain regulatory approval for its product candidates, which would materially harm its business, results of operations and prospects.

Advaxis employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on its business.

Advaxis is exposed to the risk of employee and third-party fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to Advaxis. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Advaxis' reputation. It is not always possible to identify and deter this type of misconduct, and the precautions Advaxis takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a federal False Claims Act, or FCA, case against Advaxis even if the government considers the claim unmeritorious and declines to intervene, which could require Advaxis to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against Advaxis, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

Advaxis must comply with significant government regulations.

The research and development, manufacturing and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, distribution, advertising and promotion of the products that Advaxis is developing. If Advaxis obtains approval for any of its product candidates, its operations will be directly or indirectly through its customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the FCA, and privacy laws. Advaxis, its product candidates, and its products, if it receives marketing approval are and will continue to be subject to extensive governmental regulation and regulatory authorities do and will continue to closely monitor Advaxis and its contractor's compliance through, among other methods, inspections. Noncompliance with applicable laws and requirements can result in various adverse consequences and regulatory enforcement actions, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, restitution or disgorgement of profits, recall or seizure of products, exclusion from having its products reimbursed by federal health care programs, the curtailment or restructuring of Advaxis' operations, corporate integrity agreements or consent decrees, refusal to permit product import or export, modifications to labeling or promotional materials, issuance of corrective information, regulatory authority public statements, warning, untitled, or cyber letters, requirements for post-market studies or REMS, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts. Any of these events could prevent Advaxis from achieving or maintaining product approval and market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent Advaxis from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on Advaxis' operations and business and could adversely impact its stock price and could significantly harm Advaxis' business, financial condition, results of operations, and prospects.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for marketing approval of a biologic, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its cGMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The cGMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to Advaxis in terms of getting its immunotherapies through clinical testing and to market.

Advaxis may not obtain or maintain the benefits associated with Orphan Drug Designation, including market exclusivity.

Although Advaxis has been granted a designation from the FDA under the Orphan Drug Act, or ODA, intended to treat a rare disease or condition (Orphan Drug Designation, or "ODD") for AXAL for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as the European Medicines Agency, or EMA, ODD for AXAL for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU, Advaxis may not receive the benefits associated with ODD. This may result from a failure to maintain orphan drug status or result from a competing product reaching the market that has an orphan designation for the same disease indication. Moreover, while ODD does provide Advaxis with certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Under U.S. rules for orphan drugs, if such a competing product reaches the market before Advaxis does, if such product is considered by FDA to be the same as Advaxis', and if such product is intended for the same orphan indication, the competing product could potentially obtain a scope of market exclusivity that limits or precludes its product from being sold in the United States for seven years unless Advaxis can demonstrate that its product is clinically superior. Even if Advaxis obtains exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior to Advaxis in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which Advaxis' orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Moreover, Advaxis may not be able to maintain its ODD or exclusivity and its product candidates would not be eligible for exclusivity if the approved indication is broader than the ODD.

In addition, if and when Advaxis requests ODD in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Advaxis may incur substantial liabilities from any product liability claims if its insurance coverage for those claims is inadequate.

Advaxis faces an inherent risk of product liability exposure related to the testing of its immunotherapies in human clinical trials and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against Advaxis if one of the immunotherapies causes, or merely appears to have caused, an injury. If Advaxis cannot successfully defend itself against the product liability claim, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Advaxis' immunotherapies;
- damage to Advaxis' reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize immunotherapies; and
- increased difficulty in raising required additional funds in the private and public capital markets.

Advaxis has product liability and clinical trial liability insurance coverage for each clinical trial. Advaxis does not have product liability insurance for sold commercial products because it does not have products on the market. Advaxis plans to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of its immunotherapies. However, insurance coverage is increasingly expensive and Advaxis may not be able to maintain insurance coverage at a reasonable cost. Further, Advaxis may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Advaxis may not receive Fast Track designation, Breakthrough Therapy Designation or any other designation that it may apply for from the FDA and, if granted, such designations may not actually lead to a faster development or regulatory review or approval process.

The FDA has granted a designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need (the "Fast Track" designation) for AXAL for adjuvant therapy for high-risk locally advanced cervical cancer patients, and has granted Fast Track designation for ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. Advaxis may seek Breakthrough Therapy Designation for its product candidates or Fast Track designation for certain of its other product candidates. There is no guarantee, however, that Advaxis will be able to obtain or maintain such designations.

The FDA has broad discretion whether or not to grant any special designation, so even if Advaxis believes one of its product candidates is eligible for this designation, it cannot assure you that the FDA would decide to grant it. Additionally, even if Advaxis receives a special designation, it may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw the designation if it believes that the designation is no longer supported by data from Advaxis' clinical development program.

The results of clinical trials conducted at clinical trial sites outside the United States might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

Some of the clinical trials for Advaxis product candidates that are being or will be conducted through its partnerships and collaborations may be conducted outside the United States, and it intends in the future to conduct additional clinical trials outside the United States. Although the FDA, EMA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles such as IRB or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application. Similarly, Advaxis must also ensure that any data submitted to foreign regulatory authorities adheres to their standards and requirements for clinical trials and there can be no assurance a comparable foreign regulatory authority would accept data from trials conducted outside of its jurisdiction.

Advaxis' relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute (the "AKS") and the FCA which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of Advaxis' product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect Advaxis' ability to operate include, but are not limited to:

- the AKS, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, or ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, of the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that Advaxis' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against Advaxis, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of Advaxis' operations, as well as additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom Advaxis expects to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Obtaining and maintaining regulatory approval of Advaxis' product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of Advaxis' product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that Advaxis intends to charge for its products are also subject to approval.

Advaxis may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which it must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for Advaxis and could delay or prevent the introduction of its products in certain countries. If Advaxis fails to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of its product candidates will be harmed.

Even if Advaxis receives regulatory approval of any product candidates, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and it may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

If any of Advaxis' product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, distribution, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, Advaxis will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that it conducts post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, Advaxis and its contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspection observations. Accordingly, Advaxis and others with whom it works must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that Advaxis receives for its product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data Advaxis hopes to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of Advaxis' product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves Advaxis' product candidates, it will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with Advaxis' product candidates, including adverse events of unanticipated severity or frequency, or with its third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of Advaxis' products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by Advaxis or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of Advaxis' product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Advaxis' product candidates. Advaxis cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If Advaxis is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Advaxis is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for Advaxis' product candidates, if approved, which could make it difficult for Advaxis to sell any product candidates profitably.

The success of Advaxis' product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. Advaxis cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, its product candidates or assure that coverage and reimbursement will be available for any product that it may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require Advaxis to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of its products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if Advaxis obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for it to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use Advaxis' product candidates, once approved, unless coverage is provided and reimbursement is adequate

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on Advaxis' business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact Advaxis' business in the future by requiring, for example: (i) changes to its manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of its products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of Advaxis' business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." As a result of the individual mandate repeal, subsequent litigation challenged the validity of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, or TCJA, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when the court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. Advaxis will continue to evaluate the effect that the ACA and its possible repeal and replacement has on its business.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Bipartisan bills to appropriate funds for CSR payments were proposed in 2017 and 2018, but the proposals have not been enacted into law. Multiple state Attorneys General filed suit to stop the administration from terminating the subsidies, but their case was dismissed by a federal judge in California on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace and providers, and the potential effect on Advaxis' business, are not yet known.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Advaxis' business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Advaxis' business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process Advaxis' regulatory submissions, which could have a material adverse effect on its business. Further, upon completion of this offering and in Advaxis' operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Approval of Advaxis' product candidates does not ensure successful commercialization and reimbursement.

Advaxis is not currently marketing its product candidates, nor can it until they are approved; however, Advaxis is seeking partnering and commercial opportunities for its products. Advaxis cannot assure you that it will be able to commercialize any of its product candidates itself or find a commercialization partner or that it will be able to agree to acceptable terms with any partner to launch and commercialize its products.

The commercial success of Advaxis' product candidates is subject to risks in both the United States and European countries. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, Advaxis' ability or any potential partner's ability to successfully commercialize in such a country would be impacted negatively. Furthermore, if these measures prevent Advaxis or any potential partner from selling on a profitable basis in a particular country, they could prevent the commercial launch or continued sale in that country and could adversely impact the commercialization market opportunity in other countries.

Moreover, as a condition of approval, the regulatory authorities may require that Advaxis conduct post-approval studies. Those studies may reveal new safety or efficacy findings regarding Advaxis' drug that could adversely impact the continued commercialization or future market opportunity in other countries.

In addition, Advaxis predominantly relies on a network of suppliers and vendors to manufacture its products. Should a regulatory authority make any significant findings on an inspection of Advaxis' own operations or the operations of those companies, the ability for it to continue producing its products could be adversely impacted and further production could cease. Regulatory GMP requirements are extensive and can present a risk of injury or recall, among other risks, if not manufactured or labeled properly under GMPs.

Advaxis' potential revenues from the commercialization of its product candidates are subject to these and other factors, and therefore it may never reach or maintain profitability.

Even if Advaxis is successful in obtaining market approval, commercial success of any of its product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require Advaxis to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert its resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of Advaxis' products once approved, market acceptance and commercial success would be reduced.

In addition, if one of Advaxis' products is approved for marketing, it will be subject to significant regulatory obligations regarding product promotion, the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that Advaxis' third-party providers comply) with cGMPs, and GCPs for any clinical trials that it conducts post-approval. In addition, there is always the risk that Advaxis or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with Advaxis product candidates' post-market approval could have a material adverse effect on its business, financial condition and results of operations.

Risks Related to Advaxis' Intellectual Property

Advaxis relies on patents to protect its technology. Advaxis may be unable to protect its intellectual property rights and it may be liable for infringing the intellectual property rights of others.

Advaxis' ability to compete effectively will depend on its ability to maintain the proprietary nature of its technologies, including the *Lm*-LLO based immunotherapy platform technology, and the proprietary technology of others with whom Advaxis has entered into collaboration and licensing agreements.

Currently, Advaxis owns or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with Penn and Merck. Advaxis has obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel, at the University of Pennsylvania.

Advaxis owns or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Advaxis' success depends in part on its ability to obtain patent protection both in the United States and in other countries for its product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and Advaxis cannot guarantee that sufficient funds will be available. Advaxis' ability to protect its product candidates from unauthorized or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, Advaxis' ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if Advaxis' product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide Advaxis with sufficient protection for its product candidates or provide sufficient protection to afford it a commercial advantage against competitive products or processes.

In addition, Advaxis cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to Advaxis. Even if patents have issued or will issue, Advaxis cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide it with any significant protection against competitive products or otherwise be commercially valuable to Advaxis. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If Advaxis encounters such difficulties in protecting or are otherwise precluded from effectively protecting its intellectual property rights in foreign jurisdictions, its business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including Advaxis' patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented as a result of laws, rules and guidelines that are changed due to legislative, judicial or administrative actions, or review, which render Advaxis' patents unenforceable or invalid. Advaxis' patents can be challenged by its competitors who can argue that its patents are invalid, unenforceable, lack utility, sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect Advaxis' product candidates if competitors devise ways of making or using these product candidates without infringing its patents.

Advaxis will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and Advaxis has the funds to enforce its rights, if necessary.

The expiration of Advaxis' owned or licensed patents before completing the research and development of its product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect Advaxis' business and results of operations.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If Advaxis is involved in such litigation, it could cause delays in bringing product candidates to market and harm its ability to operate.

Advaxis' success will depend in part on its ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of Advaxis' technologies infringe these patent claims or that it is employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon Advaxis' existing or future patents. Proceedings involving Advaxis' patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of Advaxis' inventions relating to its product candidates; and/or
- the enforceability, validity or scope of protection offered by Advaxis' patents relating to its product candidates.

Even if Advaxis is successful in these proceedings, it may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on Advaxis. If Advaxis is unable to avoid infringing the patent rights of others, it may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. Advaxis may not have sufficient resources to bring these actions to a successful conclusion. In addition, if Advaxis does not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared valid, Advaxis may:

- incur substantial monetary damages;
- encounter significant delays in bringing Advaxis product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of Advaxis product candidates or methods of treatment requiring licenses.

Advaxis may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

Advaxis also relies on trade secrets to protect its proprietary technologies, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Advaxis relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect its trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover Advaxis' trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of Advaxis' proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect its competitive business position.

Some of Advaxis' products are dependent upon its license agreement with Penn; if Advaxis breaches the license agreement and/or fail to make payments due and owing to Penn under its license agreement, its business may be materially and adversely affected.

Pursuant to the terms of Advaxis' license agreement with Penn, which has been amended from time to time, it has acquired exclusive worldwide licenses for patents and patent applications related to its proprietary *Listeria* vaccine technology. The license provides Advaxis with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires Advaxis to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of July 31, 2022, Advaxis did not have outstanding payables to Penn. Advaxis can provide no assurance that it will be able to make all future payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that it will be able to obtain licenses from Penn for other rights that may be important to Advaxis, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm Advaxis' business, financial condition and operating results.

If Advaxis is unable to obtain licenses needed for the development of its product candidates, or if it breaches any of the agreements under which Advaxis licenses rights to patents or other intellectual property from third parties, it could lose license rights that are important to its business.

If Advaxis is unable to maintain and/or obtain licenses needed for the development of its product candidates in the future, it may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of Advaxis' licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. Advaxis can provide no assurance that it will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, Advaxis can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by Advaxis are based on licensed technology, royalty payments on the licenses will reduce its gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm Advaxis' business, financial condition and its operations.

Risks Related to Ownership of Advaxis' Securities

Because Advaxis is quoted on the OTCQX instead of an exchange or national quotation system, its investors find it more difficult to trade in its stock or might experience volatility in the market price of Advaxis' Common Stock.

Advaxis' Common Stock is quoted on the OTCQX. The OTCQX is often highly illiquid, in part because it does not have a national quotation system by which potential investors can follow the market price of shares except through information received and generated by a limited number of broker-dealers that make markets in particular stocks. There is a greater chance of volatility for securities that are quoted on the OTCQX as compared to a national exchange or quotation system. This volatility may be caused by a variety of factors, including the lack of readily available price quotations, the absence of consistent administrative supervision of bid and ask quotations, lower trading volume, and market conditions. Investors in Advaxis' Common Stock may experience high fluctuations in the market price and volume of the trading market for its securities. These fluctuations, when they occur, have a negative effect on the market price for Advaxis' securities. Accordingly, Advaxis stockholders may not be able to realize a fair price from their shares when they determine to sell them or may have to hold them for a substantial period of time until the market for its Common Stock improves.

Advaxis' stock is quoted on the OTCQX, if it fails to remain current on its reporting requirements, Advaxis could be removed from the OTCQX which would limit the ability of broker-dealers to sell its securities in the secondary market.

Companies trading on the OTCQX, must be reporting issuers under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTCQX. As a result, the market liquidity for Advaxis' securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market. In addition, it may be unable to get relisted on the OTCQX, which may have an adverse material effect on Advaxis.

Advaxis could issue additional "blank check" preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights, and provisions in its charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Advaxis' certificate of incorporation, as amended, provides that it may authorize and issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights, and preferences as may be determined from time to time by Advaxis' Board. Advaxis' Board is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting, or other rights, which could dilute the interest of or impair the voting power of its holders of Common Stock. The issuance of a series of preferred stock could be used as a method of discouraging, delaying, or preventing a change in control. For example, it would be possible for Advaxis' Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of Advaxis.

Sales of additional equity securities may adversely affect the market price of Advaxis' Common Stock and your rights may be reduced.

Advaxis expects to continue to incur drug development and selling, general and administrative costs, and to satisfy its funding requirements, it will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of Advaxis' Common Stock or other equity securities in the public markets may adversely affect the market price of its Common Stock and stock price may decline substantially. Advaxis shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than Advaxis' existing Common Stock.

The price of Advaxis' Common Stock and warrants may be volatile.

The trading price of Advaxis' Common Stock and warrants may fluctuate substantially. The price of Advaxis' Common Stock and warrants that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond Advaxis' control and may not be related to its operating performance. These fluctuations could cause you to lose part or all of your investment in Advaxis' Common Stock and warrants. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in Advaxis' net loss or fluctuations in its operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of Advaxis stock;
- significant dilution caused by the anti-dilutive clauses in Advaxis' financial agreements;
- departures of key personnel;
- changes in the regulatory status of Advaxis' immunotherapies, including results of its clinical trials;

- events affecting Penn or any current or future collaborators;
- announcements of new products or technologies, commercial relationships or other events by Advaxis or its competitors;
- regulatory developments in the United States and other countries;
- failure of Advaxis' Common Stock or warrants to be listed or quoted on the OTCQX® Best Market or on a national market system;
- changes in accounting principles; and
- discussion of Advaxis or its stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of Advaxis' stock price, it may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from its business.

The market prices for Advaxis' Common Stock may be adversely impacted by future events.

Advaxis' Common Stock began trading on the over-the-counter-markets on July 28, 2005 and is currently quoted on the OTCQX under the symbol ADXS. Market prices for Advaxis' Common Stock and warrants will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in Advaxis' financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for Advaxis' Common Stock and warrants;
- investor perceptions of Advaxis and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

So long as Advaxis' Common Stock continues to be quoted on the OTCQX, it could be subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

As Advaxis' Common Stock has been de-listed from The Nasdaq Capital Market and is now quoted on the OTCQX, which is not a "national securities exchange" as defined by the Exchange Act, and thus its Common Stock will be become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that so long as Advaxis' Common Stock is not listed on a national securities exchange, the ability of stockholders to sell their Common Stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

Advaxis may be at an increased risk of securities litigation, which is expensive and could divert management attention.

The market price of Advaxis' Common Stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Advaxis may be the target of this type of litigation in the future. Securities litigation against Advaxis could result in substantial costs and divert its management's attention from other business concerns, which could seriously harm its business.

Advaxis does not intend to pay cash dividends.

Advaxis has not declared or paid any cash dividends on its Common Stock, and it does not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on Advaxis' Common Stock will be at its Board of Directors' discretion and will depend on its financial condition, operating results, capital requirements and other factors that its Board of Directors considers to be relevant.

Advaxis' certificate of incorporation, bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause Advaxis' stock price to decline.

Advaxis' certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire Advaxis, even if closing such a transaction would be beneficial to its shareholders. Advaxis is authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by Advaxis' Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of Advaxis' Common Stock, and therefore, reduce the value of its Common Stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict Advaxis' ability to merge with, or sell its assets to, a third party and thereby preserve control by the present management.

Provisions of Advaxis' certificate of incorporation, Bylaws and Delaware law also could have the effect of discouraging potential Acquisition Proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by Advaxis shareholders to replace or remove its management. In particular, the certificate of incorporation, Bylaws and Delaware law, as applicable, among other things; provide the Board of Directors with the ability to alter the By-laws without shareholder approval and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, and less than a quorum.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of Advaxis to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with Advaxis, which may cause the market price of its Common Stock to decline.

Risks Related to the Business of Ayala

You should carefully consider the risks and uncertainties described below and the other information included in this proxy statement/prospectus before making an investment in Ayala's Common Stock. Ayala's business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of Ayala's Common Stock could decline and you could lose all or part of your investment. This proxy statement/prospectus also contains forward-looking statements that involve risks and uncertainties. See "*Cautionary Statement Concerning Forward-Looking Statements*." Ayala's actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Ayala's Financial Position and Need for Additional Capital

Ayala has incurred significant losses since inception and anticipates that it will continue to incur losses for the foreseeable future. Ayala is not currently profitable, and may never achieve or sustain profitability. If Ayala is unable to achieve or sustain profitability, the market value of its common stock will likely decline.

Ayala is a clinical-stage biopharmaceutical company with a limited operating history and has incurred significant losses since its formation. Ayala had a net loss of approximately $10.2 million and $28.4 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, Ayala had an accumulated deficit of $139.6 million. As noted below, Ayala has identified conditions and events that raise substantial doubt about its ability to continue as a going concern. Ayala has not commercialized any products and has never generated revenue from the commercialization of any product. To date, Ayala has devoted most of its financial resources to licensing product candidates and research and development, including its preclinical development activities and clinical trials.

Ayala expects to incur significant operating expenses and increasing net losses for the next several years, at least, as it advances AL101, AL102 and any future product candidate through preclinical and clinical development, seek regulatory approvals and commercialize AL101, AL102 or any other product candidate, if approved. The costs of advancing product candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of Ayala's product candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, Ayala is unable to accurately predict the timing or amount of increased expenses or when, or if, Ayala will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Ayala's expenses will also increase substantially if and as Ayala:

- advances its Phase 2/3 RINGSIDE pivotal trial of AL102 for the treatment of desmoid tumors and its Phase 2 ACCURACY trial of AL101 for the treatment of recurrent/metastatic adenoid cystic carcinoma, or R/M ACC;
- initiates a Phase 2 clinical trial for relapse refractory T cell acute lymphoma, or R/R T-ALL, or obtains and conducts clinical trials for any other product candidates;
- assuming successful completion of Ayala's Phase 2 ACCURACY trial of AL101 for the treatment of R/M ACC, may be required by the FDA, to complete Phase 3 clinical trials to support submission of an NDA, of AL101 for the treatment of R/M ACC;
- establishes a sales, marketing and distribution infrastructure to commercialize AL101 and/or AL102, if approved, and for any other product candidates for which Ayala may obtain marketing approval;

- collaborates with leading diagnostic companies to develop diagnostic tests for identifying patients with Notch-activating mutations;
- maintains, expands and protects its intellectual property portfolio;
- hires additional staff, including clinical, scientific, technical, regulatory operations, financial, commercial and other personnel, to execute its business plan; and
- adds clinical, scientific, operational, financial and management information systems and personnel to support its product development and potential future commercialization efforts, and enable Ayala to operate as a public company.

Furthermore, Ayala's ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under "Risks Related to the Business of Ayala—Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval" and "Risks Related to the Business of Ayala—Risks Related to Commercialization." As a result, Ayala expects to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on Ayala's stockholders' equity and working capital. The amount of Ayala's future net losses will depend, in part, on the rate of future growth of its expenses and ability to generate revenues. If Ayala is unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, Ayala will not achieve profitability. Even if Ayala does achieve profitability, Ayala may not be able to sustain profitability or meet outside expectations for its profitability. If Ayala is unable to achieve or sustain profitability or to meet outside expectations for its profitability, the value of its common stock will be materially and adversely affected.

Ayala's recurring losses from operations raise substantial doubt regarding its ability to continue as a going concern.

Ayala has incurred significant losses since its inception and has never generated revenue or profit, and it is possible Ayala will never generate revenue or profit. As of September 30, 2022, Ayala had cash and cash equivalents and restricted bank deposits totaling $11.5 million. Based on Ayala's current operating plans, and without additional funding, Ayala believes it will not have sufficient funds to meet its obligations within the next twelve months from the issuance of Ayala's unaudited and audited consolidated financial statements that are included elsewhere in this proxy statement/prospectus. These factors raise substantial doubt about Ayala's ability to continue as a going concern. Ayala will need to raise additional capital to fund its future operations and remain as a going concern. There can be no assurance that Ayala will be able to obtain additional funding on acceptable terms, if at all. To the extent that Ayala raises additional capital through future equity offerings, the ownership interest of common stockholders will be diluted, which dilution may be significant. However, Ayala cannot guarantee that it will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to Ayala. In the event that Ayala is unable to obtain any or sufficient additional funding, there can be no assurance that Ayala will be able to continue as a going concern, and Ayala will be forced to delay, reduce or discontinue its product development programs or commercialization efforts.

Substantial doubt about Ayala's ability to continue as a going concern may materially and adversely affect the price per share of its common stock, and it may be more difficult for Ayala to obtain financing. If potential collaborators decline to do business with Ayala or potential investors decline to participate in any future financings due to such concerns, Ayala's ability to increase its cash position may be limited. The perception that Ayala may not be able to continue as a going concern may cause others to choose not to deal with Ayala due to concerns about Ayala's ability to meet its contractual obligations.

Ayala has prepared its consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Ayala's unaudited and audited consolidated financial statements included in this proxy statement/prospectus do not include any adjustments to reflect the possible inability of Ayala to continue as a going concern within one year after the issuance of such financial statements. If Ayala is unable to continue as a going concern, you could lose all or part of your investment in Ayala.

Ayala will require additional capital to fund its operations, and if Ayala fails to obtain necessary financing, it may not be able to complete the development and commercialization of AL101 and AL102.

Ayala expects to spend substantial amounts of capital to complete the development of, seek regulatory approvals for and, if approved, commercialize AL101 and AL102. These expenditures will include costs related to Ayala's clinical development and costs associated with its license agreement with BMS under which Ayala is obligated to make milestone payments, royalty payments in connection with the sale of resulting products and payments consisting of a portion of all consideration Ayala receives in connection with the sublicense or assignment of any patent rights Ayala licensed from BMS. For more information regarding this agreement, please see "*Ayala's Business—License Agreements*."

Ayala anticipates that it will use its cash and cash equivalents, including the net proceeds from its initial public offering, or IPO, and other issuances of common stock and short-term restricted bank deposits, to advance the clinical development of AL101 and AL102 and the remainder, if any, for working capital and general corporate purposes.

Ayala will require additional capital to enable it to complete the development and commercialization of AL101 for the treatment of R/M ACC, and R/R T-ALL, AL102 for the treatment of desmoid tumors and any other potential indications, if approved, which Ayala may obtain through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Adequate additional financing may not be available to Ayala on acceptable terms, or at all. Ayala's failure to raise capital as and when needed would have a negative effect on its financial condition and its ability to pursue its business strategy. In addition, attempting to secure additional financing may divert the time and attention of Ayala's management from day-to-day activities and harm Ayala's development efforts.

As noted above, Ayala has identified conditions and events that raise substantial doubt about its ability to continue as a going concern. Because the length of time and activities associated with successful development of AL101 and AL102 is highly uncertain, Ayala is unable to estimate the actual funds it will require for development and any approved marketing and commercialization activities. Ayala's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the progress, timing, costs and results of its clinical trials of AL101 and AL102 and the development of any future product candidates, including any unforeseen costs it may incur as a result of clinical trial delays due to the COVID-19 pandemic or other causes;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of testing drug substances and drug products at release and during stability programs;

- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against it;
- the effect of competing technological and market developments;
- the costs of operating as a public company;
- the extent to which it in-licenses or acquires other product candidates or technologies;
- the cost of establishing sales, marketing and distribution capabilities for AL101 and AL102;
- the timing and amount of milestone, royalty and other payments that it may receive or that it may be required to make under its license agreements;
- its ability to establish and maintain collaborations on favorable terms, if at all;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- the initiation, progress and timing of its commercialization of AL101 and AL102, if approved.

If Ayala is unable to raise additional capital in sufficient amounts or on terms acceptable to it, Ayala may have to significantly delay, scale back or discontinue the development or commercialization of AL101 and AL102 or potentially discontinue operations.

Raising additional capital may cause dilution to Ayala's stockholders, restrict Ayala's operations or require Ayala to relinquish rights to its technologies or product candidates.

Until such time, if ever, as Ayala can generate sufficient revenue to support its operations, Ayala may finance its cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Ayala does not currently have any committed external source of funds. In addition, Ayala may seek additional capital due to favorable market conditions or strategic considerations, even if Ayala believes that it has sufficient funds for its current or future operating plans.

To the extent that Ayala raises additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Ayala's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Ayala raises additional funds through marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements with third parties, Ayala may be required to relinquish valuable rights to its technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to Ayala. If Ayala is unable to raise additional funds through equity or debt financings when needed, Ayala may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Ayala has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.

Ayala was established and began operations in November 2017. Ayala's operations to date have been limited to financing and staffing Ayala, licensing product candidates, developing AL101 for the treatment of R/M ACC, and developing AL102 for the treatment of desmoid tumors and R/R T-ALL, and conducting preclinical studies and clinical trials of AL101 and AL102. Ayala has not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on Ayala's behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about Ayala's future success or viability may not be as accurate as they could be if Ayala had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, Ayala may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Ayala will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. Ayala may not be successful in such a transition and, as a result, its business may be adversely affected.

As Ayala continues to build its business, it expects its financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond its control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

Ayala is heavily dependent on the success of AL101 and AL102, its most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, Ayala's business may be harmed.

To date, Ayala has invested a significant portion of its efforts and financial resources in the development of AL101 for the treatment of R/M ACC, and in the development of AL102 for the treatment of desmoid tumors, R/R T-ALL and multiple myeloma, or MM. Ayala's future success is substantially dependent on its ability to successfully complete clinical development for, obtain regulatory approval for and successfully commercialize AL101 and AL102, which may never occur. Ayala currently has no products that are approved for commercial sale and may never be able to develop a marketable product. Ayala expects that a substantial portion of its efforts and expenditures over the next few years will be devoted to AL101 and AL102, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before Ayala can generate any revenues from any commercial sales. Ayala cannot be certain that it will be able to successfully complete any of these activities.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. Ayala is not permitted to market AL101 and AL102 in the United States until it receives approval of an NDA from the FDA, or in any foreign countries until it receives the requisite approval from such countries. Ayala has not submitted an NDA to the FDA or comparable applications to other regulatory authorities for AL101 and AL102 and may not be in a position to do so for several years, if ever. If Ayala is unable to obtain the necessary regulatory approvals for AL101 or AL102, it will not be able to commercialize AL101 and AL102 and its financial position will be materially adversely affected and it may not be able to generate sufficient revenue to continue its business.

Ayala may be required to make significant payments under its license of AL101 and AL102 from BMS.

In November 2017, Ayala licensed rights to AL101 and AL102 pursuant to a license agreement with BMS, or the BMS License Agreement. Under the BMS License Agreement, Ayala is subject to significant obligations, including milestone payments, royalty payments on product sales and clinical development obligations, as well as other material obligations. Under the BMS License Agreement, Ayala will be obligated to pay BMS fixed royalty payments that could range from a high single-digit to a low teen percentage on net sales of products containing AL101 or AL102, as well as a portion of all consideration Ayala receives in connection with the sublicense or assignment of any patent rights Ayala licensed from BMS, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced product candidate that is subject to the applicable sublicense or assignment. For more information regarding the BMS License Agreement, please see "*Ayala's Business—License Agreements*." If these payments become due under the terms of the BMS License Agreement, Ayala may not have sufficient funds available to meet its obligations and its development efforts may be materially harmed. Furthermore, if Ayala is forced to raise additional funds, Ayala may be required to delay, limit, reduce or terminate its product development or future commercialization efforts, or grant rights to develop and market product candidates that it would otherwise develop and market itself.

Due to Ayala's limited resources and access to capital, Ayala must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect Ayala's business.

Ayala may fail to identify and acquire, through purchase or license, viable new product candidates for clinical development for a number of reasons. If Ayala fails to identify and acquire additional product candidates, its business could be materially harmed.

Efforts to identify and pursue new product candidates and disease targets require substantial technical, financial and human resources, regardless of whether they are ultimately successful. Programs may initially show promise in preclinical studies, yet fail to yield positive results during clinical development for a number of reasons, including:

- the methodology used may not be successful in identifying potential indications and/or product candidates; or
- product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products.

Because Ayala has limited financial and human resources, Ayala intends to initially focus on programs and product candidates for a limited set of indications. As a result, Ayala may forego or delay pursuit of opportunities with other product candidates or for other indications with its existing product candidates that may later prove to have greater commercial potential or a greater likelihood of success. Ayala may focus its efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Ayala will need to expand its organization, and may experience difficulties in managing this growth, which could disrupt its operations.

As of September 30, 2022, Ayala had 29 employees. Ayala expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of product candidate development, regulatory affairs and sales and marketing. Ayala may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on Ayala's management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, Ayala's management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. Ayala may not be able to effectively manage the expansion of its operations, which may result in weaknesses in its infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Ayala's expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If Ayala's management is unable to effectively manage its growth, its expenses may increase more than expected, its ability to generate and/or grow revenues could be reduced, and it may not be able to implement its business strategy. Ayala's future financial performance and ability to commercialize its product candidates and compete effectively will depend, in part, on its ability to effectively manage any future growth.

Many of the biotechnology companies that Ayala competes against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than Ayala does. If Ayala is unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which Ayala can discover and develop product candidates and operate its business will be limited.

COVID-19 may adversely affect Ayala's business, including its clinical trials.

The COVID-19 pandemic and government measures taken in response have had significant direct and indirect impacts on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, Ayala's administrative employees work remotely at times. In addition, Ayala has modified its business practices, including restricting a portion of employee travel, developing social distancing plans for some of its employees and canceling some physical participation in meetings, events and conferences. As a result of the COVID-19 pandemic, Ayala may experience additional disruptions that could severely impact its business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in its clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of its product candidates from its contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of its clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to its sourced discovery and clinical activities.

In addition, the outbreak and the resulting government actions may adversely impact Ayala's planned and ongoing clinical trials. Clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be willing and/or able to comply with clinical trial protocols due to the COVID-19 pandemic, particularly if quarantines impede patient movement or interrupt healthcare services. Similarly, Ayala's ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 may be impeded, which would adversely impact its clinical trial operations. The diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as Ayala's clinical trial investigators and hospitals serving as Ayala's clinical trial sites, diversion of hospitals and medical centers or sites serving as Ayala's clinical trial sites and hospital or other staff supporting the conduct of Ayala's clinical trials may significantly disrupt its research activities. As a result, the expected timeline for data readouts of Ayala's clinical trials and certain regulatory filings will likely be negatively impacted, which would adversely affect and delay its ability to obtain regulatory approvals for its product candidates, increase its operating expenses and have a material adverse effect on its financial condition.

Furthermore, the response to the COVID-19 pandemic may redirect resources with respect to regulatory matters and intellectual property matters in a way that would adversely impact Ayala's ability to progress regulatory approvals and protect its intellectual property. In addition, Ayala may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. For example, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process Ayala's regulatory submissions, which could have a material adverse effect on Ayala's business.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts Ayala's business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread, trajectory, and duration of the pandemic, including due to the emergence of variants; travel restrictions in the United States, Canada, Europe, Israel and other regions; business closures or business disruptions; the effectiveness of vaccines, vaccine distribution efforts, and other treatments; and the effectiveness of other actions taken in the United States, Canada, Europe, Israel and other regions to contain the pandemic. As a result, the COVID-19 pandemic could have a material adverse effect on Ayala's business, results of operations, financial condition and prospects and heighten many of Ayala's known risks described in this "Risks Related to the Business of Ayala" section.

Ayala's ability to use its net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2021, Ayala had net operating loss carryforwards, or NOLs, of $91.6 million for U.S. federal income tax purposes and $57.7 million for U.S. state income tax purposes, which may be available to offset Ayala's future taxable income, if any, and begin to expire in various amounts in 2037 and 2038, respectively, provided that NOLs generated in tax years ending after December 31, 2017 will not be subject to expiration. In general, under Sections 382 and 383 of the Code a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and certain other tax attributes to offset future taxable income. If the IRS challenges Ayala's determinations with respect to the existence of previous ownership changes or the effects thereof, its ability to use its NOLs could be limited by Section 382 of the Code. Future changes in Ayala's stock ownership, some of which are outside of Ayala's control, could also result in an ownership change under Sections 382 and 383 of the Code. In addition, for taxable years beginning after December 31, 2020, utilization of federal NOLs generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year, after taking into account utilization of NOLs generated in years beginning before January 1, 2018 and determined without regard to such NOL deduction. Furthermore, Ayala's ability to use NOLs of companies that it may acquire in the future may be subject to limitations. For these reasons, Ayala may not be able to use a material portion of the NOLs, even if it attains profitability.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

Ayala's product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach Ayala is taking to discover and develop product candidates is novel and may never lead to marketable products.

The discovery and development of targeted therapies for patients with genetically defined cancers is an emerging field, and the scientific discoveries that form the basis for Ayala's efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. The patient populations for Ayala's product candidates are not completely defined but are substantially smaller than the general treated cancer population, and Ayala will need to screen and identify these patients. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to Ayala's product candidates and developing companion diagnostics to identify such genetic alterations. Furthermore, even if Ayala is successful in identifying patients, Ayala cannot be certain that the resulting patient populations will be large enough to allow it to successfully conduct clinical trials, and if approved, commercialize its products and achieve profitability. Therefore, Ayala does not know if its approach of treating patients with genetically defined cancers will be successful, and if its approach is unsuccessful, its business will suffer.

Clinical trials are expensive, time-consuming and difficult to design and implement, and involve an uncertain outcome.

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of Ayala's product candidates, Ayala must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of its product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Ayala may experience delays in initiating and completing any clinical trials that it is conducting or intends to conduct, including as a result of the COVID-19 pandemic, and does not know whether its ongoing or planned clinical trials will begin or progress on schedule, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of Ayala's clinical studies;
- obtaining regulatory authorizations to commence a trial or consensus with regulatory authorities on trials design;

- reaching an agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- changes to clinical trial protocols;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- having patients complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- the occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- subjects choosing an alternative treatment for the indication for which Ayala is developing its product candidates, or participating in competing clinical trials;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate with sufficient quality for use in clinical trials;
- lack of adequate funding to continue the clinical trial;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing Ayala's product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of GMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to Ayala's manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform Ayala's clinical trials, not performing Ayala's clinical trials on Ayala's anticipated schedule or consistent with the clinical trial protocol, GCP or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case Ayala may need to find a substitute contractor, and may not be able to use some or all of the data produced by such contractors in support of its marketing applications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that Ayala encounters such difficulties or delays in initiating, enrolling, conducting or completing its planned and ongoing clinical trials. Ayala could also encounter delays if a clinical trial is suspended or terminated by Ayala, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or Ayala's clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, Ayala relies on CROs and clinical trial sites to ensure the proper and timely conduct of its clinical trials and, while Ayala has agreements governing their committed activities, it has limited influence over their actual performance, as described in "Risks Related to the Business of Ayala—Risks Related to Ayala's Dependence on Third Parties."

Ayala has limited experience in designing clinical trials and may be unable to design and execute a clinical trial which, if successful, would represent a well-controlled trial for purposes of seeking marketing approval. It may be necessary to re-design Ayala's clinical trials, including to conduct clinical trials of Ayala's product candidates in combination with other therapies, in an effort to achieve the response rates sufficient to support marketing approval. Ayala cannot be certain that its ongoing or planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of Ayala's clinical trials in Ayala's targeted indications could limit the prospects for regulatory approval of its product candidates in those and other indications, which could seriously harm its business.

Further, conducting clinical trials in foreign countries, as Ayala may do for its product candidates, presents additional risks that may delay completion of its clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for Ayala's clinical trials may serve as scientific advisors or consultants to Ayala from time to time and receive compensation in connection with such services. Under certain circumstances, Ayala may be required to report some of these relationships to the FDA or foreign regulatory authorities. The FDA or foreign regulatory authorities may conclude that a financial relationship between Ayala and a principal investigator has created a conflict of interest or otherwise affected interpretation of a clinical trial. The FDA or foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of Ayala's marketing applications by the FDA or foreign regulatory authorities and may ultimately lead to the denial of marketing approval of a product candidate.

If Ayala experiences delays in the commencement or completion of any clinical trials, or if Ayala terminates a clinical trial prior to completion, the commercial prospects of AL101, AL102 or any other product candidate Ayala develops could be harmed, and Ayala's ability to generate revenues may be delayed. In addition, any delays in Ayala's clinical trials could increase its costs, slow the development and approval process and jeopardize its ability to commence product sales and generate revenues. Any of these occurrences may harm Ayala's business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of Ayala's product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an IEC, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by Ayala and its third-party service providers, such as CROs, may impact Ayala's developments plans

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for Ayala's product candidates on the basis of clinical trials conducted in the UK.

If Ayala is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, its development plans may be impacted.

Ayala was not involved in the early development of its lead product candidates; therefore, Ayala is dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for its product candidates.

Ayala licensed exclusive worldwide rights to AL101 and AL102 from BMS in November 2017, and was not involved in or able to control the development of AL101 and AL102 prior to such time. While BMS is contractually obligated to provide all data it generated from preclinical studies and clinical trials conducted for AL101 and AL102 prior to Ayala's licensing of such products, in certain instances Ayala is currently reliant upon reports BMS generated analyzing such data. In the event further data is required by a regulatory authority or otherwise in Ayala's development of AL101 and/or AL102 and BMS does not comply with its contractual obligation to provide such data, Ayala could incur increased costs in re-analyzing certain preclinical and clinical data and will experience delays in the development of AL101 and AL102, which could adversely affect Ayala's financial position and delay its ability to commercialize AL101 and AL102.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if Ayala is ultimately unable to obtain regulatory approval for AL101, AL102 or any other product candidates, its business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that Ayala's data are insufficient for approval and require additional preclinical, clinical or other data. Even if Ayala eventually completes clinical testing and receives approval of any regulatory filing for its product candidates, the FDA and other comparable foreign regulatory authorities may approve Ayala's product candidates for a more limited indication or a narrower patient population than Ayala originally requested. Ayala has not obtained regulatory approval for any product candidate and it is possible that it will never obtain regulatory approval for AL101, AL102 or any other product candidate. Ayala is not permitted to market any of its product candidates in the United States until it receives regulatory approval of an NDA from the FDA, or in any foreign countries until it receives the requisite approval from foreign regulatory authorities.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, Ayala must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidate is safe and effective for its intended use. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if Ayala believes the preclinical or clinical data for its product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of Ayala's product candidates or require Ayala to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of Ayala's clinical trials;
- Ayala may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in Ayala's clinical trials or by individuals using drugs similar to its product candidates, or other products containing the active ingredient in its product candidates;
- negative or ambiguous results from Ayala's clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which Ayala seeks approval;
- Ayala may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with Ayala's interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of Ayala's product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and Ayala may be required to conduct additional clinical trials;

- the FDA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling and/or the specifications of Ayala's product candidates;

- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which Ayala contracts for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering Ayala's clinical data insufficient for approval.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. Ayala cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as Ayala does, and more trials could be required before Ayala is able to submit applications seeking approval of its product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, Ayala may be required to expend significant resources, which may not be available to Ayala, to conduct additional trials in support of potential approval of its product candidates. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering Ayala's clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of its product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in Ayala's failing to obtain regulatory approval to market AL101, AL102 or any other product candidate, which would significantly harm its business, results of operations and prospects.

In addition, the FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than Ayala originally requested, and the FDA or applicable foreign regulatory agency may approve a product candidate with a REMS or similar risk management measures, or a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory authorities may also grant approval contingent on the performance of costly post-marketing clinical trials. Any of the foregoing scenarios could materially harm the commercial prospects for Ayala's product candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Ayala's control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on Ayala's ability to enroll a sufficient number of patients who remain in the study until its conclusion. Ayala may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of its clinical trials, and even once enrolled, Ayala may be unable to retain a sufficient number of patients to complete any of its trials.

Patient enrollment and retention in clinical trials depends on many factors, including:

- the size and nature of the patient population;

- the severity of the disease under investigation;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the existing body of safety and efficacy data with respect to the product candidate;
- the number of clinical sites and the proximity of patients to clinical sites;
- Ayala's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications Ayala is investigating;
- competing clinical trials being conducted by other companies or institutions;
- the COVID-19 pandemic;
- Ayala's ability to maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Furthermore, any negative results Ayala may report in clinical trials of any product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs or program delays, which could have a harmful effect on Ayala's strategy to rapidly advance the clinical development of its product candidates or could render further development impossible.

If Ayala does not achieve its projected development and commercialization goals in the timeframes it announces and expects, the commercialization of its product candidates may be delayed and its business will be harmed.

For planning purposes, Ayala sometimes estimates the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include Ayala's expectations regarding the commencement or completion of scientific studies and clinical trials, the regulatory submissions or commercialization objectives. From time to time, Ayala may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of Ayala's control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from Ayala's estimates, including:

- Ayala's available capital resources or capital constraints Ayala experiences;
- the rate of progress, costs and results of Ayala's clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- Ayala's ability to identify and enroll patients who meet clinical trial eligibility criteria;

- Ayala's receipt of authorizations by the FDA and comparable foreign regulatory authorities, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- Ayala's ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of its product candidates;
- Ayala's ability to manufacture and supply clinical trial materials to its clinical sites on a timely basis;
- the severity, duration and impact of the COVID-19 pandemic;
- the efforts of Ayala's collaborators with respect to the commercialization of its products, if any; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities.

If Ayala fails to achieve announced milestones in the timeframes it expects, the commercialization of any of its product candidates may be delayed, and its business, results of operations, financial condition and prospects may be adversely affected.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of Ayala's product candidates, including its *post hoc* analyses of AL101 and AL102, may not be predictive of the results of later-stage clinical trials or the results of clinical trials of the same product candidates in other indications. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results, such as Ayala's *post hoc* analyses, may be shown to be incorrect when implemented in prospective clinical trials. Even if Ayala's clinical trials of AL101 or AL102 are completed as planned, Ayala cannot be certain that its results will support the safety and efficacy sufficient to obtain regulatory approval. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Moreover, the results of clinical trials of a product candidate in a particular indication may not be predictive of the results of clinical trials of that product candidate in other indications.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with Ayala's product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to Ayala's product candidate. As a result, assessments of efficacy and safety can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, Ayala's clinical trial outcomes. Ayala does not know whether any clinical trials it may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market its product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Interim, "top-line" and preliminary data from Ayala's clinical trials that it announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, Ayala may publicly disclose interim top-line or preliminary data from its clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Ayala also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that Ayala reports may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data Ayala previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, Ayala may also disclose interim data from its preclinical studies and clinical trials. Interim data from clinical trials that Ayala may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, top-line or preliminary data and final data could significantly harm Ayala's business prospects. Further, disclosure of interim data by Ayala or by its competitors could result in volatility in the price of its common stock.

Further, others, including regulatory agencies, may not accept or agree with Ayala's assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and Ayala's company in general. In addition, the information Ayala chooses to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what Ayala determines is material or otherwise appropriate information to include in its disclosure.

If the interim top-line or preliminary data that Ayala reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, Ayala's ability to obtain approval for, and commercialize, its product candidates may be harmed, which could harm its business, operating results, prospects or financial condition.

Ayala's product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with Ayala's product candidates' use. Results of any clinical trial Ayala conducts could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Serious adverse events or undesirable side effects caused by AL101, AL102 or any other product candidates could cause Ayala or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm Ayala's business, financial condition and prospects significantly. Patients in Ayala's ongoing and planned clinical trials may in the future suffer other serious adverse events or other side effects not observed in Ayala's preclinical studies or previous clinical trials. In addition, if Ayala's product candidates are used in combination with other therapies, its product candidates may exacerbate adverse events associated with the therapy and the severity and frequency of adverse events may be greater than the cumulative severity and frequency of such adverse events when the therapies are used as monotherapies. Patients treated with Ayala's product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to Ayala's product candidates, but may still impact the success of Ayala's clinical trials. The inclusion of critically ill patients in Ayala's clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If unacceptable side effects arise in the development of Ayala's product candidates, Ayala, the FDA or comparable foreign regulatory authorities, or the IRBs at the institutions in which Ayala's studies are conducted, or the DSMB, if constituted for Ayala's clinical trials, could recommend a suspension or termination of Ayala's clinical trials, or the FDA or comparable foreign regulatory authorities could order Ayala to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Ayala expects to have to train medical personnel using its product candidates to understand the side effect profiles for its clinical trials and upon any commercialization of any of its product candidates. Inadequate training in recognizing or managing the potential side effects of Ayala's product candidates could result in patient injury or death. Any of these occurrences may harm Ayala's business, financial condition and prospects significantly.

Additionally, if one or more of Ayala's product candidates receives marketing approval, and Ayala or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- Ayala may be required to implement a REMS or similar risk management measures or create a medication guide outlining the risks of such side effects for distribution to patients;
- Ayala could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- Ayala's reputation may suffer.

Any of these events could prevent Ayala from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm its business, results of operations and prospects.

The market opportunities for AL101 and AL102, if approved, may be smaller than Ayala anticipates.

Ayala expects to initially seek approval of AL101 for the treatment of R/M ACC. Ayala's projections of the number of ACC patients, the number of R/M ACC patients and the proportion of R/M ACC patients with Notch-activating mutations are based on its beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations and publicly available databases, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of patients, and the number of patients may turn out to be lower than expected. Additionally, the potential addressable patient population for Ayala's current programs or future product candidates may be limited. The ultimate market opportunity for Ayala's product candidates will depend on, among other things, the final labeling for such product candidates as agreed with the FDA or comparable foreign regulatory authorities, acceptance by the medical community and patient access, potential competition and drug pricing and reimbursement. Even if Ayala obtains significant market share for any product candidate, if approved, if the potential target populations are small, Ayala may never achieve profitability without obtaining marketing approval for additional indications.

Ayala may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations.

Ayala is currently developing product candidates that target the aberrant activation of the Notch pathway and believe that its product candidates, if approved, would be used as treatments for patients with Notch-activating mutations. Commercially available diagnostic tests are limited in their ability to uncover all potential Notch-activating mutations, as they do not cover all four Notch genes and only uncover simple mutations in the Notch gene locus, such as point mutations, insertions, deletions and copy number variations. These tests are able to detect only a subset of the patients with Notch-activating mutations. To identify additional patients with Notch-activating mutations who Ayala believes may benefit from the use of its product candidates, Ayala intends to collaborate with leading diagnostics companies to improve the testing capabilities for Notch-activating mutations. However, the development of such diagnostic tests is expensive, difficult and Ayala and its collaborators may be unable to successfully do so within a reasonable amount of time with acceptable costs, if at all.

In addition, collaborations are subject to substantial additional risks and uncertainties, as described under "Risks Related to the Business of Ayala—Risks Related to Ayala's Dependence on Third Parties." For example, if Ayala's collaborators do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines, the addressable patient population for Ayala's product candidates may be limited. Further, if Ayala's relationship with any collaborator terminates, Ayala may not be able to enter into alternative collaborative arrangements or do so on commercially reasonable terms. The occurrence of any of the above will have an adverse impact on Ayala's business, financial condition and prospects.

Even if Ayala or its collaborators are successful in developing diagnostic tests that uncover additional Notch-activating mutations, such diagnostic tests may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community for reasons such as cost, ease of use and belief regarding the effectiveness of Ayala's product candidates.

Ayala has never obtained marketing approval for a product candidate and may be unable to obtain, or may be delayed in obtaining, marketing approval for any of its product candidates.

Ayala has never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that Ayala submits for its product candidates or may conclude after review of its data that its application is insufficient to obtain marketing approval of its product candidates. If the FDA does not accept or approve Ayala's NDAs for its product candidates, it may require that Ayala conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider Ayala's applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that Ayala submits may be delayed, or may require Ayala to expend more resources than Ayala has available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve Ayala's NDAs. Similar risks exist in foreign jurisdictions where Ayala would seek marketing authorization for its product candidates.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent Ayala from commercializing its product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occurs, Ayala may be forced to abandon its development efforts for its product candidates, which could significantly harm its business.

Even if Ayala obtains FDA approval for AL101, AL102 or any other product candidate in the United States, it may never obtain approval for or commercialize AL101, AL102 or any other product candidate in any other jurisdiction, which would limit its ability to realize their full market potential.

In order to market any products in any particular jurisdiction, Ayala must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact Ayala's ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for Ayala and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of Ayala's products in those countries. Ayala does not have any product candidates approved for sale in any jurisdiction, including in international markets, and does not have experience in obtaining regulatory approval in international markets. If Ayala fails to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, Ayala's target market will be reduced and its ability to realize the full market potential of any product it develops will be unrealized.

Additionally, the UK left the EU on January 31, 2020, an event commonly referred to as "Brexit", under the terms of a withdrawal agreement, entering into a "transition period" which ended on December 31, 2020 during which the UK was essentially treated as a member state of the EU and the regulatory regime remained the same across the UK and the EU. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement which became effective on January 1, 2021. Since January 1, 2021, the U.K. operates under a distinct regulatory regime. EU pharmaceutical laws now only apply to the UK in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland, including but not limited to marketing authorization applications). Since January 1, 2021, EU laws which have been transposed into U.K. law through secondary legislation continue to be applicable as "retained EU law".

In addition, following the Brexit vote, the EU moved the EMA's, headquarters from the UK to the Netherlands. This transition may cause disruption in the administrative and medical scientific links between the EMA and the U.K. Medicines and Healthcare products Regulatory Agency, including delays in granting CTA or marketing authorization, disruption of import and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the UK and/or the EU. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent Ayala from commercializing its product candidates in the UK and/or the EU, and restrict its ability to generate revenue and achieve and sustain profitability. If any of these outcomes occurs, Ayala may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for its product candidates, which could significantly and materially harm its business.

Even if Ayala obtains regulatory approval for AL101, AL102 or any product candidate, it will still face extensive and ongoing regulatory requirements and obligations and any product candidates, if approved, may face future development and regulatory difficulties.

Any product candidate for which Ayala obtains marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP and similar foreign requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that Ayala conducts post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS or similar risk management measures. If any of Ayala's product candidates receives marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA or foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Similar regulations apply in countries outside the United States and may lead to foreign regulatory authorities' enforcement actions and investigations.

In addition, later discovery of previously unknown adverse events or other problems with Ayala's products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product manufacturing, distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that Ayala submits;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of Ayala's products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could impose extensive and ongoing regulatory requirements and obligations on any product candidate for which Ayala obtains marketing approval. Ayala also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If Ayala is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Ayala is not able to maintain regulatory compliance, it may be subject to enforcement action and may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of drugs for off-label uses.

If any of Ayala's product candidates is approved and Ayala is found to have improperly promoted off-label uses of those products, Ayala may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as Ayala's product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If Ayala receives marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If Ayala is found to have promoted such off-label uses, it may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required that companies enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If Ayala cannot successfully manage the promotion of its product candidates, if approved, Ayala could become subject to significant liability, which would materially adversely affect its business and financial condition.

If Ayala is required by the FDA or foreign regulatory authorities to obtain approval or certification of a companion diagnostic device in connection with approval of one of its product candidates, and does not obtain or face delays in obtaining FDA approval or foreign certification of a companion diagnostic device, it will not be able to commercialize the product candidate and its ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Ayala plans to collaborate with patient diagnostic companies during its clinical trial enrollment process to help identify patients with tumor gene alterations that it believes are most likely to respond to its product candidates. If a satisfactory companion diagnostic is not commercially available, Ayala may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a therapeutic product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval (or certification, or clearance) of a companion diagnostic for any of Ayala's product candidates, whether before or after the product candidate obtains marketing approval, Ayala and/or third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by Ayala or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of Ayala's related product candidates.

Ayala may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent Ayala from completing its clinical trials or commercializing its product candidates, if approved, on a timely or profitable basis, if at all.

Inadequate funding for the FDA, the SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Ayala's business may rely, which could negatively impact Ayala's business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which Ayala's operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Ayala's business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA has postponed or limited most of its routine inspectional activities. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and foreign regulatory authorities to timely review and process Ayala's regulatory submissions, which could have a material adverse effect on Ayala's business. Further, future government shutdowns could impact Ayala's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Ayala has been granted Orphan Drug Designation for AL101 for the treatment of ACC and may seek Orphan Drug Designation for other indications or product candidates, and may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for its other product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs intended for relatively small patient populations as orphan drugs. Under the ODA, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA to market the same product for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. However, ODD neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

In May 2019, the FDA granted ODD to AL101 for the treatment of ACC. Ayala may seek ODD for AL101 in other indications or for AL102 or other product candidates. There can be no assurances that Ayala will be able to obtain such designations.

Even if Ayala obtains ODD for any product candidate in specific indications, it may not be the first to obtain marketing approval of such product candidate for the orphan-designated disease or condition due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if Ayala seeks approval for a disease or condition broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Further, even if Ayala obtains orphan drug exclusivity in the United States for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same disease or condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same disease or condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Further, the composition of matter patents for AL101 and AL102 will expire in 2032 and 2033, respectively, and if orphan drug exclusivity does not protect these products from competition, Ayala's business and financial condition could be materially adversely affected.

Although Ayala has received Fast Track designation for AL101 and AL102, and may seek Fast Track designation for its other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process.

If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a drug sponsor may apply for Fast Track designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Ayala has received Fast Track designation for AL101 for the treatment of patients with R/M ACC, and may seek Fast Track designations for additional indications for AL101 or for its other product candidates. AL102 has also received Fast Track designation from the U.S. FDA and is currently in the Phase 3 portion of a pivotal study for patients with desmoid tumors (RINGSIDE) and may seek Fast Track designations for additional indications for AL102 or for its other product candidates. However, the FDA has broad discretion whether or not to grant such designations. If Ayala seeks a designation for a product candidate, Ayala may not receive it from the FDA. Even if Ayala receives it, such designation does not ensure that Ayala will receive marketing approval or that approval will be granted within any particular time frame. Ayala may not experience a faster development or regulatory review or approval process compared to conventional FDA procedures. In addition, the FDA may withdraw a designation if it believes that the designation is no longer supported by data from Ayala's clinical development program.

Ayala may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways or comparable pathways in foreign countries. If Ayala is unable to obtain such approval, it may be required to conduct additional preclinical studies or clinical trials beyond those that it contemplates, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if Ayala receives accelerated approval from the FDA, if its confirmatory trials do not verify clinical benefit, or if it does not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Ayala may in the future seek an accelerated approval for one or more of its product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

Prior to seeking accelerated approval for any of its product candidates, Ayala intends to seek feedback from the FDA and will otherwise evaluate its ability to seek and receive accelerated approval. There can be no assurance that after Ayala's evaluation of the feedback and other factors Ayala will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback Ayala will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if Ayala initially decides to do so. Furthermore, if Ayala decides to submit an application for accelerated approval or receive an expedited regulatory designation for its product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require Ayala to conduct further studies prior to considering its application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for Ayala's product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm Ayala's competitive position in the marketplace.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Ayala's product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including bridging or comparability testing to demonstrate the validity of clinical data obtained in clinical trials following manufacturing changes, FDA or foreign regulatory authorities' notification or FDA or foreign regulatory authorities' approval.

Because certain of Ayala's prior clinical trials of AL101 and AL102 were conducted by third parties, Ayala will need to perform analytical and other tests to demonstrate that any new drug product material is comparable in all respects, including potency, to the product used in such earlier clinical trials. There is no assurance that any such product will pass the required comparability testing, that any other future third-party manufacturer that Ayala engages will be successful in producing Ayala's product candidates or that any materials produced by any third-party manufacturer that Ayala engages will have the same effect in patients that Ayala has observed to date with respect to materials used in prior clinical trials.

All of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Ayala's product candidates and jeopardize Ayala's ability to commence sales and generate revenue.

Moreover, Ayala has not yet manufactured or processed on a commercial scale and may not be able to do so for any of its product candidates if approved. Ayala may make changes as it works to optimize its manufacturing processes, but cannot be sure that even minor changes in its processes will result in therapies that are safe and effective and approved for commercial sale.

Potential product liability lawsuits against Ayala could cause it to incur substantial liabilities and limit commercialization of any products that it may develop.

The use of AL101, AL102 or any other product candidates Ayala may develop in clinical trials and the sale of any products for which Ayala obtains marketing approval expose it to the risk of product liability claims. Product liability claims might be brought against Ayala by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with Ayala's products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If Ayala cannot successfully defend against product liability claims, it could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of Ayala's business reputation and significant negative media attention;
- withdrawal of participants from Ayala's clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from Ayala's primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize AL101, AL102 or any other product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product, if approved; and
- loss of revenue.

Ayala's insurance policies are expensive and protect it only from some business risks, which leaves Ayala exposed to significant uninsured liabilities.

Ayala currently carries insurance with an aggregate of $10.0 million in coverage. However, Ayala does not carry insurance for all categories of risk that its business may encounter. Some of the policies Ayala currently maintains include general liability, property, umbrella, clinical trials and directors' and officers' insurance.

Any additional product liability insurance coverage Ayala acquires in the future, may not be sufficient to reimburse it for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future Ayala may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses due to liability. If Ayala obtains marketing approval for any of its product candidates, Ayala intends to acquire insurance coverage to include the sale of commercial products; however, Ayala may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against Ayala could cause its share price to decline and, if judgments exceed its insurance coverage, could adversely affect its results of operations and business, including preventing or limiting the commercialization of any product candidates it develops.

Ayala also expects that operating as a public company will make it more difficult and more expensive for it to obtain director and officer liability insurance, and it may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for Ayala to attract and retain qualified people to serve on its board of directors, its board committees or as executive officers. Ayala does not know, however, if it will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require Ayala to pay substantial amounts, which would adversely affect its cash position and results of operations.

Risks Related to Commercialization

Ayala faces significant competition from other biotechnology and pharmaceutical companies and its operating results will suffer if it fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Ayala's competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than those achieved by Ayala's product candidates. Ayala's potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of Ayala's competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that Ayala's product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that Ayala develops obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in Ayala's competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Ayala's competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than Ayala's product candidates or may develop proprietary technologies or secure patent protection that Ayala may need for the development of its technologies and products.

Ayala considers its most direct competitors with respect to AL101 and AL102 to be companies developing gamma secretase inhibitors, including SpringWorks Therapeutics, Inc. and Celgene Corporation, recently acquired by BMS, or companies that develop Notch inhibitors, including Cellestia Biotech AG and Ciclomed LLC. In addition, with respect to AL101 for the treatment of ACC, Ayala is aware that other companies are, or may be, developing products for this indication, including GlaxoSmithKline plc, Cellestia Biotech AG and LSK BioPartners, Inc. Ayala believes the key competitive factors that will affect the development and commercial success of its product candidates are efficacy, safety, tolerability and reliability, convenience of use, price and reimbursement.

Even if Ayala obtains regulatory approval of its product candidates, the availability and price of its competitors' products could limit the demand and the price Ayala is able to charge for its product candidates. Ayala may not be able to implement its business plan if the acceptance of its product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to its product candidates, or if physicians switch to other new drug or biologic products or choose to reserve its product candidates for use in limited circumstances. For additional information regarding Ayala's competition, see "*Ayala's Business—Competition*."

The successful commercialization of AL101, AL102 and any other product candidate Ayala develops will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for Ayala's product candidates, if approved, could limit Ayala's ability to market those products and decrease its ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as AL101 and AL102, if approved. Ayala's ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on its ability to successfully commercialize AL101, AL102 and any other product candidates it develops. Assuming Ayala obtains coverage for its product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Ayala cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for its product candidates or any product that it may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider Ayala's product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if Ayala shows improved efficacy or improved convenience of administration with its product candidates, pricing of existing drugs may limit the amount it will be able to charge for its product candidates. Increasingly, other third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable Ayala to realize an appropriate return on its investment in its product candidates. If reimbursement is not available or is available only at limited levels, Ayala may not be able to successfully commercialize its product candidates and may not be able to obtain a satisfactory financial return on its product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Ayala's product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require Ayala to provide scientific and clinical support for the use of its product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and Ayala believes that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and Ayala believes the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of its product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of the national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that Ayala is able to charge for its product candidates. Accordingly, in markets outside the United States, the reimbursement for Ayala's product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for Ayala's product candidates. Ayala expects to experience pricing pressures in connection with the sale of its product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if AL101, AL102 or any other product candidate Ayala develops receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If AL101, AL102 or any other product candidate Ayala develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, Ayala may not generate significant product revenues or become profitable. The degree of market acceptance of Ayala's product candidates, if approved, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- Ayala's ability to offer its products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;

- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations on warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects; and
- any restrictions on the use of Ayala's product together with other medications.

Because Ayala expects sales of its product candidates, if approved, to generate substantially all of its revenues for the foreseeable future, the failure of its product candidates to find market acceptance would harm its business and could require it to seek additional financing.

If Ayala is unable to establish sales, marketing and distribution capabilities either on its own or in collaboration with third parties, it may not be successful in commercializing AL101 and AL102, if approved.

Ayala does not have any infrastructure for the sales, marketing or distribution of AL101 and AL102, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market and successfully commercialize AL101, AL102 or any other product candidate Ayala develops, if approved, Ayala must build its sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. Ayala expects to build a focused sales, distribution and marketing infrastructure to market AL101 and AL102, if approved. There are significant expenses and risks involved with establishing Ayala's own sales, marketing and distribution capabilities, including Ayala's ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of Ayala's internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of that product. Additionally, if the commercial launch of AL101 or AL102 for which Ayala recruits a sales force and establish marketing capabilities is delayed or does not occur for any reason, Ayala would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and Ayala's investment would be lost if it cannot retain or reposition its sales and marketing personnel.

Factors that may inhibit Ayala's efforts to commercialize its product candidates on its own include:

- Ayala's inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe Ayala's products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Ayala does not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of its product candidates, if approved, in certain markets overseas. Therefore, Ayala's future success will depend, in part, on its ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. Ayala intends to pursue collaborative arrangements regarding the sale and marketing of AL101 and AL102, if approved, for certain markets overseas; however, Ayala cannot assure you that it will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that Ayala depends on third parties for marketing and distribution, any revenues Ayala receives will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If Ayala is unable to build its own sales force or negotiate a collaborative relationship for the commercialization of AL101 and AL102, Ayala may be forced to delay the potential commercialization of AL101 and AL102 or reduce the scope of its sales or marketing activities for AL101 or AL102. If Ayala needs to increase its expenditures to fund commercialization activities for AL101 and AL102, it will need to obtain additional capital, which may not be available to it on acceptable terms, or at all. Ayala may also have to enter into collaborative arrangements for AL101 and AL102 at an earlier stage than otherwise would be ideal and may be required to relinquish rights to AL101 and AL102 or otherwise agree to terms unfavorable to it. Any of these occurrences may have an adverse effect on Ayala's business, operating results and prospects.

If Ayala is unable to establish adequate sales, marketing and distribution capabilities, either on its own or in collaboration with third parties, it will not be successful in commercializing its product candidates and may never become profitable. Ayala will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, Ayala may be unable to compete successfully against these more established companies.

A variety of risks associated with operating internationally could materially adversely affect Ayala's business.

Ayala's principal executive offices are located in Israel and certain of its product candidates may be manufactured at third-party facilities located in the United States, UK, India and Australia. In addition, Ayala's business strategy includes potentially expanding internationally if any of its product candidates receives regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by Ayala to obtain and maintain regulatory approvals for the use of its products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing Ayala's intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in Ayala's ability to penetrate international markets;
- global macroeconomic conditions, including inflation, labor shortages, supply chain shortages, or other economic, political or legal uncertainties or adverse developments;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for Ayala's products and exposure to foreign currency exchange rate fluctuations;

- political unrest, terrorism and wars, such as the current situation with Ukraine and Russia, which could delay or disrupt Ayala's business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A;
- natural disasters and economic instability, including outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm Ayala's international expansion and operations and, consequently, its results of operations.

Risks Related to Ayala's Dependence on Third Parties

Ayala's employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties Ayala may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on Ayala's business.

Ayala's employees and independent contractors, including principal investigators, consultants, vendors and any third parties Ayala may engage in connection with development and commercialization of Ayala's product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to Ayala's reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions Ayala takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, Ayala is subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against Ayala and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of its operations.

Ayala currently relies on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of AL101 and AL102 and intend to rely on CMOs for the production of commercial supply of AL101 and AL102, if approved. Ayala's dependence on CMOs may impair the development of AL101 and AL102 and may impair the commercialization of AL101 and AL102, if approved, which would adversely impact its business and financial position.

Ayala has limited personnel with experience in manufacturing, and does not own facilities for manufacturing AL101, AL102 or any product candidate. Instead, Ayala relies on and expects to continue to rely on CMOs for the supply of cGMP-grade clinical trial materials and commercial quantities of AL101, AL102 and any future product candidates, if approved. Reliance on CMOs may expose Ayala to more risk than if it were to manufacture its product candidates itself. Ayala plans to rely on CMOs to provide a sufficient clinical and commercial supply of AL101 and AL102.

The facilities used to manufacture Ayala's product candidates must be inspected by the FDA and comparable foreign authorities. While Ayala provides oversight of manufacturing activities, it does not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, its CMOs for compliance with cGMP or similar foreign requirements outside the United States for the manufacture of its product candidates. As a result, Ayala is subject to the risk that its product candidates may have manufacturing defects that it has limited ability to prevent. CMOs may also have competing obligations that prevent them from manufacturing Ayala's product candidates in a timely manner. If a CMO cannot successfully manufacture material that conforms to Ayala's specifications and the regulatory requirements, Ayala will not be able to secure or maintain regulatory approval for the use of its product candidates in clinical trials, or for commercial distribution of its product candidates, if approved. In addition, Ayala has limited control over the ability of its CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of Ayala's product candidates or if it withdraws any such approval or finds deficiencies in the future, Ayala may need to find alternative manufacturing facilities, which would delay its development program and significantly impact its ability to develop, obtain regulatory approval for or commercialize its product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject Ayala to the risk that it may have to suspend the manufacture of its product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with Ayala because of factors beyond its control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for Ayala. If Ayala was unable to find an adequate CMO or another acceptable solution in time, Ayala's clinical trials could be delayed or its commercial activities could be harmed.

Ayala relies on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce its product candidates. Ayala does not and will not have control over the process or timing of the acquisition of these raw materials by its CMOs. The COVID-19 pandemic may also have an impact on the ability of Ayala's CMOs to acquire raw materials. Moreover, Ayala currently does not have any agreements for the production of these raw materials. Supplies of raw materials could be interrupted from time to time and Ayala cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of Ayala's product candidates, if approved, or result in a shortage in supply, which would impair Ayala's ability to generate revenues from the sale of its product candidates. Growth in the costs and expenses of raw materials may also impair Ayala's ability to cost effectively manufacture its product candidates. There are a limited number of suppliers for the raw materials that Ayala may use to manufacture its product candidates and Ayala may need to assess alternative suppliers to prevent a possible disruption of the manufacture of its product candidates. Moreover, Ayala's product candidates utilize drug substances that are produced on a small scale, which could limit its ability to reach agreements with alternative suppliers.

Finding new CMOs or third-party suppliers involves additional cost and requires Ayala's management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although Ayala generally has not begun, and does not intend to begin, a clinical trial unless it believes it has on hand, or will be able to obtain, a sufficient supply of its product candidates to complete the clinical trial, any significant delay in the supply of its product candidates or the raw materials needed to produce its product candidates, could considerably delay conducting its clinical trials and potential regulatory approval of its product candidates.

As part of their manufacture of Ayala's product candidates, Ayala's CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to Ayala, Ayala may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which would significantly impact its ability to develop, obtain regulatory approval for or commercialize its product candidates, if approved. Further, the extent to which the COVID-19 pandemic impacts Ayala's ability to procure sufficient supplies for the development of its product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

Ayala is dependent on a small number of suppliers for some of the materials used to manufacture its product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of its product candidates.

Ayala currently depends on a small number of suppliers for some of the materials used in, and processes required to develop, its product candidates. Ayala cannot ensure that these suppliers or service providers will remain in business or have sufficient capacity or supply to meet Ayala's needs, or that they will not be purchased by one of Ayala's competitors or another company that is not interested in continuing to work with Ayala. Ayala's use of a small number of suppliers exposes it to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute materials. Ayala's current vendors may be unable or unwilling to meet its future demands for its clinical trials or commercial sale. Finding suitable replacement suppliers, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption or delay in supply could compromise Ayala's ability to pursue development and eventual commercialization of its product candidates.

Ayala intends to rely on third parties to conduct, supervise and monitor its clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm Ayala's ***business.***

Ayala relies, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of its clinical trials. Ayala's reliance on CROs for clinical development activities limits its control over these activities, but Ayala remains responsible for ensuring that each of its trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

Ayala and its CROs will be required to comply with the Good Laboratory Practice requirements for Ayala's preclinical studies and GCP requirements for Ayala's clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If Ayala or its CROs fail to comply with GCP requirements, the clinical data generated in Ayala's clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Ayala to perform additional clinical trials before approving its marketing applications. Ayala cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of Ayala's clinical trials complies with GCP requirements.

In addition, Ayala's clinical trials must be conducted with product produced under cGMP or similar requirements outside the United States. Accordingly, if Ayala's CROs fail to comply with these requirements, Ayala may be required to repeat clinical trials, which would delay the regulatory approval process. Moreover, Ayala's business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Ayala's CROs are not its employees, and Ayala does not control whether or not they devote sufficient time and resources to its clinical trials. Ayala's CROs may also have relationships with other commercial entities, including Ayala's competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could affect their performance on Ayala's behalf. Ayala faces the risk of potential unauthorized disclosure or misappropriation of its intellectual property by CROs, which may reduce its trade secret protection and allow its potential competitors to access and exploit its proprietary technology. If Ayala's CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to Ayala's clinical protocols or regulatory requirements or for any other reason, Ayala's clinical trials may be extended, delayed or terminated, and Ayala may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that it develops. As a result, Ayala's financial results and the commercial prospects for any product candidate that Ayala develops would be harmed, its costs could increase, and its ability to generate revenue could be delayed.

If Ayala's relationship with any CROs terminates, Ayala may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact Ayala's ability to meet its desired clinical development timelines. Though Ayala intends to carefully manage its relationships with its CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on its business, financial condition and prospects.

Any future collaborations will be important to Ayala's business. If Ayala is unable to enter into collaborations, or if these collaborations are not successful, its business could be adversely affected.

An important part of Ayala's strategy is to evaluate and, as deemed appropriate, enter into collaborations in the future, including potentially with major biopharmaceutical companies. Ayala has limited capabilities for product development and do not yet have any capability for commercialization. Ayala may also enter into collaborations with other companies to provide it with important technologies or funding for its programs.

Any future collaborations Ayala may enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical study or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Ayala's product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than Ayala's, which may cause collaborators to cease to devote resources to the commercialization of Ayala's product candidates;

- for collaborations involving combination therapies that have not yet been tested together, treatment emergent adverse events may be unforeseen and may negatively impact the development of Ayala's product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of Ayala's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for Ayala with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce or defend Ayala's intellectual property rights or proprietary rights or may use Ayala's proprietary information in such a way as to invite litigation that could jeopardize or invalidate Ayala's intellectual property or proprietary information or expose Ayala to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose Ayala to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, Ayala would potentially lose the right to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about Ayala's technology and use this knowledge to compete with Ayala in the future;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and type of Ayala's collaborations could adversely affect its attractiveness to future collaborators or acquirers; and
- the loss of, or a disruption in Ayala's relationship with, any one or more collaborators could harm its business.

If any collaborations do not result in the successful development and commercialization of products or if one of Ayala's collaborators terminates its agreement with Ayala, Ayala may not receive any future research and development funding or milestone or royalty payments under such collaborations. If Ayala does not receive the funding it expects under these agreements, its continued development of its product candidates could be delayed and it may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this proxy statement/prospectus also apply to the activities of any collaborators and there can be no assurance that Ayala's collaborations will produce positive results or successful products on a timely basis or at all.

Additionally, subject to its contractual obligations to Ayala, if one of Ayala's collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of Ayala's product candidates. If a collaborator terminates its agreement with Ayala, Ayala may find it more difficult to attract new collaborators and the perception of its business and its stock price could be adversely affected. For example, on June 2, 2022, Novartis International Pharmaceutical Limited, or Novartis, informed Ayala that Novartis did not intend to exercise its option to obtain an exclusive license for AL102 for multiple myeloma, in accordance with the terms of the evaluation, option and license agreement dated December 19, 2018, by and between Ayala and Novartis, thereby terminating the agreement.

Ayala may in the future collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of its product candidates. Ayala faces significant competition in seeking appropriate collaborators. Ayala's ability to reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Ayala is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, it may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If Ayala elects to fund and undertake development or commercialization activities on its own, it may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms or at all. If Ayala fails to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, it may not be able to further develop its product candidates or bring them to market or continue to develop its programs, and its business may be materially and adversely affected.

If Ayala fails to comply with its obligations in the agreements under which it in-licenses or acquires development or commercialization rights to products, technology or data from third parties, including those for AL101 and AL102, it could lose such rights that are important to its business.

In November 2017, Ayala licensed rights to AL101 and AL102 pursuant to the BMS License Agreement. This agreement imposes on Ayala, and additional agreements Ayala may enter into with other parties in the future may impose on Ayala, diligence, development and commercialization timelines, milestone and royalty payment, insurance and other obligations.

For example, in exchange for the rights granted to Ayala under the BMS License Agreement, Ayala is obligated to pay BMS up to a total of $16.5 million in milestone payments for the ultimate approval of AL101 for the treatment of ACC in addition to other milestone payments that Ayala is required to pay upon the achievement of other clinical development and commercial milestones, royalty payments that could range from a high single-digit to a low teen percentage on net sales of products containing AL101 or AL102, as well as a portion of all consideration Ayala receives in connection with the sublicense or assignment of any patent rights Ayala licensed from BMS, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced product candidate that is subject to the applicable sublicense or assignment. If Ayala or any of its collaborators fail to comply with Ayala's obligations under the BMS License Agreement or other current or future agreements, BMS or counterparties to other agreements may have the right to terminate such agreements, in which event Ayala might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of Ayala's rights under these agreements may result in Ayala's having to negotiate new or reinstated agreements with less favorable terms, or cause Ayala to lose its rights under these agreements, including its rights to important intellectual property or technology, and it may be required to cease the development and commercialization of AL101 and AL102 and any future product candidates that are subject to such agreements.

License agreements may also require Ayala to meet specified development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which Ayala's technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under Ayala's collaborative development relationships;
- Ayala's diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Ayala's licensors and Ayala and its partners; and
- the priority of invention of patented technology.

In addition, intellectual property license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what Ayala believes to be the scope of its rights to the relevant intellectual property or technology or increase what it believes to be its financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property that Ayala has licensed prevent or impair its ability to maintain its current licensing arrangements on commercially acceptable terms, Ayala may be unable to successfully develop and commercialize the affected product candidates. Any of the foregoing risks could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for Ayala to obtain marketing approval of and commercialize its product candidates, if approved, and may affect the prices Ayala may set.

In the United States, EU, and other jurisdictions, there have been, and Ayala expects there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect Ayala's future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively and an extension of the rebate program to individuals enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain IND products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect Ayala's customers and accordingly, its financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. Ayala expects that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for its product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm Ayala's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for Ayala's product candidates or put pressure on its product pricing.

In the EU, similar political, economic and regulatory developments may affect Ayala's ability to profitably commercialize its product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase Ayala's operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of Ayala's product candidates, restrict or regulate post-approval activities and affect its ability to commercialize its product candidates, if approved.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation which entered into force in January 2022 intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Ayala cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If Ayala or any third parties Ayala may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Ayala or such third parties are not able to maintain regulatory compliance, Ayala's product candidates may lose any regulatory approval that may have been obtained and Ayala may not achieve or sustain profitability.

Ayala's business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose Ayala to penalties.

Ayala's business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose Ayala to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which Ayala conducts its operations, including how Ayala researches, markets, sells and distributes its product candidates, if approved. Such laws include:

- the AKS, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- The FCA and civil monetary penalties laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to Ayala's business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that Ayala's internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that Ayala's business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Ayala's operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to Ayala, Ayala may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of its operations. If any of the physicians or other providers or entities with whom Ayala expects to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect Ayala's ability to operate its business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if Ayala is successful in defending against any such actions that may be brought against it, its business may be impaired.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect Ayala's business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and Ayala is or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that Ayala may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and Ayala cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on its business. This evolution may create uncertainty in Ayala's business, affect Ayala's ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in Ayala's contracts, result in liability or impose additional costs on Ayala. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by Ayala to comply with federal, state or foreign laws or regulation, its internal policies and procedures or its contracts governing its processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to its reputation, any of which could have a material adverse effect on its operations, financial performance and business.

As Ayala's operations and business grow, it may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for Ayala and its future customers and strategic partners. For example, the California Consumer Privacy Act of 2018, or the CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase Ayala's compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act, or the CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. In the event that Ayala is subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect its financial condition.

If Ayala conducts clinical trials or enter into research collaborations in the European Economic Area, or EEA, it may be subject to the General Data Protection Regulation, or GDPR, which imposes strict requirements for processing the personal data of individuals within the EEA. If Ayala's or its partners' or service providers' privacy or data security measures fail to comply with GDPR requirements, Ayala may be subject to litigation, regulatory investigations, enforcement notices requiring it to change the way it uses personal data and/or fines of up to €20 million or 4% of its total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the UK SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, Ayala could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if Ayala is otherwise unable to transfer personal data between and among countries and regions in which it operates, it could affect the manner in which Ayala provides its services, the geographical location or segregation of its relevant systems and operations, and could adversely affect its financial results.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

Although Ayala works to comply with applicable laws, regulations and standards, its contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which Ayala must comply. Any failure or perceived failure by Ayala or its employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to Ayala, damage its reputation, and adversely affect its business and results of operations.

Ayala is subject to environmental, health and safety laws and regulations, and may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Ayala's operations, including its development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If Ayala fails to comply with such laws and regulations, it could be subject to fines or other sanctions.

As with other companies engaged in activities similar to Ayala's, Ayala faces a risk of environmental liability inherent in its current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. Ayala may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of its third-party manufacturers or its development efforts may be interrupted or delayed.

Ayala is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations and can face serious consequences for violations.

Trade Laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Ayala has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Ayala also expects its non-U.S. activities to increase in time. Ayala plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and can be held liable for the corrupt or other illegal activities of its personnel, agents or partners, even if it does not explicitly authorize or have prior knowledge of such activities. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, Ayala's dealings with these prescribers and purchasers are subject to regulation under the Trade Laws. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Ayala's Intellectual Property

If Ayala fails to comply with its obligations under its existing intellectual property license with BMS and any future intellectual property licenses with third parties, it could lose rights that are important to its business, including the right to develop and commercialize the AL101 and AL102 product candidates.

Ayala is party to a license agreement with BMS which gives Ayala the right to practice certain issued patents to develop and commercialize AL101 and AL102 and methods of use thereof. Ayala may enter into additional license agreements in the future. Ayala's existing license agreements impose, and any future license agreements are likely to impose, various diligence, milestone payment, royalty, insurance and other obligations on Ayala. Any uncured, material breach under these license agreements could result in the loss of Ayala's rights to practice such in-licensed intellectual property and could compromise Ayala's development and commercialization efforts for any current product candidates, including requiring Ayala to cease the development and commercialization of AL101 and AL102, or future product candidates and methods of use thereof.

If Ayala is unable to obtain, maintain, protect and enforce patent and other intellectual property protection for its technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, Ayala's competitors could develop and commercialize products and technology similar or identical to Ayala's, and Ayala may not be able to compete effectively in its markets.

Ayala relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to its proprietary technologies, product candidate development programs and product candidates. Ayala's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to AL101, AL102 and any future product candidates. Ayala seeks to protect its proprietary position by filing or collaborating with its licensors to file patent applications in the United States and abroad related to its development programs and product candidates. The patent prosecution process is expensive, time-consuming and complex, and Ayala and its collaborators may not be able to file, prosecute, maintain or enforce all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of Ayala's patent rights are highly uncertain.

It is possible that Ayala will fail to identify further patentable aspects of its research and development output before it is too late to obtain patent protection. Although Ayala enters into confidentiality agreements with employees, consultants, CROs, contractors, manufacturers, advisors and other third parties who have access to its confidential information, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing Ayala's ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, or in some cases not at all. Therefore, Ayala cannot be certain that it was the first to make the inventions claimed in its owned or any licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. The patent applications that Ayala owns, or in-licenses, may fail to result in issued patents with claims that provide further coverage of AL101, AL102 or any other product candidate or methods of use thereof in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to Ayala's patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Additionally, any U.S. provisional patent application that Ayala or its licensors file is not eligible to become an issued patent until, among other things, Ayala files a non-provisional patent application within 12 months of filing the related provisional patent application. If Ayala or its licensors do not timely file any non-provisional patent application, Ayala may lose its priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application. Even if patents do successfully issue and even if such patents further cover AL101, AL102 or any future product candidate or methods of use thereof, third parties may challenge their validity, ownership, enforceability or scope, which may result in such patents being narrowed, invalidated, circumvented, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to Ayala could deprive Ayala of rights necessary for the successful commercialization of AL101, AL102 or the methods of use thereof, or any other product candidates that Ayala may develop. Further, if Ayala encounters delays in regulatory approvals, the period of time during which Ayala could market a product candidate under patent protection could be reduced.

If the patent applications Ayala owns or has in-licensed with respect to its development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for AL101, AL102 or any future product candidate, it could dissuade companies from collaborating with Ayala to develop product candidates, and threaten Ayala's ability to commercialize future product candidates. Any such outcome could have a material adverse effect on Ayala's business.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal, scientific, and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement, misappropriation or other violations. In addition, the laws of jurisdictions outside the United States may not protect Ayala's rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish Ayala's ability to protect its inventions or obtain, maintain, and enforce its intellectual property rights and, more generally, could affect the value of its patents or narrow the scope of its patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of Ayala's patent rights are highly uncertain. Ayala's pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect Ayala's technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and Ayala may be subject to a third-party pre-issuance submission of prior art, or its owned and licensed patents may be challenged, in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit Ayala's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and products. Thus, even if Ayala's patent applications issue as patents, they may not issue in a form that will provide Ayala with meaningful protection, prevent competitors from competing with Ayala or otherwise provide Ayala with any competitive advantage. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Patent term extensions may be available; however the life of a patent, and the protection it affords, is limited. Without sufficient patent protection for Ayala's current or future product candidates, Ayala may be open to competition from generic versions of such products. Ayala's competitors or other third parties may also be able to circumvent Ayala's patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Moreover, some of Ayala's owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If Ayala is unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including Ayala's competitors, and Ayala's competitors could market competing products and technology. In addition, Ayala may need the cooperation of any such co-owners of its patents in order to enforce such patents against third parties, and such cooperation may not be provided to Ayala. As a result, Ayala's owned and licensed patent portfolio may not provide Ayala with sufficient rights to exclude others from commercializing products similar or identical to Ayala's. Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Third parties may assert claims against Ayala alleging infringement, misappropriation or other violation of their patents or other intellectual property rights, and Ayala may need to become involved in lawsuits to protect or enforce its patents or other intellectual property rights, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of its product candidates, prohibit its use of proprietary technology or sale of products or put its patents and other proprietary rights at risk.

Ayala's commercial success depends, in part, upon Ayala's ability and the ability of Ayala's collaborators to develop, manufacture, market and sell Ayala's product candidates without alleged or actual infringement, misappropriation or other violations of the patents and proprietary rights of third parties. Litigation relating to infringement, misappropriation or other violation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and post-grant review, *inter partes* review, reexamination and derivation proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which Ayala plans to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights, and third parties may assert infringement claims against Ayala based on existing patents or patents that may be granted in the future, regardless of their merit. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Ayala is developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Ayala's product candidates may be subject to claims of infringement, misappropriation or other violation of the intellectual property rights of third parties. Some claimants may have substantially greater resources than Ayala does and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than Ayala could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target Ayala.

Ayala may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review, *inter partes* review and reexamination proceedings before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. In order to successfully challenge the validity of any such U.S. patent in federal courts, Ayala would need to overcome a presumption of validity. As this burden is a high one requiring Ayala to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if Ayala believes such claims are without merit, a court of competent jurisdiction could hold that any such third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block Ayala's ability to commercialize the applicable product candidate unless Ayala obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of Ayala's compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit Ayala's use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking Ayala's ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless Ayala obtained a license.

In addition, defending such claims would cause Ayala to incur substantial expenses and, if successful, could cause Ayala to pay substantial damages if Ayala is found to be infringing a third party's patent or other intellectual property rights. These damages potentially include increased damages (possibly treble damages) and attorneys' fees if Ayala is found to have infringed such rights willfully. Further, if a patent or other intellectual property infringement suit is brought against Ayala or its third-party service providers, Ayala's development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated, as parties making claims against Ayala may obtain injunctive or other equitable relief. As a result of patent or other intellectual property infringement claims, or in order to avoid potential infringement claims, Ayala may choose to seek, or be required to seek, a license from the third party in order to develop and commercialize the applicable product candidate, which may require payment of substantial royalties or fees, or require Ayala to grant a cross-license under its intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be non-exclusive, which would give Ayala's competitors access to the same intellectual property rights. If Ayala is unable to enter into a license on acceptable terms, it could be prevented from commercializing one or more of its product candidates, or forced to modify such product candidates, or to cease some aspect of its business operations, which could harm its business significantly. Ayala might also be forced to redesign or modify its product candidates so that it no longer infringes the third-party intellectual property rights, which may result in significant cost or delay to Ayala, or which redesign or modification could be impossible or technically infeasible. Even if Ayala was ultimately to prevail, any of these events could require Ayala to divert substantial financial and management resources that it would otherwise be able to devote to its business. In addition, if the breadth or strength of protection provided by the patents and patent applications Ayala owns or in-licenses is threatened, it could dissuade companies from collaborating with Ayala to license, develop or commercialize current or future product candidates.

If Ayala or one of its licensors or collaborators were to initiate legal proceedings against a third party to enforce an owned or in-licensed patent covering one of Ayala's product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace, and a court may decide that a patent owned or in-licensed by Ayala is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that Ayala's owned and in-licensed patents do not cover the technology in question. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of Ayala's patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, Ayala cannot be certain that there is no invalidating prior art of which it and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, Ayala would lose at least part, and perhaps all, of the patent protection on its product candidates. Ayala's patents and other intellectual property rights also will not protect its technology if competitors design around its protected technology without infringing its patents or other intellectual property rights.

Even if resolved in Ayala's favor, litigation or other legal proceedings relating to intellectual property claims may cause Ayala to incur significant expenses and could distract Ayala's technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Ayala's confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of Ayala's Common Stock could be adversely affected. Such litigation or proceedings could substantially increase Ayala's operating losses and reduce its resources available for development activities. Ayala may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of Ayala's competitors may be able to sustain the costs of such litigation or proceedings more effectively than Ayala can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on Ayala's ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Ayala may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect its ability to develop, manufacture and market its product candidates.

Ayala cannot guarantee that any of its or its licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can Ayala be certain that it has identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of its product candidates in any jurisdiction. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering Ayala's product candidates could be filed by others without Ayala's knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover Ayala's product candidates or the use of Ayala's product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Ayala's interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact Ayala's ability to market its product candidates. Ayala may incorrectly determine that its product candidates or methods of use thereof are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Ayala's determination of the expiration date of any patent in the United States, the EU or elsewhere that Ayala considers relevant may be incorrect, which may negatively impact its ability to develop and market its product candidates. Ayala's failure to identify and correctly interpret relevant patents may negatively impact its ability to develop and market its product candidates.

From time to time Ayala may identify patents or applications in the same general area as its products and product candidates and methods of use thereof. Ayala may determine these third-party patents are irrelevant to its business based on various factors including its interpretation of the scope of the patent claims and its interpretation of when the patent expires. If the patents are asserted against Ayala, however, a court may disagree with Ayala's determinations. Further, while Ayala may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, Ayala's determination may be incorrect, and the issuing patent may be asserted against Ayala. Ayala cannot guarantee that it will be able to successfully settle or otherwise resolve such infringement claims. If Ayala fails in any such dispute, in addition to being forced to pay monetary damages, it may be temporarily or permanently prohibited from commercializing its product candidates or be required to obtain a license under such patent, which may not be available on reasonable terms or at all. Ayala might, if possible, also be forced to redesign its product candidates so that it no longer infringes, misappropriates or otherwise violates the third-party intellectual property rights. Any of these events, even if Ayala were ultimately to prevail, could require Ayala to divert substantial financial and management resources that it would otherwise be able to devote to its business. Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing Ayala's ability to protect its product candidates.

As is the case with other biopharmaceutical and pharmaceutical companies, Ayala's success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before Ayala could therefore be awarded a patent covering an invention of Ayala's even if Ayala makes the invention before it was made by the third party. This will require Ayala to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent Ayala from promptly filing patent applications on its inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent with the USPTO. This applies to all of Ayala's U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate Ayala's patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of Ayala's business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of Ayala's or its licensors' patent applications and the enforcement or defense of Ayala's or its licensors' issued patents.

Ayala may become involved in opposition, interference, derivation, *inter partes* review, post-grant review, reexamination or other proceedings challenging its or its licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, Ayala's owned or in-licensed patent rights, in whole or in part, allow third parties to commercialize Ayala's technology or products and compete directly with Ayala, without payment to Ayala, or result in Ayala's inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to Ayala's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, enforceability and value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, as well as similar bodies in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken Ayala's ability to obtain new patents or to enforce Ayala's existing patents and patents that Ayala might obtain in the future. Similarly, the complexity and uncertainty of European patent laws have also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit Ayala's ability to obtain new patents in the future that may be important for its business, and these laws and regulations patents could continue to change in unpredictable ways that could have a material adverse effect on Ayala's existing patent rights and its ability to protect and enforce its intellectual property in the future.

Obtaining and maintaining Ayala's patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and Ayala's patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance, renewal and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If Ayala or its licensors fail to maintain the patents and patent applications covering Ayala's product candidates or if Ayala or its licensors otherwise allow Ayala's patents or patent applications to be abandoned or lapse, Ayala's competitors might be able to enter the market, which would hurt Ayala's competitive position and could impair Ayala's ability to successfully commercialize its product candidates in any indication for which they are approved, which could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Ayala enjoys only limited geographical protection with respect to certain patents and may not be able to protect its intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents covering Ayala's product candidates in all countries throughout the world would be prohibitively expensive, and Ayala's intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In-licensing patents covering Ayala's product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all, and even in-licensing or filing, prosecuting and defending patents in only those jurisdictions in which Ayala develops or commercializes its product candidates may still be prohibitively expensive or impractical. Competitors may use Ayala's and its licensors' technologies in jurisdictions where Ayala has not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where Ayala and its licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with Ayala's product candidates, and Ayala's or its licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, Ayala may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of Ayala's or its licensors' patents, requiring Ayala or its licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of Ayala's products. It is also common for, depending on the country, the scope of patent protection to vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for Ayala to prevent competitors in some jurisdictions from marketing competing products in violation of its proprietary rights generally. Proceedings to enforce Ayala's patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert Ayala's efforts and attention from other aspects of its business, and additionally could put at risk Ayala's or its licensors' patents of being invalidated or interpreted narrowly, could increase the risk of Ayala's or its licensors' patent applications not issuing, or could provoke third parties to assert claims against Ayala. Ayala may not prevail in any lawsuits that it initiates, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If Ayala prevails, damages or other remedies awarded to it, if any, may not be commercially meaningful. Accordingly, Ayala's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses. Furthermore, while Ayala intends to protect its intellectual property rights in its expected significant markets, Ayala cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which it may wish to market its product candidates. Accordingly, Ayala's efforts to protect its intellectual property rights in such countries may be inadequate, which may have an adverse effect on Ayala's ability to successfully commercialize its product candidates in all of its expected significant foreign markets. If Ayala or its licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for Ayala's business in such jurisdictions, the value of these rights may be diminished and Ayala may face additional competition in those jurisdictions.

In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Ayala or any of its licensors are forced to grant a license to third parties under patents relevant to Ayala's business, or if Ayala or its licensors are prevented from enforcing patent rights against third parties, Ayala's competitive position may be substantially impaired in such jurisdictions. Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

If Ayala does not obtain patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for its product candidates, its business may be materially harmed.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if Ayala or its licensors obtain patents covering Ayala's product candidates, when the terms of all patents covering a product expire, Ayala's business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, Ayala's owned and licensed patent portfolio may not provide Ayala with sufficient rights to exclude others from commercializing products similar or identical to Ayala's.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of Ayala's product candidates, one or more of Ayala's U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. While the length of such patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per approved drug may be extended and only those claims covering the approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, Ayala's product candidates may be eligible for patent term extensions based on similar legislation. In either jurisdiction, however, Ayala may not receive an extension if it fails to apply within applicable deadlines, fails to apply prior to expiration of relevant patents, fails to exercise due diligence during the testing phase or regulatory review process or otherwise fails to satisfy applicable requirements. Even if Ayala is granted such extension, the duration of such extension may be less than its request. If Ayala is unable to obtain a patent term extension, or if the term of any such extension is less than its request, the period during which Ayala can enforce its patent rights for that product will be in effect shortened and Ayala's competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Further, under certain circumstances, patent terms covering Ayala's products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as patent term adjustment, or PTA). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third party. If Ayala does not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact Ayala's ability to exclude competitors.

Because PTA added to the term of patents covering pharmaceutical products has particular value, Ayala's business may be adversely affected if the PTA is successfully challenged by a third party and Ayala's ability to exclude competitors is reduced or eliminated.

Ayala's proprietary rights may not adequately protect its technologies and product candidates, and do not necessarily address all potential threats to its competitive advantage.

The degree of future protection afforded by Ayala's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect Ayala's business, or permit Ayala to maintain its competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to AL101, AL102 or Ayala's future product candidates and methods of use thereof but that are not covered by the claims of the patents that Ayala owns or exclusively licensed;
- others, including inventors or developers of Ayala's owned or in-licensed patent technologies who may become involved with competitors, may independently develop similar or alternative technologies or otherwise circumvent any of Ayala's technologies without infringing Ayala's intellectual property rights;
- Ayala or any of its collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that Ayala owns, licenses or will own or license;
- Ayala or any of its collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that Ayala or they own, license or will own or license;
- it is possible that Ayala's pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate Ayala's or its licensors' patents;
- issued patents that Ayala owns or exclusively licenses may not provide Ayala with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by Ayala's competitors;

- Ayala's competitors might conduct research and development activities in countries where Ayala does not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in Ayala's major commercial markets;
- ownership, validity or enforceability of Ayala's or its licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on Ayala's business.
- Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Ayala's reliance on third parties requires it to share its trade secrets, which increases the possibility that its trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

Ayala considers proprietary trade secrets and confidential or unpatented know-how to be important to its business. Ayala may rely on trade secrets or confidential know-how to protect its technology, especially where patent protection is believed by Ayala to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and Ayala has limited control over the protection of trade secrets and confidential know-how used by its licensors, collaborators and suppliers. Because Ayala expects to rely on third parties to manufacture AL101, AL102 and any future product candidates, and to collaborate with third parties on the development of AL101, AL102 and any future product candidates, Ayala must, at times, share trade secrets with them. Ayala also conducts joint research and development programs that may require it to share trade secrets under the terms of its research and development partnerships or similar agreements. Under such circumstances, trade secrets or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, Ayala's policy is to require its employees, consultants, CROs, contractors, manufacturers, advisors and other third parties who have access to its confidential information to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with Ayala prior to beginning research or Ayala disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose Ayala's confidential information, including Ayala's trade secrets. However, Ayala cannot guarantee that it has entered into such agreements with each party that may have or have had access to its trade secrets or proprietary technology. Despite Ayala's efforts, any such parties may breach these agreements and unintentionally or willfully disclose Ayala's confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by Ayala's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that Ayala's competitive position is based, in part, on Ayala's know-how and trade secrets, a competitor's discovery of Ayala's trade secrets or other unauthorized use or disclosure would impair Ayala's competitive position and may have an adverse effect on Ayala's business and results of operations. Enforcing a claim that a third party obtained illegally or misappropriated trade secrets or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements and the protection of trade secrets generally may vary from jurisdiction to jurisdiction.

In addition, Ayala's agreements typically restrict the ability of Ayala's advisors, employees, third-party contractors, consultants, CROs, manufacturers, advisors and other third parties to publish data potentially relating to Ayala's trade secrets, although the agreements may grant certain limited publication rights. Despite Ayala's efforts to protect its trade secrets, Ayala's competitors or other third parties may discover Ayala's trade secrets, either through breach of Ayala's agreements with third parties, independent development or publication of information by any of Ayala's third-party collaborators. A competitor's or other third party's discovery of Ayala's trade secrets would impair Ayala's competitive position and have a material adverse effect on Ayala's business.

Ayala may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The growth of Ayala's business may depend in part on Ayala's ability to acquire or in-license additional intellectual property or proprietary rights. For example, Ayala's programs may involve product candidates that may require the use of additional intellectual property or proprietary rights held by third parties. Ayala's product candidates may also require specific formulations to work effectively and efficiently, which may be covered by intellectual property rights held by others. Ayala may also develop products containing combinations of its compositions and pre-existing pharmaceutical compositions, and could be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with its product candidates, both of which may also be covered by intellectual property rights held by others. Ayala may be unable to acquire or in-license any relevant third-party intellectual property rights that it identifies as necessary or important to its business operations at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that Ayala may consider attractive or necessary. These established companies may have a competitive advantage over Ayala due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Ayala to be a competitor may be unwilling to assign or license rights to Ayala. In cases where Ayala is unable to procure sufficient rights to third-party intellectual property rights, it might need to cease use of the compositions or methods covered by such third-party intellectual property rights and/or develop alternative approaches that do not infringe, misappropriate or otherwise violate such intellectual property rights. This could entail additional costs and development delays, and the development of such alternatives may not be feasible. Even if Ayala is able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow Ayala's competitors access to the same technologies licensed to Ayala. Any of the foregoing could prevent Ayala from developing or commercializing one or more of its product candidates, or force it to modify such product candidates, or to cease some aspect of its business operations, which could have a material adverse effect on its business.

Ayala may be subject to claims that its employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what Ayala regards as its own intellectual property.

Ayala does and may employ and contract with individuals who were previously employed by other biotechnology or pharmaceutical companies. Although Ayala seeks to protect its ownership of intellectual property rights by ensuring that its agreements with its employees, collaborators and other third parties with whom it does business include provisions requiring such parties to assign rights in inventions to it and to not use the know-how or confidential information of their former employer or other third parties, Ayala cannot guarantee that it has executed such agreements with all applicable parties. Ayala may be subject to claims that it or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of Ayala's employees' former employers or other third parties. Ayala may also be subject to claims that former employers or other third parties have an ownership interest in Ayala's patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if Ayala fails in defending any such claims, in addition to paying monetary damages, it may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if Ayala is successful, litigation could result in substantial cost and be a distraction to Ayala's management and other employees.

In addition, while it is Ayala's policy to require its employees, contractors and other third parties who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to Ayala, Ayala may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that Ayala regards as its own. The assignment of intellectual property rights under such agreements may not be self-executing, or the assignment agreements may be breached, and Ayala may be forced to bring claims against third parties, or defend claims that they may bring against Ayala, to determine the ownership of what Ayala regards as its intellectual property. Any of the foregoing could have a material adverse effect on Ayala's business, financial condition, results of operations, and prospects.

Ayala's use of "open source" software could subject Ayala's proprietary software to general release and subject Ayala to possible litigation.

Ayala's bioinformatics platform incorporates software licensed under so-called "open source" licenses and Ayala may incorporate open source software into other technologies in the future. Usage of open source software can lead to greater risks than the use of other third-party commercial software, as open source licensors generally do not provide warranties or controls on origin of the software or other contractual protections or code quality, as it is generally freely accessible and made available to the general public on an "as-is" basis under the terms of a non-negotiable license. Some open source licenses contain requirements that the user disclose source code for modifications it makes to the open source software and license such modifications to third parties at no cost. Ayala monitors its use of open source software in an effort to avoid uses in a manner that would require it to disclose or grant licenses under its proprietary source code based on its modifications of open source code. However, there can be no assurance that such efforts will be successful and Ayala could face claims that it is utilizing open source software in breach of the applicable licenses, which could result in litigation that may cause Ayala to be required to disclose its proprietary source code based on its modifications of open source code, incur expenses and be liable for damages and such litigation could distract Ayala's personnel from their normal responsibilities.

Risks Related to Ayala's Employees, Managing Ayala's Growth and Ayala's Operations

Ayala's future success depends on its ability to retain its key personnel and to attract***, retain and motivate qualified personnel.***

Ayala is highly dependent on the development, regulatory, commercialization and business development expertise of Roni Mamluk, M.D., Ph.D., Ayala's President and Chief Executive Officer and President, as well as the other principal members of Ayala's management, scientific and clinical teams. Although Ayala has formal employment agreements, offer letters or consulting agreements with its executive officers, these agreements do not prevent them from terminating their services at-will with 60 days to three months' advance notice. Immediately following the closing of the Merger, Dr. Mamluk's employment with Ayala will terminate. In addition, the employment of Yossi Maimon, Ayala's Chief Financial Officer, will terminate immediately following the closing of the Merger.

If Ayala loses one or more of its executive officers or key employees, its ability to implement its business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in Ayala's industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and Ayala may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Ayala also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Ayala relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research and development and commercialization strategy. Ayala's consultants and advisors may be engaged by entities other than Ayala and may have commitments under consulting or advisory contracts with other entities that may limit their availability to Ayala. If Ayala is unable to continue to attract and retain highly qualified personnel, Ayala's ability to develop and commercialize product candidates will be limited.

Ayala may engage in acquisitions or in-licensing transactions that could disrupt its business, cause dilution to its stockholders or reduce its financial resources.

In the future, Ayala may enter into transactions to acquire or license, as applicable, other businesses, products or technologies. If Ayala does identify suitable candidates, it may not be able to make such acquisitions or licenses on favorable terms, or at all. Any acquisitions or in-license Ayala makes may not strengthen its competitive position, and these transactions may be viewed negatively by customers or investors. Ayala may decide to incur debt in connection with an acquisition or in-license or issue common stock or other equity securities to the stockholders of the counterparty, which would reduce the percentage ownership of its existing stockholders. Ayala could incur losses resulting from undiscovered liabilities of the acquired business, product or technology that are not covered by the indemnification Ayala may obtain from the seller. In addition, Ayala may not be able to successfully integrate the acquired personnel, technologies and operations into its existing business in an effective, timely and non-disruptive manner. Acquisitions and in-licensing may also divert management attention from day-to-day responsibilities, increase Ayala's expenses and reduce its cash available for operations and other uses. Ayala cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on its operating results.

Ayala's business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in Ayala's cybersecurity.

In the ordinary course of Ayala's business, Ayala collects and stores sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of its clinical trial subjects and employees, in its data centers and on its networks. The secure processing, maintenance and transmission of this information is critical to Ayala's operations. Ayala's information technology systems, as well as those of its CROs, other contractors and consultants, and other third parties that Ayala interacts with, are vulnerable to attack, damage or interruption from computer viruses, malware (e.g. ransomware), malicious code, hacking, cyberattacks, phishing attacks and other social engineering schemes, theft, natural disasters (including hurricanes), terrorism, war, power disruptions, telecommunication and electrical failures, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access or use by persons inside Ayala's organization or persons with access to systems inside Ayala's organization or other events or disruptions. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic and the current conflict between Russia and Ukraine, Ayala and third parties who Ayala interacts with may also face increased cybersecurity risks due to increase reliance on internet technology and the number of Ayala's employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, Ayala, its CROs, other contractors and consultants, and other third parties that Ayala interacts with may be unable to anticipate these techniques or implement adequate preventative measures. Ayala, its CROs, other contractors and consultants, and other third parties that Ayala interacts with may also experience security breaches that may remain undetected for an extended period. Even if identified, Ayala may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. System redundancy and other continuity measures may be ineffective or inadequate, and business continuity and disaster recovery planning may not be sufficient for all eventualities.

Although, to Ayala's knowledge, it has not experienced any such significant security breach to date, any such breach could compromise Ayala's networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt Ayala's operations, damage its reputation, and cause a loss of confidence in Ayala and its ability to conduct clinical trials, which could adversely affect Ayala's reputation and delay its clinical development of its product candidates. If such an event were to occur and cause interruptions in Ayala's operations or the operations of Ayala's CROs, other contractors and consultants, it could result in a material disruption of Ayala's development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in Ayala's regulatory approval efforts and significantly increase Ayala's costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to Ayala's data or applications, or inappropriate disclosure of personal, confidential or proprietary information, Ayala could incur liability and the further development of AL101, AL102 or any other product candidate could be delayed.

Risks Related to Ayala's Common Stock

An active trading market for Ayala's Common Stock may not be sustained.

If an active trading market for Ayala's Common Stock is not sustained, you may not be able to sell your shares quickly or at the market price or at all. Ayala's ability to raise capital to continue to fund operations by selling shares of its common stock and its ability to acquire other companies or technologies by using shares of its common stock as consideration may also be impaired.

Ayala's Common Stock may be delisted from The Nasdaq Global Market if Ayala cannot regain compliance with Nasdaq's continued listing requirements, which could harm Ayala's business, the trading price of its common stock, its ability to raise additional capital and the liquidity of the market for its common stock.

Ayala's Common Stock is currently listed on The Nasdaq Global Market. To maintain the listing of its common stock on The Nasdaq Global Market, Ayala is required to meet certain listing requirements. On November 10, 2022, Ayala received written notice, or the Equity Notice, from The Nasdaq Stock Market LLC, or Nasdaq, notifying Ayala that its stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2022, or the Form 10-Q, did not satisfy the continued listing requirement under Nasdaq Listing Rule 5450(b)(1)(A) for The Nasdaq Global Market, which requires that a listed company's stockholders' equity be at least $10 million, or the Equity Requirement. As reported on its Form 10-Q, Ayala's stockholders' equity as of September 30, 2022 was approximately $8.16 million. Additionally, on November 16, 2022, Ayala received written notice, or the Bid Price Notice, from Nasdaq notifying Ayala that, for the last 30 consecutive business days, the bid price for Ayala's Common Stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1), or the Bid Price Requirement. Further, on November 18, 2022, Ayala received written notice, or the MVPHS Notice and, together with the Equity Notice and the Bid Price Notice, the Notices, from Nasdaq notifying Ayala that it is no longer in compliance with the minimum Market Value of Publicly Held Shares, or MVPHS, of $5,000,000 required for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(1)(C), or the MVPHS Requirement and, together with the Equity Requirement and the Bid Price Requirement, the Requirements.

The Notices have no immediate effect on the listing of Ayala's Common Stock, which continues to trade on The Nasdaq Global Market under the symbol "AYLA."

With respect to the Equity Notice, in accordance with Nasdaq Listing Rules, Ayala has a period of 45 calendar days, or until December 27, 2022, or the Equity Compliance Date, to submit a plan to regain compliance with the Equity Requirement. If Ayala's compliance plan is accepted by Nasdaq, then Nasdaq may, in its discretion, grant Ayala up to 180 calendar days from the date of the Equity Notice, or until May 9, 2023, to evidence compliance. If Nasdaq does not accept Ayala's plan, then Ayala will have the opportunity to appeal that decision to a Nasdaq Hearings Panel.

With respect to the Bid Price Notice and, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), Ayala has been provided a period of 180 calendar days, or until May 15, 2023, or the Bid Price Compliance Date, to regain compliance with the Bid Price Requirement. If, at any time before the Bid Price Compliance Date, the bid price for Ayala's Common Stock closes at $1.00 or more for a minimum of 10 consecutive business days as required under 5810(c)(3)(A) (unless Nasdaq exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H)), Nasdaq will provide written notification to Ayala that it has regained compliance with the Bid Price Requirement.

If Ayala does not regain compliance with the Bid Price Requirement by the Bid Price Compliance Date, Ayala may be eligible for an additional 180 calendar day compliance period. To qualify, Ayala would need to transfer the listing of its Common Stock to The Nasdaq Capital Market, provided that it meets the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, Ayala would also need to pay an application fee to Nasdaq and will need to provide written notice to Nasdaq of its intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, Nasdaq will make a determination of whether it believes Ayala will be able to cure this deficiency.

With respect to the MVPHS Notice and, in accordance with Nasdaq Listing Rule 5810(c)(3)(D), Ayala has a period of 180 calendar days, or until May 17, 2023, or the MVPHS Compliance Date and, together with the Equity Compliance Date and the Bid Price Compliance Date, the Compliance Dates, to regain compliance with the MVPHS Requirement. To regain compliance, Ayala's MVPHS must close at $5,000,000 or more for a minimum of 10 consecutive business days prior to the MVPHS Compliance Date. Ayala intends to actively monitor its MVPHS. In the event Ayala does not regain compliance with the MVPHS Requirement prior to the MVPHS Compliance Date, Nasdaq will notify Ayala that its securities are subject to delisting, at which point Ayala may appeal the delisting determination to a Nasdaq Hearings Panel.

Ayala is currently evaluating various alternative courses of action, including transferring to The Nasdaq Capital Market, or submitting a plan to regain compliance with the Requirements before the Compliance Dates. However, there can be no assurance that Ayala will be able to regain compliance with the Requirements, or maintain compliance with any other listing requirements, or satisfy the requirements necessary to transfer the listing of its Common Stock to The Nasdaq Capital Market. Delisting from The Nasdaq Global Market or any Nasdaq market could make trading Ayala's Common Stock more difficult for investors, potentially leading to declines in Ayala's share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of Ayala's Common Stock, the sale or purchase of Ayala's Common Stock would likely be made more difficult and the trading volume and liquidity of Ayala's Common Stock could decline. Delisting from Nasdaq could also result in negative publicity and make it more difficult for Ayala to raise additional capital. The absence of such a listing may adversely affect the acceptance of Ayala's Common Stock as currency or the value accorded to Ayala's Common Stock by other parties. If Ayala's Common Stock is delisted by Nasdaq, Ayala's Common Stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell Ayala's Common Stock or obtain accurate quotations as to the market value of Ayala's Common Stock. Ayala cannot assure you that its Common Stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

The market price of Ayala's Common Stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of Ayala's Common Stock.

Ayala's stock price may be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your Ayala Common Stock at or above the price which you paid for it. The market price for Ayala's Common Stock may be influenced by many factors, including:

- any delay in the enrollment and completion of Ayala's clinical trials;
- inability to obtain additional funding;
- the success of competitive products or technologies;
- actual or expected changes in Ayala's growth rate relative to its competitors;
- results of clinical trials of Ayala's product candidates or those of its competitors;
- developments related to Ayala's existing or any future collaborations;
- adverse regulatory decisions;
- regulatory actions with respect to Ayala's product candidates or its competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address Ayala's markets and make its product candidates less attractive;

- changes in physician, hospital or healthcare provider practices that may make Ayala's product candidates less useful;
- inability to obtain adequate product supply for AL101, AL102 or any other product candidate, or the inability to do so at acceptable prices;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of Ayala's product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that Ayala provides to the public;
- the results of Ayala's efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in Ayala's financial results or those of companies that are perceived to be similar to Ayala;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by Ayala or its competitors;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to Ayala's proprietary rights, including patents, litigation matters and Ayala's ability to obtain patent protection for its technologies;
- trading volume of Ayala's Common Stock;
- short selling activities;
- general economic, industry and market conditions; and
- the other factors described in this "Risks Related to the Business of Ayala" section and elsewhere in this proxy statement/prospectus.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and the current conflict between Russia and Ukraine. These situations continue to rapidly evolve. The extent to which they may impact Ayala's business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for Ayala because biopharmaceutical companies have experienced significant stock price volatility in recent years. If Ayala faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm Ayala's business.

Ayala's executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

Based on the number of shares of Ayala Common Stock outstanding as of October 31, 2022, Ayala's executive officers, directors and stockholders who own more than 5% of its outstanding Common Stock and their respective affiliates, in the aggregate, hold shares representing approximately 62.4% of its outstanding voting stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to Ayala's stockholders for approval, as well as Ayala's management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of Ayala's management and approval of any merger, consolidation or sale of all or substantially all of Ayala's assets.

A significant portion of Ayala's total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of Ayala's Common Stock to drop significantly, even if Ayala's business is doing well.

Sales of a substantial number of shares of Ayala's Common Stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of Ayala's Common Stock. There were 14,820,727 shares of Ayala Common Stock outstanding as of October 31, 2022. Of those shares 9,940,455 shares were held by Ayala's affiliates and are subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act, or Rule 144. Moreover, certain holders of Ayala's Common Stock have rights, subject to specified conditions, to require Ayala to file registration statements covering their shares or to include their shares in registration statements that Ayala may file for itself or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the investors' rights agreement between Ayala and such holders. Pursuant to that certain Securities Purchase Agreement, dated February 19, 2021, by and among Ayala and the purchasers named therein, or the 2021 Purchase Agreement, Ayala agreed to sell (i) an aggregate of 333,333 shares of its Common Stock, par value $0.01 per share, together with warrants to purchase an aggregate of 116,666 shares of its Common Stock with an exercise price of $18.10 per share, or the Common Warrants, for an aggregate purchase price of $4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of its Common Stock with an exercise price of $0.01 per share, together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of $19,986,661.67, collectively, the Private Placement. Pursuant to the 2021 Purchase Agreement, Ayala also agreed to use reasonable best efforts to register 2,249,998 shares issued, or issuable upon exercise of warrants issued, in the Private Placement, on a registration statement on Form S-3 promptly following the date such form is available for use by Ayala, but in no event later than June 15, 2021. On June 6, 2021, Ayala registered 2,249,998 shares, of which 333,333 shares were issued and outstanding and 1,916,665 shares were issuable upon exercise of warrants to purchase shares of Common Stock, on a registration statement on Form S-3 (File No. 333-256793). Ayala has also registered all shares of Common Stock that issued under Ayala's equity compensation plans. Such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Ayala is an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make Ayala's Common Stock less attractive to investors.

Ayala is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of its initial public offering. However, if certain events occur prior to the end of such five-year period, including if Ayala becomes a "large accelerated filer," its annual gross revenues exceed $1.07 billion or it issues more than $1.0 billion of non-convertible debt in any three-year period, Ayala will cease to be an emerging growth company prior to the end of such five-year period. For so long as Ayala remains an emerging growth company, it is permitted and intends to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Ayala Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this proxy statement/prospectus;

- not being required to comply with the auditor attestation requirements in the assessment of Ayala's internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Ayala has taken advantage of reduced reporting burdens in this proxy statement/prospectus. In particular, in this proxy statement/prospectus, Ayala has provided only two years of audited financial statements and has not included all of the executive compensation related information that would be required if Ayala was not an emerging growth company. Ayala cannot predict whether investors will find its Common Stock less attractive because it relies on these exemptions. If some investors find Ayala's Common Stock less attractive as a result, there may be a less active trading market for Ayala's stock and Ayala's stock price may be reduced or become more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. Ayala has elected to take advantage of this extended transition period.

If securities or industry analysts do not publish research or reports about Ayala's business, or if they issue an adverse, inaccurate or misleading opinion regarding Ayala's business, Ayala's stock price and trading volume may be negatively impacted.

The trading market for Ayala's Common Stock will be influenced by the research and reports that industry or securities analysts publish about Ayala or its business. In the event any of the analysts who cover Ayala issue an adverse, inaccurate or misleading opinion regarding Ayala, its business model, its intellectual property or its stock performance, or if Ayala's target operating results fail to meet the expectations of analysts, Ayala's stock price would likely decline. If one or more of these analysts ceases coverage of Ayala or fails to publish reports on Ayala regularly, Ayala could lose visibility in the financial markets, which in turn could cause its stock price or trading volume to decline.

Ayala is a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make its Common Stock less attractive to investors.

Ayala is considered a "smaller reporting company." Ayala is therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. Ayala is also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures in Ayala's SEC filings due to its status as a smaller reporting company mean its auditors do not review its internal control over financial reporting and may make it harder for investors to analyze its results of operations and financial prospects. Ayala cannot predict if investors will find its Common Stock less attractive because it may rely on these exemptions. If some investors find Ayala's Common Stock less attractive as a result, there may be a less active trading market for Ayala's Common Stock and Ayala's stock prices may be more volatile.

Provisions in Ayala's restated certificate of incorporation and restated bylaws and under Delaware law could make an acquisition of Ayala, which may be beneficial to its stockholders, more difficult and may prevent attempts by Ayala's stockholders to replace or remove Ayala's current management.

Provisions in Ayala's restated certificate of incorporation and its restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of Ayala's company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of Ayala's Common Stock, thereby depressing the market price of Ayala's Common Stock. In addition, because Ayala's board of directors is responsible for appointing the members of Ayala's management team, these provisions may frustrate or prevent any attempts by Ayala's stockholders to replace or remove Ayala's current management by making it more difficult for stockholders to replace members of Ayala's board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of Ayala's board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of Ayala's board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on Ayala's board of directors;
- the ability of Ayala's board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of Ayala's board of directors to alter Ayala's bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal Ayala's bylaws or repeal the provisions of Ayala's restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of Ayala's stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of Ayala's stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to Ayala's board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of Ayala.

Moreover, because Ayala is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of its outstanding voting stock from merging or combining with it for a period of three years after the date of the transaction in which the person acquired in excess of 15% of its outstanding voting stock, unless the Merger or combination is approved in a prescribed manner. Furthermore, Ayala's restated certificate of incorporation specifies that, unless Ayala consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against Ayala by stockholders. Any person or entity purchasing or otherwise acquiring any interest in shares of Ayala's capital stock shall be deemed to have notice of and to have consented to the provisions of Ayala's restated certificate of incorporation described above.

Ayala believes this provision benefits it by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against Ayala's directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with Ayala or its directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against Ayala, a court could find the choice of forum provisions contained in Ayala's restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in Ayala's restated certificate of incorporation to be inapplicable or unenforceable in an action, Ayala may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect its business, financial condition or results of operations.

Ayala's restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by Ayala's stockholders, which could limit Ayala's stockholders' ability to obtain a favorable judicial forum for disputes with Ayala.

Ayala's restated certificate of incorporation specifies that, unless Ayala consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against Ayala by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Ayala's restated certificate of incorporation further provides that, unless Ayala consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of Ayala's capital stock shall be deemed to have notice of and to have consented to the provisions of Ayala's restated certificate of incorporation described above.

Ayala believes these provisions benefit it by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against Ayala's directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with Ayala or its directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against Ayala, a court could find the choice of forum provisions contained in Ayala's restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in Ayala's restated certificate of incorporation to be inapplicable or unenforceable in an action, Ayala may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect its business, financial condition or results of operations.

It may be difficult to enforce a U.S. judgment against Ayala, its officers and directors named in this proxy statement/prospectus in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on Ayala's officers and directors.

Not all of Ayala's directors or officers are residents of the United States and most of their and Ayala's assets are located outside the United States. Service of process upon Ayala's non-U.S. resident directors and officers may be difficult to obtain within the United States. Ayala has been informed by its legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against Ayala or its non-U.S. officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Additionally, Israeli courts might not enforce judgments obtained in the United States against Ayala or its non-U.S. directors and executive officers, which may make it difficult to collect on judgments rendered against Ayala or its non-U.S. officers and directors.

Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

Risks Related to Ayala's Operations in Israel

Political, economic and military instability in Israel may impede Ayala's ability to operate and harm its financial results.

Ayala's principal executive offices and research and development facilities are located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region could directly affect Ayala's business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors, Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon). Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect Ayala's operations. Ongoing and revived hostilities or other Israeli political or economic factors, could prevent or delay shipments of Ayala's products, harm Ayala's operations and product development and cause any future sales to decrease. In the event that hostilities disrupt the ongoing operation of Ayala's facilities or the airports and seaports on which Ayala depends to import and export its supplies and products, Ayala's operations may be materially adverse affected. Furthermore, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries, principally those in the Middle East, still restrict business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. These restrictive laws and policies may seriously limit Ayala's ability to sell its products in these countries and may have an adverse impact on Ayala's operating results, financial conditions or the expansion of its business.

In addition, political uprisings and conflicts in various countries in the Middle East are affecting the political stability of those countries. This instability has raised concerns regarding security in the region and the potential for armed conflict. In Syria, a country bordering Israel, a civil war is taking place. In addition, there are concerns that Iran, which has previously threatened to attack Israel, may step up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, as well as a growing presence in Syria. Additionally, the Islamic State of Iraq and Levant, a violent jihadist group whose stated purpose is to take control of the Middle East, remains active in areas within close proximity to Israeli borders. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and Ayala in particular. Any potential future conflict could also include missile strikes against parts of Israel, including Ayala's offices and facilities. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and certain other countries. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm Ayala's results of operations and could make it more difficult for Ayala to raise capital. Parties with whom Ayala does business may be disinclined to travel to Israel during periods of heightened unrest or tension, forcing Ayala to make alternative arrangements, when necessary, in order to meet its business partners face to face. In addition, the political and security situation in Israel may result in parties with whom Ayala has agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Ayala's insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East or for any resulting disruption in its operations. Although the Israeli government has in the past covered the reinstatement value of direct damages that were caused by terrorist attacks or acts of war, Ayala cannot be assured that this government coverage will be maintained or, if maintained, will be sufficient to compensate it fully for damages incurred and the government may cease providing such coverage or the coverage might not suffice to cover potential damages. Any losses or damages incurred by Ayala could have a material adverse effect on its business. Any armed conflicts, political instability, terrorism, cyberattacks or any other hostilities involving or threatening Israel would likely negatively affect business conditions generally and could harm Ayala's results of operations.

Ayala's operations may be disrupted by the obligations of its personnel to perform military service.

Some of Ayala's employees in Israel are obligated to perform up to 36 days, and in some cases longer periods, of military reserve duty annually until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict or emergency situations, could be called to immediate active duty for extended periods of time. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be similar large-scale military reserve duty call-ups in the future. Ayala's operations could be disrupted by the absence due to military service of a significant number of Ayala's employees or of one or more of its key employees for extended periods of time, and such disruption could materially adversely affect its business. Additionally, the absence of a significant number of the employees of Ayala's Israeli suppliers and subcontractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations which may subsequently disrupt Ayala's operations.

Ayala may become subject to claims for remuneration or royalties for assigned service invention rights by its employees, which could result in litigation and adversely affect its business.

Ayala has entered into assignment of invention agreements with its employees pursuant to which such individuals agree to assign to Ayala all rights to any inventions created during their employment or engagement with Ayala. A significant portion of Ayala's intellectual property has been developed by Ayala's employees in the course of their employment with Ayala. Under the Israeli Patent Law, 1967, or the Patent Law, inventions conceived by an employee during the scope of his or her employment with a company and as a result thereof are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no agreement between an employer and an employee with respect to the employee's right to receive compensation for such "service inventions," the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her service inventions and the scope and conditions for such remuneration. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patent Law). Although Ayala's employees have agreed to assign to Ayala service invention rights, as a result of uncertainty under Israeli law with respect to the efficacy of waivers of service invention rights, Ayala may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, Ayala could be required to pay additional remuneration or royalties to its current and/or former employees, or be forced to litigate such claims, which could negatively affect its business.

Ayala's operations may be affected by negative economic conditions or labor unrest in Israel.

General strikes or work stoppages, including at Israeli ports, have occurred periodically or have been threatened in the past by Israeli trade unions due to labor disputes. These general strikes or work stoppages may have an adverse effect on the Israeli economy and on Ayala's business, including Ayala's ability to receive raw materials from its suppliers in a timely manner and could have a material adverse effect on Ayala's results of operations.

General Risks

If Ayala's trademarks and trade names are not adequately protected, then Ayala may not be able to build name recognition in its markets of interest and its business may be adversely affected.

Ayala may also rely on trademarks and trade names to protect its business. If Ayala's trademarks and trade names are not adequately protected, Ayala may not be able to build name recognition in its markets of interest and its business may be adversely affected. Ayala may not be able to protect its rights to these trademarks and trade names, which Ayala needs to build name recognition among potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Ayala's, thereby impeding Ayala's ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Ayala's unregistered trademarks or trade names. Over the long term, if Ayala is unable to successfully register its trademarks and trade names and establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively and its business may be adversely affected. Ayala's efforts to enforce or protect its proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact its financial condition or results of operations.

Ayala will incur increased costs as a result of operating as a public company, and its management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after Ayala is no longer an emerging growth company, Ayala will incur significant legal, accounting and other expenses that it did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Ayala's management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase Ayala's legal and financial compliance costs and will make some activities more time-consuming and costly. For example, Ayala expects that these rules and regulations may make it more difficult and more expensive for it to obtain director and officer liability insurance, which in turn could make it more difficult for it to attract and retain qualified members of its board of directors.

Ayala is evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs it may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, Ayala is required to furnish a report by its management on its internal control over financial reporting. However, while Ayala remains an emerging growth company, Ayala will not be required to include an attestation report on internal control over financial reporting issued by its independent registered public accounting firm. To remain in compliance with Section 404, Ayala needs to document and evaluate its internal control over financial reporting, which is both costly and challenging. In this regard, Ayala will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite Ayala's efforts, there is a risk that in certain periods Ayala will not be able to conclude, within the prescribed time frame or at all, that its internal control over financial reporting is effective as required by Section 404. Additionally, if Ayala identifies one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of its financial statements.

Because Ayala does not anticipate paying any cash dividends on its Common Stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

Ayala has never declared or paid any cash dividends on its Common Stock. Ayala currently anticipates that it will retain future earnings for the development, operation and expansion of its business and does not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of Ayala's Common Stock would be your sole source of gain on an investment in Ayala's Common Stock for the foreseeable future.

Ayala could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for Ayala because biopharmaceutical companies have experienced significant stock price volatility in recent years. If Ayala faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm Ayala's business.

Ayala could be subject to changes in tax laws or their interpretation or additional taxes in or out of the United States, or could otherwise have exposure to additional tax liabilities.

Ayala is subject to tax laws in each jurisdiction where it does business. Changes in tax laws or their interpretation could decrease the amount of revenues Ayala receives, the value of any tax loss carry-forwards and tax credits recorded on its balance sheet and the amount of its cash flow, and adversely affect its business, financial condition or results of operations. In addition, other factors or events, including business combinations and investment transactions, changes in the valuation of Ayala's deferred tax assets and liabilities, adjustments to taxes upon finalization of various tax returns or as a result of deficiencies asserted by taxing authorities, increases in expenses not deductible for tax purposes, changes in available tax credits, changes in transfer pricing methodologies, other changes in the apportionment of Ayala's income and other activities among tax jurisdictions, and changes in tax rates, could also increase Ayala's future effective tax rate.

Ayala's tax filings are subject to review or audit by the IRS and state, local and non-U.S. taxing authorities. Ayala exercises significant judgment in determining its worldwide provision for taxes and, in the ordinary course of its business, there may be transactions and calculations where the proper tax treatment is uncertain. Ayala may also be liable for taxes in connection with businesses it acquires. Ayala's determinations are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in its tax provisions, accruals and returns. An assessment of additional taxes because of an audit could have a material adverse effect on Ayala's business, financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to Ayala, any of which could adversely affect its business operations and financial performance. In particular, the United States government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations and an addition of further limitations on the deductibility of business interest. For example, on August 16, 2022, the Inflation Reduction Act (the "IRA") was signed into law in the U.S. Among other changes, the IRA introduced a corporate minimum tax on certain corporations with average adjusted financial statement income over a three-tax year period in excess of $1 billion and an excise tax on certain stock repurchases by certain covered corporations for taxable years beginning after December 31, 2022. Ayala is currently unable to predict whether such changes will occur and, if so, the ultimate impact on its business. To the extent that such changes have a negative impact on Ayala, its suppliers or its customers, including as a result of related uncertainty, these changes may materially and adversely impact Ayala's business, financial condition, results of operations and cash flows.

THE SPECIAL MEETING OF AYALA STOCKHOLDERS

Date, Time, and Place

The Ayala Special Meeting will be held at on as a virtual meeting via the Internet at www.virtualshareholdermeeting.com/AYLA2023SM.

On or about December 13, 2022 Ayala will commence mailing this proxy statement/prospectus and the enclosed form of proxy card to its stockholders entitled to vote at the Ayala Special Meeting.

Purposes of the Ayala Special Meeting

At the Ayala Special Meeting, Ayala stockholders will be asked to consider and vote upon the following proposals:

- ***Proposal No. 1 – The Ayala Merger Proposal***: the proposal to adopt the Merger Agreement, which is further described in the section titled "*The Merger Agreement*" and a copy of which is attached to this proxy statement/prospectus as Annex A; and

- ***Proposal No. 2 – The Ayala Adjournment Proposal***: the proposal to approve the adjournment of the Ayala Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes to approve the Ayala Merger Proposal.

In accordance with the Amended and Restated Bylaws of Ayala and the DGCL, except as otherwise required by law, business transacted at the Ayala Special Meeting will be limited to those matters set forth in the notice of the meeting.

Recommendation of Ayala's Board of Directors

Ayala's board of directors recommends that the Ayala stockholders vote "**FOR**" the Ayala Merger Proposal and "**FOR**" the Ayala Adjournment Proposal. See "*The Merger—Ayala's Reasons for the Merger; Recommendation of Ayala's Board of Directors*" beginning on page 153 of this proxy statement/prospectus.

Consummation of the Merger is conditioned on approval of the Ayala Merger Proposal. If you abstain, which means that you are affirmatively choosing to decline to vote, or fail to vote on the Ayala Merger Proposal, or if you fail to give voting instructions to your bank, broker, or other nominee, it will have the same effect as a vote "**AGAINST**" the Ayala Merger Proposal. Consummation of the Merger is not conditioned on the approval of the Ayala Adjournment Proposal.

Record Date for the Ayala Special Meeting and Quorum

Record Date

Only holders of record of shares of Ayala's Common Stock at the close of business, Eastern Time, on December 7, 2022, the Record Date for the Ayala Special Meeting, will be entitled to receive notice of, and to vote, at the Ayala Special Meeting or any postponement or adjournment thereof. Each share of Ayala Common Stock entitles the holder thereof to cast one vote on each matter that comes before the Ayala Special Meeting.

As of the Record Date for the Ayala Special Meeting, there were 14,820,727 shares of Ayala's Common Stock outstanding and entitled to vote at the Ayala Special Meeting.

Quorum

In order for business to be conducted at the Ayala Special Meeting, a quorum must be present. A quorum requires the presence in person, by remote communication or represented by proxy of the holders of a majority in voting power of Ayala's Common Stock issued and outstanding and entitled to vote on the Record Date. If a quorum is present when the Ayala Special Meeting is convened, the stockholders present may continue to transact business until adjournment, even if the withdrawal of a number of the stockholders originally present leaves less than a quorum. Abstentions will be counted as present and entitled to vote for purposes of determining a quorum. If you hold your shares of Ayala's Common Stock in a bank, broker or other nominee, your shares of Ayala's Common Stock will be counted toward determining whether a quorum is present only if you instruct your bank, broker, or other nominee on how to vote your shares with respect to one or more of the proposals. If you do not instruct your bank, broker, or other nominee on how to vote your shares, your shares will not be included in the calculation of the number of shares of Ayala's Common Stock represented at the Ayala Special Meeting for purposes of determining whether a quorum is present.

Required Vote, Abstentions and Failure to Vote

Approval of the Ayala Merger Proposal is a condition to the consummation of the Merger. If the Ayala Merger Proposal is not approved, the Merger will not be consummated. The approval of the Ayala Adjournment Proposal is not a condition to the consummation of the Merger.

The following table presents the votes required for, and the effect of abstentions or a failure to vote on, approval of the Ayala Merger Proposal and the Ayala Adjournment Proposal.

Proposal	Votes Required	Effect of Abstentions or Failure to Vote
Ayala Merger Proposal	Affirmative vote of the holders of a majority of the outstanding shares of Ayala's Common Stock entitled to vote.	Abstentions or the failure to vote will have the effect of a vote "**AGAINST**" the Ayala Merger Proposal.
Ayala Adjournment Proposal	The affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively.	Abstentions or the failure to vote will have no effect.

Voting and Support Agreements

Concurrently with the execution of the Merger Agreement, Advaxis entered into a Voting and Support Agreement with each of Israel Biotech Fund I, L.P. ("IBF I") and aMoon 2 Fund Limited Partnership ("aMoon"), pursuant to which each of IBF I and aMoon has agreed, among other things, to vote the shares of Ayala's Common Stock that it beneficially owns as of the Record Date in favor of the Ayala Proposals and against approval of any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger. IBF I and aMoon are the beneficial owners of approximately 22% and 20%, respectively, of the outstanding shares of Ayala's Common Stock as of the Record Date.

Voting by Ayala's Directors and Executive Officers

As of the Record Date, directors and executive officers of Ayala and their affiliates owned and were entitled to vote 3,709,106 shares of Ayala's Common Stock, representing approximately 25% of the shares of Ayala's Common Stock outstanding on the Record Date. Ayala currently expects that Ayala's directors and executive officers will vote any shares of Ayala's Common Stock they hold in favor of the Ayala Merger Proposal and, if necessary, the Ayala Adjournment Proposal, although none of them has entered into any agreement obligating him or her to do so. Approval of the Ayala Merger Proposal requires the affirmative vote of a majority of the outstanding shares of Ayala Common Stock entitled to vote on the proposal. Approval of the Ayala Adjournment Proposal requires the affirmative vote of a majority in voting power of the votes cast affirmatively or negatively at the Ayala Special Meeting.

Voting of Proxies

Stockholders of Record

If you are a stockholder of record of shares of Ayala's Common Stock as of the Record Date, a proxy card is enclosed with this proxy statement/prospectus for your use. Ayala requests that Ayala stockholders of record submit their proxies over the Internet, by telephone or by completing and signing the accompanying proxy card and returning it promptly. Information and applicable deadlines for authorizing a proxy to vote by telephone or through the Internet are set forth on the enclosed proxy card. When the accompanying proxy card is returned properly executed, the shares of Ayala's Common Stock represented by it will be voted at the Ayala Special Meeting or any adjournment or postponement thereof in accordance with the instructions contained on in the proxy card.

If a proxy is signed and returned without an indication as to how the shares of Ayala's Common Stock represented by the proxy are to be voted with regard to a particular proposal, the shares of Ayala's Common Stock represented by the proxy will be voted in favor of each such proposal, as applicable, in accordance with the recommendation of Ayala's board of directors.

Beneficial Owners of Shares Held by a Bank, Broker or Other Nominee

If you hold your shares of Ayala's Common Stock in a brokerage account or if your shares of Ayala's Common Stock are held by a bank or other nominee (that is, in "street name"), you must provide the bank, broker or other nominee that holds your shares with instructions on how to vote your shares of Ayala's Common Stock. Please follow the voting instructions provided by your bank, broker, or other nominee. Please note that you are not permitted to vote shares of Ayala's Common Stock held in "street name" by returning a proxy card directly to Ayala or by voting in person at the Ayala Special Meeting unless you provide a "legal proxy," which you must obtain from your bank, broker, or other nominee. Obtaining a legal proxy may take several days.

If your shares of Ayala's Common Stock are held in "street name," your bank, broker, or other nominee will only vote your shares if you provide instructions on how to vote on the relevant proposal. Brokers do not have discretionary authority to vote on non-routine matters. A "broker non-vote" occurs when a broker submits a proxy that states that the broker votes for at least one proposal, but does not vote for proposals on non-routine matters because the broker has not received instructions from the beneficial owners on how to vote and thus does not have discretionary authority to vote on those proposals. Because all of the matters to be considered at the Ayala Special Meeting are non-routine and brokers will not have discretionary authority to vote on any of the Ayala Proposals, Ayala does not expect to receive any broker non-votes. If your shares of Ayala's Common Stock are held in "street name" and you do not instruct your bank, broker, or other nominee on how to vote your shares, your bank, broker, or other nominee will not be permitted to vote your shares of Ayala's Common Stock on the Ayala Merger Proposal or the Ayala Adjournment Proposal. This failure to instruct your bank, broker, or other nominee will have the same effect as a vote "**AGAINST**" the Ayala Merger Proposal and will have no effect on the vote for the Ayala Adjournment Proposal.

Your vote is important. Accordingly, please submit a proxy by telephone, over the Internet, or by signing and returning the enclosed proxy card, or by submitting instructions on how to vote your shares to your broker, bank or other nominee, as soon as possible, whether or not you plan to attend the Ayala Special Meeting.

Revocability of Proxies and Changes to an Ayala Stockholder's Vote

If you are a holder of shares of Ayala's Common Stock as of the Record Date, you have the power to revoke your proxy at any time before it is voted at the Ayala Special Meeting.

If you are a record holder of shares of Ayala's Common Stock, you can revoke your proxy in one of three ways:

- sending a written notice of revocation that is received by Ayala prior to 11:59 p.m. Eastern Time on the day preceding the Ayala Special Meeting, stating that you are revoking your proxy, to Ayala's Corporate Secretary at Ayala's corporate headquarters, Oppenheimer 4, Rehovot 7670104, Israel;
- submitting a new proxy bearing a later date (by Internet, telephone or mail) that is received by Ayala prior to 11:59 p.m. Eastern Time on the day preceding the Ayala Special Meeting; or
- attending the Ayala Special Meeting and voting online or giving a written notice of revocation to the Secretary of the Ayala prior to the voting at the Ayala Special Meeting (your attendance at the meeting will not, by itself, revoke your proxy; you must vote online at the meeting to change your vote or submit a written notice of revocation to revoke your proxy).

If you wish to change your vote at the Ayala Special Meeting, you must vote online at such meeting or give a written notice of revocation to the Secretary of Ayala prior to the voting at the Ayala Special Meeting.

The latest dated completed proxy will be the one that counts. Written notices of revocation and other communications with respect to the revocation of any proxies should be addressed to:

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104, Israel
Attn: Corporate Secretary

If you are an Ayala stockholder whose shares of Ayala's Common Stock are held in "street name" by a bank, broker, or other nominee, you may revoke your proxy or voting instructions and vote your shares of Ayala's Common Stock online at the Ayala Special Meeting only in accordance with the rules and procedures of your bank, broker, or other nominee. You must follow the directions you receive from your bank, broker, or other nominee in order to change or revoke your proxy or voting instructions and should contact your bank, broker, or other nominee to do so.

Solicitation of Proxies

The Ayala Board is soliciting your proxy to vote your shares at the Ayala Special Meeting. The cost of the solicitation of proxies from Ayala stockholders will be borne by Ayala. In addition to solicitations by mail, Ayala's directors, officers and employees may solicit proxies personally, by telephone, by facsimile or otherwise, without additional compensation. Ayala will also request brokerage firms, nominees, custodians and fiduciaries to forward proxy materials to the beneficial owners of shares of Ayala's Common Stock held of record on the Record Date and will provide customary reimbursement to such firms for the cost of forwarding these materials.

Adjournments

Although it is not currently expected, the Ayala Special Meeting may be adjourned for the purpose of soliciting additional proxies if Ayala has not received sufficient proxies to constitute a quorum or sufficient votes for approval of the Ayala Merger Proposal. If a quorum is not present, the Ayala Special Meeting requires the majority in voting interest of the Ayala stockholders present (in person or by proxy) and entitled to vote at the Ayala Special Meeting to adjourn the meeting, or the chairperson of the Ayala Special Meeting may adjourn the Ayala Special Meeting. If a quorum is not present at the Ayala Special Meeting, each vote cast in favor of the Ayala Adjournment Proposal will also count as a vote cast in favor of adjourning the meeting. Pursuant to the Ayala Bylaws, notice need not be given of any such adjourned meeting if the time and place thereof are announced at the meeting at which adjournment is taken. If the Ayala Special Meeting is adjourned, stockholders who have already sent in their proxies will be allowed to revoke them at any time prior to their use.

Postponements

At any time prior to convening the Ayala Special Meeting, Ayala's board of directors may postpone the Ayala Special Meeting for any reason without the approval of the Ayala stockholders. Although it is not currently expected, Ayala's board of directors may postpone the Ayala Special Meeting for the purpose of soliciting additional proxies if Ayala has not received sufficient proxies to constitute a quorum or sufficient votes for approval of the Ayala Merger Proposal. If the Ayala Special Meeting is postponed for the purpose of soliciting additional proxies, stockholders who have already sent in their proxies will be allowed to revoke them at any time prior to their use.

Attending the Ayala Special Meeting

The Ayala Special Meeting will be conducted completely as a virtual meeting via the Internet. Ayala believes that holding the Ayala Special Meeting completely online will enable greater participation and improved communication. Stockholders may attend the meeting and vote their shares electronically during the meeting via the live webcast by visiting www.virtualshareholdermeeting.com/AYLA2023SM. You will need to have your 16-Digit Control Number included on your Notice or your proxy card (if you received a printed copy of the proxy materials) to join and vote at the Ayala Special Meeting. Stockholders may submit questions in advance of the meeting by visiting www.proxyvote.com. Questions pertinent to matters to be acted upon at the Ayala Special Meeting will be answered during the Ayala Special Meeting, subject to time constraints. In the interests of time and efficiency, Ayala reserves the right to group questions of a similar nature together to facilitate the question and answer portion of the meeting. Ayala may not be able to answer all questions submitted in the allotted time.

Even if your shares of Ayala Common Stock are held in "street name," you are welcome to attend the Ayala Special Meeting. If your shares of Ayala Common Stock are held in "street name," you may not vote your shares of Ayala Common Stock in person at the Ayala Special Meeting unless you obtain a proxy, executed in your favor, from the holder of record (*i.e.*, your bank, broker, or other nominee). If you hold your shares of Ayala Common Stock in "street name" and wish to vote in person, please contact your bank, broker, or other nominee before the Ayala Special Meeting to obtain the necessary proxy from the holder of record.

Ayala will have technicians ready to assist you with any technical difficulties you may have accessing the Ayala Special Meeting virtually. If you encounter any difficulties accessing the virtual meeting during check-in or the meeting, please call the technical support number that will be posted on the virtual meeting platform log-in page.

Stockholder List

A list of Ayala stockholders entitled to vote at the Ayala Special Meeting will be available for inspection at Ayala's principal executive offices, located at Oppenheimer 4, Rehovot 7670104, Israel, at least ten days prior to the date of the Ayala Special Meeting and continuing through the Ayala Special Meeting for any purpose germane to the Ayala Special Meeting. The list will also be available at the Ayala Special Meeting for inspection by any Ayala stockholder present at the Ayala Special Meeting.

Assistance

If you need assistance in completing your proxy card or have questions regarding the Ayala Special Meeting, please contact:

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104, Israel
Attn: Corporate Secretary
+1-857-444-0553
infor@ayalapharma.com

MATTERS BEING SUBMITTED TO A VOTE OF AYALA STOCKHOLDERS

Proposal No. 1: The Ayala Merger Proposal

Ayala stockholders are being asked to adopt the Merger Agreement that Ayala has entered into with Advaxis and Merger Sub. Ayala stockholders should carefully read this proxy statement/prospectus in its entirety, including the information set forth in the sections entitled "*The Merger*" and "*The Merger Agreement*" beginning on pages 140 and 181, respectively, of this proxy statement/prospectus. A copy of the Merger Agreement is attached as Annex A to this proxy statement/prospectus.

Approval of the Ayala Merger Proposal is a condition to the consummation of the Merger. If this Ayala Merger Proposal is not approved, the Merger will not occur. As discussed under "*The Merger—Ayala's Reasons for the Merger; Recommendation of Ayala's Board of Directors*" beginning on page 153 of this proxy statement/prospectus, Ayala's board of directors determined that the Merger and the Merger Agreement were advisable and in the best interests of Ayala and its stockholders, approved the Merger Agreement and recommended that Ayala stockholders adopt the Merger Agreement.

Approval of the Ayala Merger Proposal requires the affirmative vote of the holders of a majority of the outstanding shares of Ayala's Common Stock entitled to vote. For purposes of this vote, an abstention or a failure to vote will have the same effect as a vote "AGAINST" the Ayala Merger Proposal.

Ayala's board of directors recommends that Ayala stockholders vote "FOR" the Ayala Merger Proposal to adopt the Merger Agreement.

Proposal No. 2: The Ayala Adjournment Proposal

Ayala stockholders are being asked to approve the adjournment of the Ayala Special Meeting from time to time, if necessary or appropriate, to solicit additional affirmative votes in favor of the Ayala Merger Proposal if there are insufficient votes at the time of such adjournment to approve the Ayala Merger Proposal. Consummation of the Merger is not conditioned on the approval of this Ayala Adjournment Proposal.

If, at the Ayala Special Meeting, the number of shares of Ayala Common Stock present in person or by proxy and voting in favor of the Ayala Merger Proposal is not sufficient to approve that proposal, Ayala may move to adjourn the Ayala Special Meeting in order to enable Ayala's board of directors to solicit additional proxies for the approval of the Ayala Merger Proposal. In that event, the Ayala stockholders will be asked to vote only upon the Ayala Adjournment Proposal, and not the Ayala Merger Proposal. If the Ayala stockholders approve this Ayala Adjournment Proposal, Ayala could adjourn or postpone the Ayala Special Meeting, and any adjourned or postponed session of the Ayala Special Meeting, and use the additional time to solicit additional proxies for the approval of the Ayala Merger Proposal.

The approval of the Ayala Adjournment Proposal requires the affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively. If you abstain from voting on the Ayala Adjournment Proposal or fail to give voting instructions to your brokerage firm, bank or other nominee, it will have no effect on the Ayala Adjournment Proposal.

The Ayala Adjournment Proposal relates only to the adjournment of the Ayala Special Meeting occurring for purposes of soliciting additional proxies for approval of Ayala Merger Proposal in the event that there are insufficient votes to approve that proposal. Ayala's board of directors may also choose to (i) adjourn the meeting at any time or (ii) postpone the meeting before it is convened without stockholder approval, in each case under the authority provided by the Ayala bylaws and Delaware law. In the case that a quorum is not present at the Ayala Special Meeting, the Ayala bylaws provide that the meeting may be adjourned by a majority of the shares of Ayala Common Stock present and entitled to vote or by the chairperson of the Ayala Special Meeting. If a quorum is not present at the Ayala Special Meeting, each vote cast in favor of the Ayala Adjournment Proposal will also count as a vote cast in favor of adjourning the meeting.

Ayala's board of directors recommends that Ayala stockholders vote "FOR" the Ayala Adjournment Proposal.

THE MERGER

The following is a description of certain material aspects of the Merger. This description may not contain all of the information that may be important to you. The discussion of the Merger in this proxy statement/prospectus is qualified in its entirety by reference to the Merger Agreement, which is attached to this statement/prospectus as Annex A. We encourage you to read carefully this entire proxy statement/prospectus, including the annexes and exhibits to, and the documents incorporated by reference in, this proxy statement/prospectus and the exhibits to the registration statement to which this proxy statement/prospectus relates (the "Registration Statement"), for a more complete understanding of the Merger and the documents incorporated by reference. This section is not intended to provide you with any factual information about Advaxis or Ayala. Such information can be found elsewhere in this proxy statement/prospectus and in the public filings Advaxis and Ayala make with the SEC, as described in "Where You Can Find More Information" beginning on page 344, of this proxy statement/prospectus.

General Description of the Merger

On October 18, 2022, Ayala entered into the Merger Agreement with Advaxis and Merger Sub, pursuant to which Merger Sub will merge with and into Ayala, with Ayala as the surviving corporation and a wholly-owned subsidiary of Advaxis. If the Merger is completed, Merger Sub will merge with and into Ayala, with Ayala being the surviving entity as a wholly-owned subsidiary of Advaxis.

Under the Exchange Ratio, upon the closing of the Merger, on a pro forma basis and based upon the number of shares of Advaxis Common Stock expected to be issued in the Merger, pre-merger Advaxis stockholders will own approximately 37.5% of the combined company and pre-merger Ayala stockholders will own approximately 62.5% of the combined company. Shares of Advaxis Common Stock currently trade on OTCQX under the symbol "ADXS," and shares of Ayala Common Stock currently trade on The Nasdaq Global Market under the symbol "AYLA." In connection with the Merger, the shares of Ayala Common Stock will be de-listed from The Nasdaq Global Market and de-registered under the Exchange Act, as amended.

Each share of Advaxis Common Stock and option to purchase Advaxis Common Stock that is issued and outstanding at the Effective Time will remain issued and outstanding, and such shares will be unaffected by the Merger.

Consideration to be Received by the Ayala Stockholders

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (i) each share of the common stock, par value $0.01 per share, of Ayala Common Stock issued and outstanding immediately prior to the Merger (including restricted stock issued by Ayala under its 2017 Stock Incentive Plan) shall be automatically converted into the right to receive the Exchange Ratio of Advaxis Common Stock; (ii) each outstanding option to purchase shares of Ayala Common Stock (each, an "Ayala Option") will be substituted and converted automatically into an option (each, a "Advaxis Replacement Option") to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the Effective Time, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the Effective Time, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iii) each Ayala RSU outstanding immediately prior to the Effective Time, whether or not vested, will be substituted and converted automatically into an Adjusted RSU equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the Effective Time by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

Background of the Merger

Each of the Ayala Board and the Advaxis board of directors (the "Advaxis Board"), together with members of its management team, regularly reviews and assesses the performance, future growth prospects, business plans and overall strategic direction of Ayala or Advaxis, as applicable, and considers a variety of strategic alternatives that may be available to such company, including continuing to pursue its strategy as a standalone company or pursuing potential strategic or financing transactions with third parties, in each case with the goal of maximizing stockholder value.

On May 11, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Ernst & Young Global ("Ernst & Young") and Latham & Watkins LLP ("Latham"). At the meeting, among other items, members of Ayala's management discussed the company's cash balance and projected cash runway and representatives of Oppenheimer & Co. Inc. ("Oppenheimer") joined the meeting to provide a market update and discuss the potential for an equity financing. The Ayala Board then discussed the potential engagement of (i) Oppenheimer as a financial advisor for a potential equity financing and (ii) Torreya Capital, LLC ("Torreya") for financial and strategic advice. After such discussion, the Ayala Board approved the engagement of Oppenheimer.

During the remainder of May and June, Ayala's management team with the assistance of Oppenheimer met with potential investors to explore a private placement of Ayala's Common Stock (the "First Private Placement"). Due in part to economic conditions and the competitive landscape, Ayala was ultimately unable to consummate the First Private Placement.

On June 27, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Oppenheimer and Latham. At the meeting, among other items, representatives of Oppenheimer discussed the status of the potential equity financing and alternative strategies for a potential equity financing.

On June 28, 2022, David Sidransky, M.D., Chairman of the Ayala Board and Chairman of the Advaxis Board, provided an introduction between Roni Mamluk, Ph.D., Ayala's President and Chief Executive Officer, and Kenneth Berlin, Advaxis' President and Chief Executive Officer.

On June 29, 2022, Mr. Berlin and Dr. Mamluk had an introductory discussion regarding the potential for mutually beneficial opportunities.

On July 8, 2022, Ayala entered into an engagement letter with Torreya for Torreya to act as Ayala's advisor for financial and strategic matters. Ayala's decision to engage Torreya as its financial advisor was based on Torreya's experience and expertise as a financial advisor in a wide variety of transactions, including transactions in the life sciences industry, and its familiarity with Ayala's business. On July 11, 2022, at the direction of the Ayala Board, Torreya launched an outreach process for potential strategic alternatives for Ayala. At Ayala's direction, Torreya focused its efforts on potential strategic partners for an all-stock merger whose main asset was cash and where significant amounts of that cash were not apparently committed to existing in-house pipelines and could be used to complete a transaction and fund the operations of the combined business. It was also important that the strategic partner have an interest and ability to enter into an agreement in the near term and thereafter proceed in a timely manner toward implementing the transaction, as well as a management team and a board of directors with the breadth and skills to accomplish the transaction.

On July 18, 2022, Ayala commenced a public offering of its Common Stock and warrants to purchase its Common Stock with Oppenheimer acting as the sole underwriter (the "Public Offering"). On July 21, 2022, a pricing committee of the Ayala Board comprised of Vered Bisker-Leib, Ph.D., Murray A. Goldberg, and Dr. Sidransky (the "Pricing Committee") met with representatives of Oppenheimer and Latham at which Oppenheimer provided feedback from investors and proposed terms for the Public Offering. On July 24, 2022, the Pricing Committee met with representatives of Oppenheimer and Latham at which Oppenheimer presented revised proposed terms for the Public Offering. After careful consideration, the Pricing Committee determined that the proposed terms for the Public Offering were not in the best interests of Ayala and its stockholders and determined not to proceed with the Public Offering.

Throughout July 2022, Torreya contacted 95 companies that included strategic buyers, publicly listed biotechnology companies that had more cash than required for their existing or failed pipelines ("Cash Shells"), and privately owned companies that were interested in a merger with a public company in order to expand their drug development pipelines and become listed on Nasdaq. Even with Ayala's low share price during this period, interest from strategic buyers and privately owned companies was limited. As a result and given Ayala's diminished cash runway, Ayala and Torreya prioritized Cash Shells that could sustain Ayala's operations through its next milestone event. During July, Ayala entered into non-disclosure agreements with six companies. Each company conducted diligence by holding a call with Ayala's management at which Ayala's business was discussed and reviewing Ayala's publicly available filings with the SEC and other publicly available documents. One was a private company, which terminated discussions after an introductory call with Ayala in order to pursue its own fundraising activities. Four of the companies, after analysis of Ayala and its programs, indicated that they were not interested in a merger transaction, but might be interested in regional licensing transactions that would require several months to complete.

On July 19, 2022, Ayala entered into a mutual non-disclosure agreement with Advaxis, which did not contain a standstill limitation on either company, and Advaxis was given access to an online data room containing due diligence information regarding Ayala and Ayala was given access to an online data room containing due diligence information regarding Advaxis.

Ayala's diligence on Advaxis primarily focused on the uncommitted cash that Advaxis would have upon closing of a merger transaction by the end of 2022 and any off-balance sheet liabilities that Advaxis had. Ernst & Young reviewed an analysis performed by Advaxis on the company's uncommitted cash and confirmed that, of the approximately $23.0 million in cash that Advaxis projected having at the end of 2022, approximately $18.2 million would be available post-merger for investment in the development of Ayala's programs as well as the ongoing operations of the combined company. In addition, Ayala and Advaxis had several diligence discussions on cash forecasts, including the underlying assumptions surrounding the cash burn rate of the combined company.

Advaxis' diligence on Ayala primarily focused on Ayala's strategic fit for a potential business combination transaction with Advaxis, and particularly Ayala's clinical-stage product candidates, AL101 and AL102, including the potential market for each product candidate and the costs required for potential approval by the FDA.

During July and into August, Advaxis and Ayala, through Torreya and Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), financial advisor to Advaxis, discussed a potential merger, including the diligence required, proposed terms, the creation by Ayala of a non-binding term sheet and Advaxis' cash balance and plans for financing a combined company.

On August 2, 2022, Dr. Mamluk and Mr. Berlin met in person to discuss Ayala's programs and personnel.

On August 15, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Torreya, Ernst & Young and Latham. At the meeting, among other items, representatives of Torreya discussed the status of a potential transaction with Advaxis, including a potential timeline for simultaneous discussions with other companies that may be interested in a similar transaction and a potential timeline for the transaction overall. Dr. Sidransky recused himself from discussions regarding a potential transaction with Advaxis and exited the meeting, as he serves as Chairman of the Advaxis Board. Ayala's management also discussed Ayala's projected cash runway. The Ayala Board agreed that Ayala should work towards submitting a non-binding proposal to Advaxis. The Ayala Board also discussed a proposed equity financing from a potential investor.

On August 18, 2022, Ayala submitted a non-binding proposal regarding a potential merger with Advaxis providing for a proposed ownership split between Ayala's stockholders and Advaxis' stockholders of 80% and 20%, respectively, of the combined company (the "August 18 Proposal").

On August 18, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management, representatives of Morgan, Lewis & Bockius LLP ("Morgan Lewis") and Cantor Fitzgerald, and members of the management team of Advaxis Party A, a potential partner for a strategic transaction with Advaxis. At the meeting, among other items, members of Advaxis Party A's management discussed Advaxis Party A, its existing products and product candidates and its current cash position. The Advaxis Board then discussed a potential business combination transaction with Advaxis Party A. The Advaxis Board then raised the August 18 Proposal received from Ayala and agreed to discuss the August 18 Proposal in greater detail at a future board meeting.

On August 22, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala, as he serves as Chairman of the Ayala Board. At the meeting, among other items, the Advaxis Board discussed the status of Advaxis' discussions with various potential strategic transaction partners, including Ayala and specifically the August 18 Proposal received from Ayala. The Advaxis Board discussed Ayala's clinical-stage product candidates, specifically AL101 and AL102, and the near-term potential for each of AL101 and AL102's success in the market. The Advaxis Board then considered, among other things, Ayala's financing needs, the proposed management of a combined company and the proposed ownership split of the combined company. The Advaxis Board then agreed to hold an executive session to discuss the financial aspects of the potential strategic transaction with Advaxis Party A, which the Advaxis Board agreed to hold the following week.

On August 23, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Latham. At the meeting, the Ayala Board considered Dr. Sidranksy's service as Chairman of the Advaxis Board, and determined to establish a special committee (the "Transaction Committee"), consisting of Dr. Bisker-Leib, Dr. Roni Mamluk, and Robert Spiegel, M.D., to review and evaluate potential financing and business combination transactions. The Transaction Committee was empowered, to the extent permitted by applicable law and Ayala's organizational documents, to take any action that the Ayala Board could itself take in connection with a potential financing or business combination transaction, including overseeing, controlling and directing the evaluation and negotiation of potential financing and business combination transactions. The Ayala Board also resolved that the Ayala Board would not approve a potential financing or business combination transaction without a prior favorable recommendation of the Transaction Committee.

On August 23, 2022, Ayala's management and Torreya received a letter from the financial advisors of Ayala Party A, a potential partner for a strategic transaction with Ayala, outlining the process for submitting proposals for a potential business combination transaction with Ayala Party A.

On August 24, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, among other items, representatives of Torreya discussed third parties that had been identified for potential strategic transactions, including Ayala Party A. Torreya informed the Transaction Committee that Ayala Party A was in the midst of a structured strategic review process and was requesting non-binding proposals from interested parties by the close of business that day. The Transaction Committee agreed that Ayala should make a non-binding proposal to Ayala Party A and discussed and agreed upon the terms of such proposal. The Transaction Committee then reviewed the terms for a proposed equity financing that had recently been received from a potential investor.

Later on August 24, 2022, Ayala submitted a non-binding proposal regarding a potential merger with Ayala Party A upon the terms agreed to by the Transaction Committee and providing for a proposed ownership split between Ayala's stockholders and Ayala Party A's stockholders of 30% and 70%, respectively, of the combined company (the "Ayala Party A August 24 Proposal").

On August 24, 2022, the Advaxis Board held a meeting of an executive session, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala and Mr. Berlin recused himself from the executive session portion of the meeting. At the meeting, among other items, the Advaxis Board discussed the different valuations of the potential strategic transactions proposed by prospective transaction partners to date. The Advaxis Board then discussed the potential strategic transaction with Advaxis Party A and the August 18 Proposal. Following such discussion, the Advaxis Board agreed to continue discussions with Advaxis Party A and Ayala, and with respect to the August 18 Proposal, improve Ayala's proposed ownership split between Advaxis' stockholders and Ayala's stockholders of 20% and 80%, respectively, of the combined company. At the conclusion of the meeting, the Advaxis Board agreed to negotiate the August 18 Proposal with Ayala.

On August 25, 2022, Advaxis provided Ayala with a written mark-up to the August 18 Proposal, which provided for a proposed ownership split between Ayala's stockholders and Advaxis' stockholders of 60% and 40%, respectively, of the combined company.

On August 27, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, among other items, representatives of Torreya discussed the forecasts of Ayala that had been prepared by management, and the Ayala Board approved the forecasts through 2023. Ayala's management also discussed the status of a potential equity financing, including a summary of recent discussions with potential investors and the proposed terms for the financing.

On August 28, 2022, Ayala was informed by Ayala Party A and its financial advisor that Ayala Party A would like Ayala to sign a mutual non-disclosure agreement and present its development programs and its proposal to Ayala Party A. The mutual non-disclosure agreement was signed that day between the companies and did not contain a standstill limitation on either company.

On August 29, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, among other items, representatives of Torreya discussed the status of discussions regarding a potential strategic transaction with third parties and terms of a proposed counter-offer to Advaxis regarding a potential strategic transaction. Members of Ayala's management also discussed the terms for a proposed equity financing that had recently been received from a potential investor.

On August 30, 2022, Ayala submitted a revised non-binding proposal regarding a potential merger with Advaxis providing for a proposed ownership split between Ayala's stockholders and Advaxis' stockholders of 67.5% and 32.5%, respectively, of the combined company (the "August 30 Proposal").

On August 30, 2022, representatives from Torreya and Cantor Fitzgerald discussed additional details of the proposed transaction and Torreya confirmed that, while Ayala was committed to exploring the transaction with Advaxis, it was not in a position to enter into exclusivity with Advaxis.

During August 2022, Ayala's management engaged with a potential investor (the "Second Private Placement Investor") regarding the private placement of Ayala's Common Stock (the "Second Private Placement").

On September 1, 2022, Ayala presented its development programs and its proposal to Ayala Party A, and engaged in a question-and-answer session.

Also, on September 1, 2022, Dr. Mamluk and Mr. Berlin discussed the August 30 Proposal. The discussion was focused on Advaxis' uncommitted cash that would be available to be invested in Ayala's programs and the board of director composition of the combined company. Dr. Mamluk also confirmed that the proposed ownership split between Ayala's stockholders and Advaxis' stockholders of 67.5% and 32.5%, respectively, was Ayala's best offer. Following this call, on the same day, Torreya and Cantor Fitzgerald had a follow-up call in which Cantor Fitzgerald requested that Ayala revise the August 30 Proposal to include that the combined company would include two board seats for current members of the Advaxis' Board.

On September 1, 2022, the Advaxis Board held a meeting, together with representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. At the meeting, among other items, the Advaxis Board discussed the status of Advaxis' negotiations with Ayala on the August 30 Proposal. Mr. Berlin explained that he had discussed with Ayala Advaxis' cash position, the board composition of a potential combined company, the proposed equity split and other material terms. With respect to the equity split, Mr. Berlin explained that Ayala had initially proposed, in the August 18 Proposal, an equity split between Ayala's stockholders and Advaxis' stockholders of 80% and 20% respectively. Advaxis management had counter-offered 60% and 40%, and the August 30 Proposal received from Ayala reflected a 67.5% and 32.5% equity split. The Advaxis Board then resolved to continue negotiating the August 18 Proposal with Ayala.

On September 2, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, among other items, representatives of Torreya discussed the status of a potential transaction with third parties and in particular the request for a revised non-binding proposal from Ayala with respect to a potential strategic transaction with Advaxis, which was approved. Members of Ayala's management also discussed a proposed equity financing from a potential investor.

On September 6, 2022, Ayala submitted a non-binding proposal to Advaxis on the same economic terms as the August 30 Proposal, revised to include that the combined company would include two board seats for current members of the Advaxis' Board (the "September 6 Proposal").

On September 8, 2022, Advaxis countersigned the September 6 Proposal. Also, on the same day, the Second Private Placement Investor informed Ayala that, due to the competitive landscape, it would not proceed with the Second Private Placement.

On September 9, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham, where management's long-term forecasts were reviewed and amendments proposed.

On September 12, 2022, Torreya and Ayala attended a call with Ayala Party A and its financial advisors who informed Ayala that it was one of a small handful of companies to be shortlisted to begin mutual confidential due diligence.

On September 14, 2022, a call was held with representatives from Advaxis, Ayala, Latham, Morgan Lewis, Torreya, and Cantor Fitzgerald at which a potential timeline to signing a transaction was discussed, including diligence requirements, transactional documentation and internal process matters, with the aim of having both companies work together efficiently towards a transaction.

On September 15, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. The Transaction Committee was updated on discussions with Advaxis and Ayala Party A, as well as other potential third parties.

On September 18, 2022, after the Ayala Board reviewed management's long-term forecasts, such forecasts were approved to be shared with Advaxis and Ayala Party A. On the same day, the forecasts were shared with Ayala Party A and Advaxis.

On September 19, 2022, a call was held with representatives from Advaxis, Ayala, Latham, Morgan Lewis, Torreya and Cantor Fitzgerald to discuss ongoing diligence requirements for both sides as well as an update on transactional documentation and internal process matters.

On September 20, 2022, representatives of Cantor Fitzgerald provided representatives of Latham access to Advaxis' virtual data room to conduct diligence.

Also, on September 20, 2022, Torreya and Ayala Party A's financial advisors had a call to provide updates on the discussions between Ayala and Ayala Party A and to confirm interest from both sides in progressing the discussions.

On September 22, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. At the meeting, among other items, the Advaxis Board discussed the status of Advaxis' discussions with various potential strategic transaction partners to date. The Advaxis Board then discussed the Phase 2/3 clinical trial interim results of Ayala's clinical-stage product candidate AL102. The Advaxis Board unanimously agreed to continue negotiating a potential transaction with Ayala. Mr. Berlin then continued the meeting with a presentation regarding a strategic transaction proposal received from Advaxis Party B, a potential partner for a strategic transaction with Advaxis. The Advaxis Board discussed Advaxis Party B's product candidates, and the strength of Advaxis Party B's investors and track record of successfully bringing clinical product candidates to market. The Advaxis Board then discussed a potential strategic transaction, pursuant to which the ownership split of the combined company by Advaxis Party B's stockholders and Advaxis' stockholders would be 70% and 30% respectively. The Advaxis Board then unanimously agreed to explore Advaxis Party B's proposal in parallel with a potential strategic transaction with Ayala.

On September 22, 2022, a call was held with representatives from Advaxis, Ayala, Latham, Morgan Lewis, Torreya and Cantor Fitzgerald to discuss ongoing diligence requirements for both sides as well as an update on transactional documentation and internal process matters on both sides.

On September 23, 2022, Dr. Mamluk and the Chief Executive Officer of Ayala Party A spoke to discuss a timeline to a transaction, combined company operations, board of director composition (including that the board of directors of the combined company should include a proportionate number of directors from each company based on the ownership percentage of the combined company held by each company's stockholders following the transaction) and future financing.

On September 29, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, representatives of Torreya discussed the status of potential transactions with Ayala Party A and Advaxis, including the Ayala Party A auction process. Representatives of Latham reported on the current status of the key terms of the definitive documentation for a transaction with Advaxis, including a summary of open items and a proposed timeline for the transaction.

On September 29, 2022, Mr. Berlin met in person with representatives of Advaxis Party B to discuss Advaxis Party B's proposal for a strategic transaction between Advaxis and Advaxis Party B.

On September 30, 2022, Latham circulated the initial draft of the Merger Agreement to Morgan Lewis. The Merger Agreement contemplated a "one-step" merger structure in which Ayala's and Advaxis' stockholders would vote on the proposed merger. The Merger Agreement also contemplated that certain of Ayala's stockholders would sign binding agreements to support the transaction (collectively, the "Voting Agreements").

Also, on September 30, 2022, representatives of Torreya discussed the Ayala Party A August 24 Proposal with Ayala Party A's financial advisor, who had received feedback that day from Ayala Party A that Ayala Party A was only interested in merging with Ayala if Ayala simultaneously raised around $50 million.

After consultation between Torreya and Ayala about the status of negotiations, including Ayala Party A's requirement of third-party financing to complete a transaction and that Ayala Party A would not be ready to complete a transaction in a timely manner, at the direction the Transaction Committee, on October 3, 2022, Ayala withdrew from Ayala Party A's process.

On the afternoon of October 4, 2022, representatives of Latham and Morgan Lewis discussed the Merger Agreement, including, among other things, the purchase price adjustment related to Advaxis' net amount of cash held at closing, the inclusion of a "fiduciary-out" clause in favor of Advaxis in the event that Advaxis received a Parent Superior Proposal (as defined in the Merger Agreement), the removal of the closing condition related to the listing of the shares of Advaxis Common Stock to be issued in connection with the Merger on Nasdaq, and the addition of certain events which would make a termination fee payable by each party.

On October 6, 2022, Cantor Fitzgerald informed Torreya that Advaxis believed that it would receive approximately $4.0 million more than it had previously believed from the sale of net operating losses in New Jersey and that Advaxis and Ayala should discuss how this additional cash would impact the proposed ownership split between Ayala's stockholders and Advaxis' stockholders in the combined company.

On October 6, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. At the meeting, among other items, the Advaxis Board discussed a more specific proposal involving a licensing arrangement received from Advaxis Party B on October 5, 2022 (the "Advaxis Party B Proposal"). The Advaxis Board determined that it would require additional information in order to evaluate the Advaxis Party B Proposal, and agreed that Mr. Berlin would request additional detail regarding the Advaxis Party B Proposal from Advaxis Party B. Representatives of Morgan Lewis then summarized the status of negotiations with Ayala, including the status of the Merger Agreement and other documents related to the potential strategic transaction with Ayala. Mr. Berlin then informed the Advaxis Board of an additional $4.0 million in additional cash due to Advaxis from the sale of the New Jersey net operating losses, and that such additional cash should improve Ayala's proposed ownership split between Advaxis' stockholders and Ayala's stockholders. The Advaxis Board then agreed to continue negotiations with Ayala.

On the evening of October 7, 2022, Morgan Lewis circulated a revised draft of the Merger Agreement to Latham, which reflected the discussion from October 4, 2022.

On the morning of October 10, 2022, Latham circulated an initial draft of the form Voting Agreement to Morgan Lewis.

Also, on the morning of October 10, 2022, Yossi Maimon, Ayala's Chief Financial Officer, Igor Gitelman, Advaxis' Interim Chief Financial Officer, and representatives from Torreya and Cantor Fitzgerald discussed the sale of the New Jersey net operating losses, timeline to receiving the additional money, as well as the process to achieve it. On the same call, Mr. Gitelman discussed the near-term cash forecasts of the combined company and how to optimize the cash runway for the combined company.

On the afternoon of October 10, 2022, Advaxis Party C, a potential partner for a strategic transaction with Advaxis, contacted Mr. Berlin regarding a potential strategic transaction with Advaxis. Mr. Berlin advised Advaxis Party C to prepare a written proposal for such potential strategic transaction.

On the morning of October 11, 2022, Latham circulated a revised draft of the Merger Agreement to Morgan Lewis, which, among other changes, provided for a closing condition in favor of Ayala which required Advaxis to deliver a certificate certifying that Advaxis had at least a certain amount of cash available at the closing of the Merger ("Minimum Cash Condition").

On the afternoon of October 11, 2022, the Compensation Committee of the Ayala Board held a meeting, together with representatives from Latham. At the meeting, among other items, the Compensation Committee discussed the employment agreements with Dr. Mamluk, Mr. Maimon and Gary Gordon, M.D., Ph.D., the Company's Chief Medical Officer, and the cash severance payments and acceleration of vesting for unvested incentive awards that each are entitled to upon a change in control of the Company, subject to certain requirements.

On the afternoon of October 12, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. At the meeting, among other items, representatives of Torreya discussed the status of a potential transaction with Advaxis, and representatives of Latham reviewed the status of the definitive documentation for such transaction, including a summary of open items and a proposed timeline for the transaction. Representatives of Torreya reviewed an analysis of the fairness of the proposed transaction to the stockholders of Ayala.

On October 13, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. At the meeting, among other items, the Advaxis Board discussed its ongoing financial due diligence of Ayala. The Advaxis Board then discussed Advaxis stockholder approval to be obtained in connection with a potential strategic transaction with Ayala, including approval by Advaxis' stockholders of an amendment to the certificate of incorporation of Advaxis and Advaxis' stock plans, as applicable, to (i) effect a change of the name of Advaxis to "Ayala Pharmaceuticals, Inc.", (ii) increase the number of shares reserved and available for issuance under the Advaxis, Inc. 2015 Incentive Plan (the "Advaxis Incentive Plan"), the maximum number of shares that may be issued upon exercise of options under the Advaxis Incentive Plan and/or the number of awards that are subject to the limits set forth in Section 5.4 of the Advaxis Incentive Plan and (iii) implement a reverse stock split. Representatives of Morgan Lewis reviewed the status of the Merger Agreement and other definitive documentation in respect of a potential strategic transaction with the Advaxis Board.

On the morning of October 13, 2022, representatives of Latham and Morgan Lewis discussed the applicability of "blue sky" laws to the Merger and the related filings and consents. On the afternoon of October 13, 2022, representatives of Latham and Morgan Lewis discussed the Merger Agreement, including the Minimum Cash Condition, termination fee, and application of "blue sky" laws to the Merger.

On the evening of October 13, 2022, Morgan Lewis circulated a revised draft of the Merger Agreement to Latham, which, among other changes, removed the Minimum Cash Condition and reduced the termination fee from $1.0 million to $600,000.

On October 13, 2022, Advaxis received an indication of interest from Advaxis Party C, which presented two alternative potential strategic transactions with Advaxis (the "Advaxis Party C Proposal"). James Patton, Vice Chairman of the board of the directors of Advaxis, Mr. Berlin, and representatives from Advaxis Party C then had a call on the evening of October 14, 2022 to discuss the Advaxis Party C Proposal.

On the afternoon of October 14, 2022, representatives of Latham and Morgan Lewis discussed the Merger Agreement and the requirement that Advaxis' stockholders vote to approve the Merger Agreement.

Also, on the afternoon of October 14, 2022, representatives of Torreya and Cantor Fitzgerald spoke to discuss adjustment of the proposed ownership split given the additional cash from the sale of the New Jersey net operating losses. After consultation with the Transaction Committee members, on the same day, representatives of Torreya spoke with representatives of Cantor Fitzgerald and proposed that the ownership split between Ayala's stockholders and Advaxis' stockholders should be amended to 65% and 35%, respectively. After discussion with Mr. Berlin, on the same day, representatives of Cantor Fitzgerald informed the representatives of Torreya that this split was not sufficient and that Dr. Mamluk and Mr. Berlin should directly negotiate further.

On the afternoon of October 14, 2022, Morgan Lewis circulated a revised draft of the Voting Agreement to Latham.

On the evening of October 14, 2022, Dr. Mamluk and Mr. Berlin had a call. Mr. Berlin reiterated Advaxis' firm position that the proposed ownership split between Ayala's stockholders and Advaxis' stockholders should be amended to 62.5% and 37.5%, respectively.

On October 15, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. Mr. Berlin began the meeting by summarizing the Party C Proposal. Roni Appel and other members of the Advaxis Board expressed that the Party C Proposal undervalued Advaxis, and Mr. Berlin noted that during his call with representatives of Party C on October 13, 2022, he did not receive satisfactory answers to questions regarding Advaxis Party C's funding, product development and other matters. Representatives from Morgan Lewis then explained the Advaxis Board's rights and restrictions in responding to the Party C Proposal. After further discussion, the Advaxis Board agreed to continue to progress a potential strategic transaction with Ayala.

On October 15, 2022, the Transaction Committee held a meeting, together with members of Ayala's management and Latham. At the meeting, Ayala's management informed the Transaction Committee that Advaxis had indicated it would only proceed with a transaction with Ayala if the ownership split between Ayala's stockholders and Advaxis' stockholders was at least 37.5% to Advaxis shareholders, based in part upon the additional $4.0 million in cash anticipated to be due to Advaxis from the sale of the New Jersey net operating losses and updated estimates of Ayala's available cash after giving effect to the transaction. The Transaction Committee discussed the results of due diligence with respect to Advaxis, including the additional $4.0 million in additional cash due to Advaxis from the sale of the New Jersey net operating losses, as well as the updated estimates with respect to Ayala's available cash after giving effect to the transaction. Ayala's management then reviewed Torreya's preliminary financial analyses of Ayala and the transaction with the Transaction Committee. Following further discussion, the Transaction Committee agreed to proceed based upon the revised ownership split between Ayala's stockholders and Advaxis' stockholders of 62.5% and 37.5%, respectively.

Upon the confirmation of Ayala's and Advaxis' capital structure, Torreya and Cantor Fitzgerald used the calculation mechanics as provided in the Merger Agreement, the agreed ownership split between Ayala's stockholders and Advaxis' stockholders of 62.5% and 37.5%, respectively, and the closing Share Price on October 14, 2022, to obtain the Exchange Ratio of 0.1874, whereby each share of Ayala Common Stock would be exchanged for 0.1874 shares of Advaxis Common Stock.

On the evening of October 15, 2022, Morgan Lewis confirmed to Latham that Advaxis had agreed to remove provisions requiring that Advaxis' stockholders vote to approve the Merger Agreement, but that Advaxis should be permitted to hold a stockholder meeting in order to approve the amendment to the certificate of incorporation of Advaxis and Advaxis' stock plans, as applicable, to (i) effect a change of the name of Advaxis to "Ayala Pharmaceuticals, Inc.", (ii) increase the number of shares reserved and available for issuance under the Advaxis Incentive Plan, the maximum number of shares that may be issued upon exercise of options under the Advaxis Incentive Plan and/or the number of awards that are subject to the limits set forth in Section 5.4 of the Advaxis Incentive Plan and (iii) implement a reverse stock split. Advaxis stockholder approval of the reverse stock split is intended to assist the combined company with a potential Nasdaq "uplist" application process after the closing.

On the morning of October 16, 2022, Latham circulated a revised draft of the Merger Agreement to Morgan Lewis, which, among other changes, added a closing condition which requires all necessary state securities or "blue sky" filings or notices to have been made and any authorizations to have been received for the issuance of the shares of Advaxis Common Stock in the Merger, and removed provisions requiring that Advaxis' stockholders vote to approve the Merger Agreement.

On the morning of October 16, 2022, Latham circulated the revised versions of the Merger Agreement, Voting Agreements and other ancillary agreements to the Ayala Board via email. Also, on the morning of October 16, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. Dr. Sidransky recused himself from and exited the meeting. At the meeting, representatives of Latham reported on the resolution of certain key terms of the transaction and the remaining open issues in the definitive documentation. Representatives of Torreya then reviewed with the Ayala Board their financial analyses of the transaction and delivered to the Ayala Board an oral opinion, which was confirmed by delivery of the written Torreya Opinion dated October 16, 2022, to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written Torreya Opinion, the Exchange Ratio was fair, from a financial point of view, to the holders of Ayala Common Stock. For a detailed discussion of the Torreya Opinion, please see "*—Opinion of Ayala's Financial Advisor—Torreya Capital, LLC*" beginning on page 162 of this proxy statement/prospectus.

On October 16, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from discussions regarding a potential transaction with Ayala. At the meeting, among other items, the Advaxis Board discussed the status of the potential strategic transaction with Ayala. The Board then discussed its expectation that certain Ayala stockholders would deliver Voting Agreements obligating them to vote in favor of the transaction. Representatives from Morgan Lewis noted that Ayala intended to only request that Israel Biotech Fund I, L.P. enter into a Voting Agreement. The Advaxis Board agreed to request that Ayala arrange for aMoon to enter into a voting agreement as well.

Between the morning of October 16, 2022 and the afternoon of October 18, 2022, Ayala and Advaxis, through Latham and Morgan Lewis, continued to engage in ongoing negotiations of various definitive transaction documents, including the Merger Agreement, Voting Agreements and other ancillary agreements.

On the afternoon of October 17, 2022, Latham circulated a draft of the aMoon Voting Agreement.

On the afternoon of October 18, 2022, Latham circulated final versions of the Merger Agreement, Voting Agreements and other ancillary agreements to the Ayala Board via email. Also, on the afternoon of October 18, 2022, the Ayala Board held a meeting, together with members of Ayala's management and representatives of Torreya and Latham. Dr. Sidransky recused himself from and exited the meeting. Representatives of Torreya and Latham reviewed the proposed final terms of the Merger Agreement, focusing on the changes to the Merger Agreement since the Ayala Board meeting on October 16, 2022. In addition, the Ayala Board reviewed Ayala's liquidity and cash requirements necessary to meet its obligations, including costs to wind down operations in the event the Merger does not occur, and the projected negative liquidation value for Ayala in the event of such wind down. During the various discussions, the Ayala Board asked questions and discussed the terms and features of the proposed Merger, including the equity split between the parties in the combined company after closing, the capital structure of the parties, the required stockholder vote, the closing conditions, termination rights, and likely timing of closing the Merger, as well as Ayala's cash forecast and ability to satisfy its obligations prior to the projected closing date. Representatives of Torreya then confirmed to the Ayala Board that there was no change to the Torreya Opinion it had delivered on October 16, 2022, regarding the fairness of the Exchange Ratio. After further discussion, taking into account (i) Ayala's financial condition and prospects, including Ayala's limited cash runway and the fact that Ayala's management believes that Ayala's cash and cash equivalents will not be sufficient to meet its obligations within the next twelve months, (ii) Ayala's inability to raise additional capital on reasonable terms, (iii) Torreya's previous outreach efforts on behalf of Ayala, (iv) IBF I and aMoon's substantial stockholder positions in Ayala and strong support for a combination with Advaxis, including IBF I and aMoon's willingness to enter into the Voting Agreements, (v) Advaxis' strategic fit with Ayala, including its access to cash on its balance sheet and expertise in drug development, (vi) the potential for Ayala's stockholders to benefit from the future growth of the combined company, (vii) the certainty of obtaining stockholder approval and closing and (viii) the proposed terms of the Merger Agreement, the Ayala Board unanimously determined that the Merger Agreement, the Merger and the other Transactions were advisable and in the best interests of Ayala and its stockholders, approved and declared advisable the Merger Agreement and the Merger, and recommended that Ayala's stockholders vote to approve the Merger Agreement.

In addition to the foregoing, at the meeting, the Ayala Board reviewed and discussed Letter Agreements to be entered into with Dr. Mamluk, Mr. Maimon and Dr. Gordon. Under the terms of the Letter Agreements with Dr. Mamluk and Mr. Maimon, each agreed, among other things, that his or her employment would terminate immediately following the closing of the Merger and that each would be entitled to certain cash severance payments and the acceleration of all unvested equity awards. The Letter Agreement with Dr. Gordon provided for certain severance benefits upon his termination without cause or his resignation for justified reason within 12 months following the closing of the Merger. For a detailed discussion of the Letter Agreements, please see "*—Interests of Ayala Directors and Executive Officers in the Merger—Executive Officer Employment Agreements*" beginning on page 172 of this proxy statement/prospectus. Following discussion, the Ayala Board unanimously approved the Letter Agreements.

On the afternoon of October 18, 2022, Morgan Lewis circulated final versions of the Merger Agreement, Voting Agreements and other ancillary agreements to the Advaxis Board via email. Also, on the afternoon of October 18, 2022, the Advaxis Board held a meeting, together with members of Advaxis' management and representatives of Morgan Lewis and Cantor Fitzgerald. Dr. Sidransky recused himself from the meeting. Mr. Berlin began the meeting by summarizing the status of Advaxis' negotiations with Ayala with respect to the Merger and noted for the Advaxis Board that the Merger Agreement and the other definitive transaction documents in respect of the merger were in final form, subject to the approval of the Advaxis Board and the Ayala Board. Mr. Berlin then explained that the matters to be voted on included the adoption of the Merger Agreement and all other agreements, instruments, certificates and documents required to be delivered in connection therewith, in each case substantially in the form presented to the Advaxis Board, and the consummation of the Merger and the other Transactions. Representatives from Morgan Lewis then explained to the Advaxis Board its fiduciary duties in relation to the matters to be voted on and the Advaxis Board's approval thereof. Representatives of Cantor Fitzgerald then gave a presentation to the Advaxis Board regarding the background of the potential merger transaction of Ayala, financial forecasts of each of Advaxis and Ayala, and certain key terms of the Merger Agreement, including the Exchange Ratio, the post-closing governance of the combined company, termination fees payable by each of Advaxis and Ayala under certain circumstances, and conditions to the closing of the potential merger transaction with Ayala. Representatives of Cantor Fitzgerald then confirmed on behalf of Cantor Fitzgerald that the Exchange Ratio as set forth in the Merger Agreement was fair, from a financial point of view, to the Advaxis. During the various discussions, questions from members of the Advaxis Board were asked and answered. The Advaxis Board then concluded that, taking into account, among other things, (i) the financial condition of each of Advaxis and Ayala, (ii) Ayala's strategic fit with the Advaxis business, (iii) Ayala's clinical product candidates and the promise of such product candidates in the market, (iv) Advaxis' continued evaluation of strategic alternatives dating back to its prospective strategic transaction with Biosight Ltd. in 2021, (v) the likelihood of obtaining approval from Ayala's stockholders in favor of the Merger and (vi) the proposed terms of the Merger Agreement and other definitive transaction documents, the Advaxis Board unanimously authorized, approved, adopted and ratified the Merger Agreement and the other transaction documents, and the consummation of the Merger and the other Transactions.

On the afternoon of October 18, 2022, Ayala and Advaxis executed the Merger Agreement and Advaxis, aMoon and IBF I subsequently executed the Voting Agreements. Before the opening of Nasdaq trading on October 19, 2022, both parties issued a joint press release announcing Ayala's and Advaxis' entry into the Merger Agreement.

Advaxis Reasons for the Merger

At a meeting held on October 18, 2022, among other things, the Advaxis Board unanimously (i) determined that the Merger Agreement, the Merger and other Transactions were advisable, fair to and in the best interests of Advaxis and its stockholders, and (ii) approved, adopted and declared advisable the Merger Agreement.

During the course of its evaluation of the Merger Agreement and the other Transactions, the Advaxis Board held numerous meetings, consulted with Advaxis' senior management, legal counsel and financial advisor, and reviewed and assessed a significant amount of information. In reaching its decision to approve the Merger Agreement and the other Transactions, the Advaxis Board of directors considered a number of factors that it viewed as supporting its decision to approve the Merger Agreement, including:

- the financial condition and prospects of Advaxis and the risks associated with continuing to operate Advaxis on a stand-alone basis;
- the Advaxis Board's consideration of the financial analyses of Cantor Fitzgerald, including its opinion to the Advaxis Board, to the effect that, as of such date and based on and subject to various assumptions, matters considered and limitations, conditions and qualifications described in its opinion, the Exchange Ratio was fair, from a financial point of view, to Advaxis, as more fully described below under the caption "*The Merger—Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald*";
- the Advaxis Board's belief, after a thorough review of strategic alternatives and discussions with Advaxis' senior management, financial advisor and legal counsel, that the Merger is more favorable to Advaxis stockholders than the potential value that might have resulted from other strategic alternatives available to Advaxis;
- the Advaxis Board's belief that, as a result of arm's length negotiations with Ayala, Advaxis and its representatives negotiated the lowest Exchange Ratio to which Ayala was willing to agree, and that the other terms of the Merger Agreement include the most favorable terms to Advaxis in the aggregate to which Ayala was willing to agree;
- the Advaxis Board's view, based on the scientific, regulatory and technical due diligence conducted by Advaxis management, of the regulatory pathway for, and market opportunity of, Ayala's product candidates;
- the Advaxis Board's consideration of the expected cash resources of the combined company as of the closing of the Merger, with at least $20 million of cash and cash equivalents on a pro forma basis after giving effect to the Merger;
- the Advaxis Board's view, following a review with Advaxis' management of Ayala's current development and clinical trial plans, of the likelihood that the combined company would possess sufficient cash resources at the closing of the Merger to fund development of the product candidates of the combined company through upcoming value inflection points;
- the prospects of and risks associated with the other strategic candidates that had made proposals for a strategic transaction with Advaxis based on the scientific, technical and other due diligence conducted by Advaxis management;
- the ability of Advaxis stockholders to participate in the growth and value creation of the combined company following the closing of the Merger by virtue of their continued ownership of Advaxis Common Stock;
- the Advaxis Board's view that the combined company will be led by a board of directors with representation from each of the current boards of directors of Advaxis and Ayala; and
- the current financial market conditions and historical market prices, volatility and trading information with respect to Advaxis' Common Stock.

The Advaxis Board's also reviewed the terms of the Merger Agreement and related transaction documents, including those described below, and concluded that the terms of the Merger Agreement and related transaction documents, in the aggregate, were reasonable under the circumstances:

- the calculation of the Exchange Ratio and the estimated number of shares of Advaxis Common Stock to be issued in the Merger;
- the number and nature of the conditions to Ayala's and Advaxis' respective obligations to complete the Merger and the likelihood that the Merger will be completed on a timely basis, as more fully described below under the caption "The Merger Agreement —Conditions to the Completion of the Merger," beginning on page 185 in this proxy statement/prospectus;

- the respective rights of, and limitations on, Advaxis and Ayala under the Merger Agreement to consider and engage in discussions regarding unsolicited Acquisition Proposals under certain circumstances, and the limitations on the board of directors of each party to change its recommendation in favor of the Merger, as more fully described below under the caption "The Merger Agreement —No Solicitation," beginning on page 188 in this proxy statement/prospectus;

- the right of each party to terminate the Merger Agreement to accept an unsolicited Acquisition Proposal in certain circumstances, subject to payment of a termination fee, as more fully described below under the caption "The Merger Agreement —Termination Fee," beginning on page 200 in this proxy statement/prospectus;

- the conclusion of the Advaxis Board that the potential termination fee of $600,000, payable by Advaxis or Ayala, respectively, to the other party, and the circumstances when such fees may be payable, were reasonable, as more fully described below under the caption "The Merger Agreement —Termination Fee," beginning on page 200 in this proxy statement/prospectus; and

- the support agreements, pursuant to which certain stockholders of Ayala have agreed, solely in their capacities as stockholders, to vote all of their shares of Ayala Common Stock in favor of the proposals submitted to them in connection with the Merger and against any alternative Acquisition Proposals, as more fully described below under the caption "Agreements Related to the Merger —Support Agreements," beginning on page 201 in this proxy statement/prospectus.

In the course of its deliberations, the Advaxis Board also considered a variety of risks and other countervailing factors related to entering into the Merger, including:

- the potential effect of the $600,000 termination fee payable by Advaxis upon the occurrence of certain events in deterring other potential acquirors from proposing an alternative Acquisition Proposal that may be more advantageous to Advaxis stockholders;

- the prohibition on Advaxis to solicit alternative Acquisition Proposals during the pendency of the Merger;

- the substantial expenses to be incurred by Advaxis in connection with the Merger;

- the possible volatility of the trading price of the Advaxis Common Stock resulting from the announcement, pendency or completion of the Merger;

- the risk that the Merger might not be consummated in a timely manner or at all;

- the fact that the representations and warranties in the Merger Agreement do not survive the closing of the Merger and the potential risk of liabilities that may arise post-closing;

- the scientific, technical, regulatory and other risks and uncertainties associated with development and commercialization of Ayala's product candidates;

- the risk that the combined company may not have available sources of financing necessary to fund development of the combined company's product candidates through upcoming value inflection points;

- the lack of availability of appraisal rights under the DGCL to holders of Advaxis Common Stock which would not allow holders to seek appraisal of the fair value of their shares of Advaxis Common Stock; and

- the various other risks associated with the combined company and the transaction, including those described in the sections entitled "*Risk Factors*" and "*Cautionary Statement Concerning Forward-Looking Statements*" in this proxy statement/prospectus.

The foregoing information and factors considered by the Advaxis Board are not intended to be exhaustive but are believed to include all of the material factors considered by the Advaxis Board. In view of the wide variety of factors considered in connection with its evaluation of the Merger and the complexity of these matters, the Advaxis Board did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the Advaxis Board may have given different weight to different factors. The Advaxis Board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, the Advaxis management team and the legal and financial advisors of Advaxis, and considered the factors overall to be favorable to, and to support, its determination.

Ayala's Reasons for the Merger; Recommendation of the Ayala Board

After consideration the Ayala Board, by a unanimous vote of all directors at its meeting on October 18, 2022, approved and declared advisable the Merger Agreement and the Merger, and recommended that Ayala stockholders vote to approve the Merger Agreement.

FOR THE REASONS SET FORTH BELOW, THE AYALA BOARD UNANIMOUSLY DECLARED THAT THE MERGER AGREEMENT AND THE MERGER ARE ADVISABLE AND IN THE BEST INTERESTS OF AYALA AND ITS STOCKHOLDERS AND UNANIMOUSLY APPROVED THE MERGER AGREEMENT, THE MERGER AND THE OTHER TRANSACTIONS. THE AYALA BOARD UNANIMOUSLY RECOMMENDS TO AYALA'S STOCKHOLDERS THAT THEY VOTE "FOR" THE PROPOSAL TO APPROVE THE MERGER AGREEMENT.

In the course of evaluating the Merger Agreement and the other Transactions, the Ayala Board held numerous meetings and consulted with Ayala management and Ayala's legal and financial advisors and considered a number of factors in reaching its decision to approve the Merger Agreement, the Merger and the other Transactions, which included the following (not in order of relative importance):

- *Consideration of Alternatives*. The Ayala Board pursued several strategic and financing transactions for Ayala in 2022 and considered alternatives to the Merger and determined that entering into the Merger Agreement was more favorable to Ayala stockholders than other alternatives available to Ayala, including:
    - continued operation of Ayala on a standalone basis, and the Ayala Board's determination that Ayala could not continue to operate as an independent company given its business and financial prospects;
    - the process undertaken in connection with the pursuit of potential alternative financing transactions including with potential investors to explore a private placement of Ayala's Common Stock and a public offering of Ayala's securities; and
    - the process undertaken in connection with the pursuit of potential alternative strategic partners and the certainty of obtaining stockholder approval and closing relative to other potential strategic alternatives for Ayala.

- *Challenges that Ayala Would Face on a Standalone Basis.* The challenges facing Ayala if it were to continue on a standalone basis, including Ayala's financial condition and prospects, including Ayala's limited cash runway and the fact that Ayala's management believed that Ayala's cash and cash equivalents would not be sufficient to meet its obligations past the middle of the first quarter of 2023 (in contrast to Ayala's pro forma cash runway through the fourth quarter of 2023 upon completion of the Merger), and Ayala's inability to raise additional capital on reasonable terms;

- *Advaxis Net Cash.* The expected cash resources of the combined company as of the closing of the Merger, resulting from a minimum of approximately $20 million of net cash expected to be held by Advaxis upon completion of the Merger that would be available to be invested in the combined company's programs;

- *Participation in Potential Appreciation*. After giving effect to the Merger, Ayala stockholders will own approximately 62.5% of the combined company's outstanding common stock, and as a result, Ayala stockholders would participate in the future growth of the combined company after the consummation of the Merger;

- *Voting Agreements*. The Voting Agreements, pursuant to which IBF I., which owned approximately 22.24% of the outstanding shares of Ayala Common Stock as of the date of the Merger Agreement, and aMoon, which owned approximately 20.3% of the outstanding shares of Ayala Common Stock as of the date of the Merger Agreement, agreed to support the transaction and vote in favor of the adoption of the Merger Agreement, demonstrating strong support for a combination with Advaxis;

- *Financial Analyses of Torreya; Receipt of Fairness Opinion*. The financial analyses of Torreya and its oral opinion (which was subsequently confirmed in the written Torreya Opinion, dated October 16, 2022) to the Ayala Board to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications, set forth in the written Torreya Opinion, the Exchange Ratio was fair, from a financial point of view, to Ayala. The Torreya Opinion is more fully described under the section entitled "*The Merger — Opinion of Ayala's Financial Advisor — Torreya Capital, LLC* beginning on page 162 of this proxy statement/prospectus, and the full text of the Torreya Opinion is attached as Annex B to this proxy statement/prospectus;

- *Terms of the Merger Agreement*. The terms and conditions of the Merger Agreement, including:

  - *Ownership Split*. The determination that the expected relative percentage ownership of Ayala's stockholders (62.5%) and Advaxis' stockholders (37.5%) in the combined company was appropriate, based on the Ayala Board's judgment and assessment of the approximate valuations of Advaxis (including the value of the net cash Advaxis is expected to provide to the combined company) and Ayala;

  - *Tax Treatment*. The expectation that the Merger will be treated as a "reorganization" within the meaning of Section 368(a) of the Code for U.S. federal income tax purposes, with the result that in the Merger the holders of Ayala Common Stock will generally not recognize taxable gain or loss for U.S. federal income tax purposes (other than with respect to cash received in lieu of a fractional share of Advaxis Common Stock);

  - *Reciprocity*. The review by the Ayala Board, in consultation with Ayala's advisors, of the structure of the Merger and the terms and conditions of the Merger Agreement, including certain reciprocal provisions that may have the effect of discouraging alternative Acquisition Proposals involving Ayala or Advaxis and their ability to terminate the Merger Agreement;

  - *Conditions to Consummation of the Merger*. The limited number and nature of the conditions to the parties' obligations to complete the Merger and the belief of the Ayala Board of the likelihood of satisfying such conditions;

- *Right to Withdraw Recommendation to Ayala Stockholders*. The right of Ayala under the Merger Agreement to consider certain unsolicited Acquisition Proposals should Ayala receive a superior proposal, and the right of the Ayala Board under certain circumstances to withdraw its recommendation to Ayala stockholders that they adopt the Merger Agreement;

- *Opportunity to Vote*. The opportunity of the Ayala stockholders to vote on the adoption of the Merger Agreement; and

- *Termination Fee*. The conclusion of the Ayala Board that the potential termination fees payable by Ayala or Advaxis to the other party, and the circumstances when such fee may be payable, were reasonable.

The Ayala Board also considered various risks and other potentially negative factors concerning the Merger Agreement, the Merger and the other Transactions, which included the following factors:

- the challenges inherent in combining the businesses, operations and regulatory compliance systems of Ayala and Advaxis;

- the expectation that the combined company will need to raise substantial additional capital in the future, which could result in further dilution to stockholders;

- the fact that forecasts of future results of operations and synergies are necessarily estimates based on assumptions;

- the possibility that the Merger might not be completed, or that completion might be unduly delayed, including as a result of Ayala's stockholders failing to grant the requisite approvals to consummate the Merger, and the potential negative impact that may have on Ayala's business and stockholders;

- the risk to Ayala's business, operations and financial results in the event that the Merger is not consummated, including the diminution of Ayala's cash and the significant challenges associated with the need to raise additional capital through the public or private sale of equity securities;

- the substantial costs to be incurred in connection with the Merger, including the cash and other costs of integrating the businesses of Ayala and Advaxis, as well as the transaction expenses arising from the Merger;

- the terms of the Merger Agreement, including generally reciprocal covenants relating to (i) the two companies' conduct of their respective businesses during the period between the signing of the Merger Agreement and the completion of the Merger, and (ii) the restrictions on the two companies' ability to solicit alternative transaction proposals;

- the likely detrimental effect on Ayala's cash position, stock price and ability to initiate another process and to successfully complete an alternative transaction should the Merger not be completed;

- the likelihood of disruptive stockholder litigation following announcement of the Merger;

- the strategic direction of the combined company following the completion of the Merger; and

- various other risks associated with the combined organization and the Merger, including those described in the section entitled "*Risk Factors*", the matters described under "*Cautionary Statement Concerning Forward-Looking Statements*" and the matters described under "*Certain Prospective Financial Information for Ayala*" beginning on pages 25, 1, and 168, respectively, of this proxy statement/prospectus.

The above discussion of the factors considered by the Ayala Board is not intended to be exhaustive, but does set forth material factors considered by the Ayala Board. In light of the wide variety of factors considered in connection with its evaluation of the Merger Agreement, the Merger and the other Transactions and the complexity of these matters, the Ayala Board did not consider it practicable to, and did not attempt to, quantify or otherwise assign relative or specific weight or values to any of these factors, and individual directors may have held varied views of the relative importance of the factors considered. The Ayala Board viewed its position and recommendation as being based on an overall review of the totality of the information available to it and considered these factors in the aggregate to be favorable to, and to support, its determination regarding the Merger and the other Transactions.

This explanation of Ayala's reasons for the Merger and the other Transactions and other information presented in this section is forward-looking in nature and should be read in light of the section of this proxy statement/prospectus entitled "*Cautionary Statement Concerning Forward-Looking Statements*" beginning on page 1 of this proxy statement/prospectus.

Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald

Advaxis retained Cantor Fitzgerald to act as its financial advisor in connection with the Merger. In connection with the Merger, Cantor Fitzgerald rendered its opinion to the Advaxis Board on October 18, 2022, to the effect that, as of that date and based on and subject to various assumptions, matters considered and limitations, conditions and qualifications described in its opinion, the Exchange Ratio was fair, from a financial point of view, to Advaxis.

The full text of Cantor Fitzgerald's opinion describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken by Cantor Fitzgerald. This opinion is attached as Annex C and is incorporated herein by reference. **Cantor Fitzgerald's opinion was provided for the benefit and use of the Advaxis Board (in its capacity as such) in connection with its consideration of the Merger. Cantor Fitzgerald's opinion did not constitute a recommendation to the Advaxis Board in connection with the Merger, nor did the opinion constitute a recommendation to any holders of common stock of Advaxis or Ayala as to how they should vote or act with respect to the Merger or any related matter. Cantor Fitzgerald's opinion did not address Advaxis' underlying business decision to pursue the Merger, the relative merits of the Merger as compared to any alternative business or financial strategies that might exist for Advaxis or the effects of any other transaction in which Advaxis might engage.** The following summary is qualified in its entirety by reference to the full text of Cantor Fitzgerald's opinion.

In the course of performing its reviews and analyses for rendering its opinion, Cantor Fitzgerald:

- reviewed a draft of the Merger Agreement, dated October 18, 2022;
- reviewed certain publicly available business and financial information relating to Advaxis and Ayala;
- reviewed certain operating and financial information relating to Advaxis' business and prospects, including projections for Advaxis through December 31, 2023, all as prepared and approved for Cantor Fitzgerald's use by Advaxis' management, which reflected the near-term dissolution of Advaxis and return of cash to Advaxis shareholders (the "Advaxis Projections");
- reviewed certain operating and financial information relating to Ayala's business and prospects, including projections for Ayala for the 11 years ending December 31, 2033, all as prepared by Ayala's management and adjusted and approved for Cantor Fitzgerald's use by Advaxis' management (as adjusted, the "adjusted Ayala projections" and together with the Advaxis Projections, for purposes of this section, the "projections");
- met with certain members of Advaxis' senior management to discuss Advaxis' and Ayala's respective businesses, operations, historical and projected financial results and future prospects;
- reviewed the historical prices and trading volumes of the Advaxis Common Stock and Ayala Common Stock;
- reviewed and performed analyses based on certain publicly available financial information with respect to companies in the biopharmaceutical industry that Cantor Fitzgerald deemed to be relevant;
- performed discounted cash flow analyses based on the Advaxis Projections and the adjusted Ayala projections furnished to Cantor Fitzgerald by Advaxis;
- reviewed the pro forma financial results, financial condition and capitalization of Advaxis giving effect to the Merger; and
- conducted such other studies, analyses, inquiries and investigations as Cantor Fitzgerald deemed appropriate.

Cantor Fitzgerald relied upon and assumed, without independent verification, the accuracy and completeness of the financial and other information provided to or discussed with it by Advaxis and Ayala or obtained by Cantor Fitzgerald from public sources, including, without limitation, the projections referred to above. With respect to the projections, Cantor Fitzgerald relied on representations that they were reasonably prepared on bases reflecting the best currently available estimates and judgments of the senior management of Advaxis and Ayala, as the case may be, as to the expected future performance of Advaxis and Ayala. Cantor Fitzgerald did not assume any responsibility for the independent verification of, and did not independently verify, any such information, including, without limitation, the projections. Cantor Fitzgerald expressed no view or opinion as to such projections or the assumptions upon which they are based, and further relied upon the assurances of the senior management of Advaxis and Ayala, as the case may be, that they were unaware of any facts that would make the information or projections incomplete or misleading. Cantor Fitzgerald assumed that the executed Merger Agreement would not differ in any material respect from the draft reviewed by it.

In arriving at its opinion, Cantor Fitzgerald did not perform or obtain any independent appraisal of the assets or liabilities (contingent or otherwise) of Advaxis and Ayala, nor was Cantor Fitzgerald furnished with any such appraisals. During the course of its engagement, Cantor Fitzgerald was directed by the Ayala Board to solicit indications of interest from various third parties regarding a transaction with Advaxis, and considered the results of such solicitation in rendering its opinion. Cantor Fitzgerald assumed that the Merger will qualify as a tax-free "reorganization" within the meaning of Section 368(a) of the Code. Cantor Fitzgerald assumed that the Merger will be consummated in a timely manner and in accordance with the terms of the Merger Agreement without any limitations, restrictions, conditions, amendments or modifications, regulatory or otherwise, that would be material in any respect to its analysis or its opinion. Cantor Fitzgerald is not a legal, regulatory, tax or accounting expert and has relied on the assessments made by Advaxis, Ayala and their respective advisors with respect to such issues. Its opinion does not address any legal, tax, regulatory or accounting matters.

It was understood that Cantor Fitzgerald's opinion was intended for the benefit and use of the Advaxis Board (in its capacity as such) in connection with its consideration of the Merger. Cantor Fitzgerald was informed by the Advaxis Board, and assumed for purposes of its opinion, that David Sidransky recused himself from any board deliberations or meetings regarding, and was not otherwise involved in, the Advaxis Board's consideration of, the Merger. Cantor Fitzgerald's opinion may not be used for any other purpose, reproduced, disseminated, quoted from or referred to at any time, in whole or in part, without the prior written consent of Cantor Fitzgerald. However, Cantor Fitzgerald's opinion may be included in its entirety in this Registration Statement. Cantor Fitzgerald's opinion did not constitute a recommendation to the Advaxis Board or the Ayala Board in connection with the Merger, nor did the opinion constitute a recommendation as to how any holders of Advaxis Common Stock or Ayala Common Stock should vote or act with respect to the Merger or any related matter. Cantor Fitzgerald's opinion did not address Advaxis' underlying business decision to pursue the Merger, the relative merits of the Merger as compared to any alternative business or financial strategies that might exist for Advaxis or the effects of any other transaction in which Advaxis might engage. In addition, Cantor Fitzgerald's opinion did not constitute a solvency opinion or a fair value opinion, and Cantor Fitzgerald did not evaluate the solvency or fair value of Advaxis under any federal or state laws relating to bankruptcy, insolvency or similar matters. Furthermore, Cantor Fitzgerald did not express any view or opinion as to the fairness, financial or otherwise, of the amount or nature of any compensation payable to or to be received by any of Advaxis' officers, directors or employees, or any class of such persons, in connection with the Merger relative to the Exchange Ratio. Cantor Fitzgerald expressed no view as to any other aspect or implication of the Merger or any other agreement, arrangement or understanding entered into in connection with the Merger or otherwise.

Cantor Fitzgerald's opinion was authorized for issuance by Cantor Fitzgerald's Fairness Opinion and Valuation Committee. Cantor Fitzgerald's opinion was subject to the assumptions, limitations, qualifications and other conditions contained therein and was necessarily based on economic, market and other conditions, and the information made available to Cantor Fitzgerald, as of the date of its opinion. Cantor Fitzgerald assumed no responsibility for updating or revising its opinion based on circumstances or events occurring after the date of Cantor Fitzgerald's opinion.

In connection with rendering its opinion to the Advaxis Board, Cantor Fitzgerald performed a variety of financial and comparative analyses, which are summarized below. The following summary is not a complete description of all analyses performed and factors considered by Cantor Fitzgerald in connection with its opinion. The preparation of a financial opinion is a complex process involving subjective judgments and is not necessarily susceptible to partial analysis or summary description. With respect to the selected companies analysis summarized below, no company used as a comparison was identical to Ayala. These analyses necessarily involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the public trading or acquisition values of the companies concerned. For purposes of the analyses described below, implied multiples for selected companies that were considered not meaningful or were not publicly available were not included in the high, mean, median and low multiples for the selected companies.

Cantor Fitzgerald believes that its analyses and the summary below must be considered as a whole and that selecting portions of its analyses and factors or focusing on information presented in tabular format, without considering all analyses and factors or the narrative description of the analyses, could create a misleading or incomplete view of the processes underlying Cantor Fitzgerald's analyses and opinion. Cantor Fitzgerald did not draw, in isolation, conclusions from or with regard to any one factor or method of analysis for purposes of its opinion, but rather arrived at its ultimate opinion based on the results of all analyses undertaken by it and assessed as a whole.

The estimates of the future performance of the combined company in or underlying Cantor Fitzgerald's analyses are not necessarily indicative of future results or values, which may be significantly more or less favorable than those estimates. In performing its analyses, Cantor Fitzgerald considered industry performance, general business and economic conditions and other matters, many of which were beyond the control of Advaxis or Ayala. Estimates of the financial value of companies do not purport to be appraisals or necessarily reflect the prices at which companies or securities actually may be sold or acquired.

The Exchange Ratio was determined through negotiation between Advaxis and Ayala, and the decision by Advaxis to enter into the Merger Agreement was solely that of the Advaxis Board. Cantor Fitzgerald's opinion and financial analyses were only one of many factors considered by the Advaxis Board in its evaluation of the Merger and should not be viewed as determinative of the views of the Advaxis Board or Advaxis' management with respect to the Merger or the Exchange Ratio.

The following is a brief summary of the material financial analyses performed by Cantor Fitzgerald in connection with its opinion. **The order in which such summary is presented does not represent the relative importance of such analyses. In addition, the financial analyses summarized below include information presented in tabular format. In order to fully understand Cantor Fitzgerald's financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Cantor Fitzgerald's financial analyses.**

In the financial analyses summarized below, financial data of the selected companies were based on publicly available research analysts' estimates, public filings and other publicly available information, financial data of Advaxis were based on internal estimates of Advaxis' management provided to Cantor Fitzgerald and financial data of Ayala were based on internal estimates of Ayala's management, as adjusted and provided to Cantor Fitzgerald by Advaxis' management.

Advaxis Implied Equity Value Per Share. Cantor Fitzgerald reviewed the implied equity value per share of common stock of Advaxis based on the Advaxis Projections and Cantor Fitzgerald's calculation of risk adjusted, after-tax unlevered free cash flows derived therefrom. In performing this analysis, Cantor Fitzgerald calculated implied equity values per share of common stock of Advaxis by discounting to present value using discount rates of 4.3%, the 20-year U.S. treasury rate as of October 14, 2022, and 9.8%, after adjusting for the long-horizon expected equity risk premium. Because the Advaxis Projections reflected the near-term dissolution of Advaxis, as described further in "—*Certain Prospective Financial Information of Advaxis*", the discounted cash flow of Advaxis included only the estimated cash returned to Advaxis shareholders at December 31, 2023, using the year-end convention. This analysis indicated an implied equity value per share for Advaxis of $9.75 and $10.26, compared to the closing price of $2.00 per share of common stock of Advaxis on October 14, 2022.

Selected Companies Analysis. Cantor Fitzgerald reviewed selected financial and stock market data of Ayala and twelve selected publicly traded biopharmaceutical oncology companies (the "selected companies").

Cantor Fitzgerald reviewed enterprise values of the selected companies, calculated as fully diluted equity values based on closing stock prices on October 14, 2022, less net cash, as multiples of calendar year 2026 estimated revenue ("2026E Revenue"), which ranged from 0.2x to 17.0x and calendar year 2027 estimated revenue ("2027E Revenue"), which ranged from 0.1x to 3.9x. The mean and median revenue multiples observed in this analysis for the selected companies were 6.7 and 4.0x for 2026E Revenue and 1.7x and 1.4x for 2027E Revenue, respectively.

The selected companies and the financial data reviewed included the following:

Selected Companies	Enterprise Value / 2026E Revenue Multiple	Enterprise Value / 2027E Revenue Multiple
Aravive, Inc.	NM	NM
Caribou Biosciences, Inc.	4.4x	2.9x
Corvus Pharmaceuticals, Inc.	NM	NM
Day One Biopharmaceuticals, Inc.	3.6x	2.5x
eFFECTOR Therapeutics, Inc.	NM	0.1x
Harpoon Therapeutics, Inc.	NM	NM
Janux Therapeutics, Inc.	17.0x	1.4x
Nuvalent, Inc.	13.5x	3.9x
Onconova Therapeutics, Inc.	NM	NM
Protara Therapeutics, Inc.	NM	NM
SELLAS Life Sciences Group, Inc.	0.2x	0.1x
SpringWorks Therapeutics, Inc.	1.5x	0.9x

NM – not meaningful

Cantor Fitzgerald then applied a selected range of 2026E revenue multiples of 2.0x to 11.2x, derived from the selected companies, to corresponding data of Ayala. Cantor Fitzgerald then adjusted for Ayala's estimated net cash, and divided by the number of fully-diluted shares of Ayala Common Stock (determined using the treasury stock method) as of October 14, 2021. This analysis indicated an implied per share equity value reference range for Ayala of $3.24 to $16.36.

Using the implied equity value per share ranges derived for Ayala and Advaxis described above, Cantor Fitzgerald calculated an implied exchange ratio of 0.3236x to 1.6353x, compared to the Exchange Ratio of 0.1874x in the Merger Agreement.

Cantor Fitzgerald also applied a selected range of 2027E revenue multiples of 0.5x to 2.7x, derived from the selected companies, to corresponding data of Ayala. Cantor Fitzgerald then adjusted for Ayala's estimated net cash, and divided by the number of fully-diluted shares of Ayala Common Stock (determined using the treasury stock method) as of October 14, 2021. This analysis indicated an implied per share equity value reference range for Ayala of $2.15 to $9.99.

Using the implied equity value per share ranges derived for Ayala and Advaxis described above, Cantor Fitzgerald calculated an implied exchange ratio of 0.2153x to 0.9986x, compared to the Exchange Ratio of 0.1874x in the Merger Agreement.

Discounted Cash Flow Analysis. Cantor Fitzgerald performed a discounted cash flow analysis of Ayala based on the adjusted Ayala projections and Cantor Fitzgerald's calculation of risk adjusted, after-tax unlevered free cash flows derived therefrom. In performing this analysis, Cantor Fitzgerald calculated a range of equity values for the Ayala Common Stock by (a) discounting to present value using discount rates ranging from 13.5% to 16.5% (reflecting Ayala's estimated weighted average cost of capital) and the mid-year convention: (i) the forecasted risk adjusted and probability adjusted, after-tax unlevered free cash flows of Ayala over the period beginning on January 1, 2023 and ending on December 31, 2033 and (ii) an implied terminal value of Ayala, calculated assuming that Ayala's after-tax unlevered free cash flows would decline in perpetuity after December 31, 2033 at a range of rates of negative 40% to negative 20% year-over-year, and (b) adjusting for Ayala's estimated cash, debt and other liabilities and federal and state net operating losses. This analysis indicated an implied per share equity value reference range for Ayala of $8.87 to $15.17.

Using the implied equity value per share ranges derived for Ayala and Advaxis described above, Cantor Fitzgerald calculated an implied exchange ratio of 0.8868x to 1.5169x, compared to the Exchange Ratio of 0.1874x in the Merger Agreement.

Cantor Fitzgerald also performed a discounted cash flow analysis of the combined company based on the projections and Cantor Fitzgerald's calculation of risk adjusted, after-tax unlevered free cash flows derived therefrom. In performing this analysis, Cantor Fitzgerald calculated a range of equity values for the common stock of the combined company by (a) discounting to present value using discount rates ranging from 13.5% to 16.5% (reflecting the combined company's estimated weighted average cost of capital) and the mid-year convention: (i) the forecasted risk adjusted, after-tax unlevered free cash flows of the combined company over the period beginning on January 1, 2023 and ending on December 31, 2033 and (ii) an implied terminal value of the combined company, calculated assuming that the combined company's after-tax unlevered free cash flows would decline in perpetuity after December 31, 2033 at a range of rates of negative 40% to negative 20% year-over-year, and (b) adjusting for the combined company's estimated cash, debt and other liabilities and federal and state net operating losses. This analysis indicated a range of implied aggregate equity value of approximately $161 million to approximately $263 million, corresponding to an implied equity value of approximately $60 million to approximately $99 million attributable to Advaxis' ownership in the combined company, after giving effect to the Exchange Ratio, compared to an equity value of approximately $18 million for Advaxis based on the Advaxis Projections provided to Cantor Fitzgerald.

Miscellaneous

The Advaxis Board selected Cantor Fitzgerald as financial advisor to Advaxis in connection with the Merger based on Cantor Fitzgerald's reputation as a leading global provider of advisory and capital markets services, experience in the life sciences industry and expertise in mergers and acquisitions, as well as its familiarity with Advaxis.

Cantor Fitzgerald has acted as a financial advisor to Advaxis in connection with the Merger and will receive a fee of $1.25 million, $500,000 of which was payable upon delivery of Cantor Fitzgerald's opinion to the Advaxis Board and the remaining balance of which is contingent upon the consummation of the Merger. In addition, Advaxis has agreed to indemnify Cantor Fitzgerald against certain liabilities arising out of its engagement.

During the two years preceding the date of Cantor Fitzgerald's opinion, Cantor Fitzgerald has not provided any financial advisory or other investment banking services to Advaxis or Ayala for which Cantor Fitzgerald has received fees. Cantor Fitzgerald may seek to provide Advaxis, Ayala or their respective affiliates with certain investment banking and other services unrelated to the Merger in the future.

Consistent with applicable legal and regulatory requirements, Cantor Fitzgerald has adopted certain policies and procedures to establish and maintain the independence of Cantor Fitzgerald's research departments and personnel. As a result, Cantor Fitzgerald's research analysts may hold views, make statements or investment recommendations and/or publish research reports with respect to Advaxis, Ayala, the Merger and other participants in the Merger that differ from the views of Cantor Fitzgerald's investment banking personnel.

In the ordinary course of business, Cantor Fitzgerald and its affiliates may actively trade (for their own accounts and for the accounts of their customers) certain equity and debt securities, bank debt and/or other financial instruments issued by Advaxis and/or Ayala and their respective affiliates, as well as derivatives thereof, and, accordingly, may at any time hold long or short positions in such securities, bank debt, financial instruments and derivatives.

Opinion of Ayala's Financial Advisor–Torreya Capital, LLC

On July 8, 2022, Ayala engaged Torreya to serve as an independent financial advisor to the Ayala Board (solely in their capacity as members of the Ayala Board) to explore and evaluate potential strategic options to maximize the long-term value for Ayala stockholders as well as provide an opinion as to the fairness, from a financial point of view, to the holders of shares of Ayala Common Stock of the Exchange Ratio provided for in the Merger.

Ayala retained Torreya based on Torreya's qualifications, reputation, experience in the provision of corporate finance services in the life science's market including the valuation of businesses and their securities, and its experience in valuing companies in the biotechnology and biopharmaceutical industry. Torreya is a global investment bank and corporate finance advisor that is regularly engaged to provide financial advisory services, including fairness opinions and valuation advice in connection with mergers and acquisitions, related party transactions and recapitalization transactions within the healthcare sector.

On October 16, 2022, Torreya delivered its oral opinion to the Ayala Board, which was subsequently confirmed in written opinion dated October 16, 2022 (the "Torreya Opinion") to the Ayala Board that, as of that date thereof, the Exchange Ratio provided for in the Merger was fair, from a financial point of view, to the holders of shares of Ayala Common Stock. For purposes of the Torreya Opinion and related analyses, "Exchange Ratio" means the ratio obtained by dividing (i) 3.0266 million (calculated as 62.5% of the total outstanding shares of the pro forma company, representing the number of shares legacy Ayala stockholders will own in the combined company), by the number of fully diluted shares outstanding of Ayala as of the date of the Merger Agreement by (ii) 16.1422 million. As of immediately prior to the execution of the Merger Agreement, the Exchange Ratio was calculated to be 0.1874. The Exchange Ratio was determined through negotiations between Ayala and Advaxis and was approved by the Ayala Board. Torreya provided advice to the Ayala Board during these negotiations. Torreya, however, did not recommend any specific amount of consideration to Ayala or the Ayala Board or that any specific amount of consideration constituted the only appropriate consideration for the Merger.

The full text of the Torreya Opinion sets forth the assumptions made, procedures followed, matters considered and qualifications and limitations on the review undertaken by Torreya in connection with the Torreya Opinion. The Torreya Opinion is attached as Annex B to this proxy statement/prospectus. The summary of the Torreya Opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of the Torreya Opinion.

Ayala urges you to read carefully the Torreya Opinion, together with the summary thereof in this proxy statement/prospectus, in its entirety. Torreya provided its opinion for the information and assistance of the Ayala Board in connection with its consideration of the Merger. The Torreya Opinion addressed solely the fairness, from a financial point of view, of the Exchange Ratio in the Merger and does not address any other aspect or implication of the Merger. The Torreya Opinion was not a recommendation to the Ayala Board or any stockholder of Ayala as to how to vote, make any election or to take any other action in connection with the Merger or any other matter and does not in any manner address the prices at which shares of common stock of Ayala or Advaxis will trade at any time.

In connection with Torreya's review of the Merger and developing the opinion described above, Torreya:

i. Reviewed the draft Merger Agreement dated October 16, 2022;

ii. Reviewed and analyzed certain financial and other information with respect to Ayala and Advaxis which was publicly available

iii. Reviewed diligence findings provided by advisors (Latham and Watkins LLP and EY) instructed by Ayala

iv. Reviewed and analyzed certain information, including financial forecasts relating to the business, earnings, cash flow, assets, liabilities and prospects of Ayala and Advaxis, on a stand-alone basis, that were publicly available, as well as those that were provided to Torreya by Ayala

v. Held discussions with the senior management team of Ayala and Advaxis with respect to the matters described in the preceding three bullets, as well as the respective business

vi. Also compared the proposed financial terms of the Agreement with other financial studies and analyses and took into account such other information as Torreya deemed appropriate in evaluating the merger consideration

In connection with its review and arriving at its opinion, Torreya did not independently verify any of the foregoing information, relied on such information, assumed that all such information was complete and accurate in all material respects, and relied on assurances of management of Ayala and Advaxis that they were not aware of any facts that would make such information misleading. With respect to the cash projections of Advaxis prepared by management of Advaxis and reviewed by EY on behalf of Ayala, the projected cash balance of Ayala prepared by management of Ayala, and any other estimates or forward looking information reviewed by Torreya, Torreya assumed, with the consent of the Ayala Board, that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of management as to the matters covered thereby, and Torreya relied, at the direction of the Ayala Board, on such information for purposes of its analysis and opinion. Torreya expressed no view or opinion as to such information or the assumptions on which it was based. Torreya also relied on information provided by the management of Ayala and Advaxis as to the capitalization of Ayala and Advaxis, respectively, and Torreya assumed, with the consent of the Ayala Board, that such information will not vary in any material respect that would be meaningful to Torreya's analysis.

Torreya also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without any adjustment to the Exchange Ratio or any waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to Torreya's analysis, (ii) the representations and warranties made by the parties to the Merger Agreement are and will be true and correct in all respects material to Torreya's analysis, and (iii) in the course of obtaining necessary governmental, regulatory and third-party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed which would have an adverse effect on Ayala or Advaxis or be in any way meaningful to Torreya's analysis. Torreya is not a legal, accounting, regulatory or tax expert and relied on the assessments made by Ayala and its advisors with respect to such matters. Torreya's opinion is limited to and addresses only the fairness, from a financial point of view to Ayala of the Exchange Ratio as of the date of the opinion. Torreya expressed no opinion as to the fairness of the Merger to the holders of any class of securities, creditors, or other constituencies of Ayala. Torreya's opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Ayala, nor does it address the underlying business decision of Ayala to proceed with the Merger or any view on another term or aspect of the Merger, including, without limitation, the structure or form of the Merger. Torreya did not consider, and did not express an opinion as to, the fairness of the amount or nature of the compensation to any of the officers, directors or employees of Ayala or any other party, or class of such persons. Further, Torreya did not express any opinion as to in the future what the value of Ayala Common Stock or any other securities will be when issued or the price or range of prices at which Ayala Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

Torreya was not requested to conduct, and did not conduct, nor did Torreya rely upon, any independent valuation or appraisal of any of the assets or liabilities (contingent, derivative, off balance sheet or otherwise) of Ayala or Advaxis. Torreya also did not evaluate nor express any opinion as to the solvency of any party to the Merger Agreement, or the ability of Ayala or Advaxis to pay its obligations when they become due, or as to the impact of the Merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency, or similar matters.

Summary of Financial Analysis by Torreya

Set forth below is a summary of the material financial analyses performed by Torreya in connection with the preparation of the Torreya Opinion. The information set forth below summarizes the material financial and comparative analyses performed by Torreya but does not purport to be a complete description of the financial analyses performed by Torreya or the data considered by it in connection with the Torreya Opinion. The preparation of a financial opinion involves various subjective determinations as to the most appropriate and relevant methods of financial analysis and the application of these methods to circumstances. In arriving at the Torreya Opinion, Torreya considered several analytical methodologies. Each analytical technique has inherent strengths and weaknesses, and the nature of the available information may further affect the strengths and weaknesses of any technique. The conclusion reached by Torreya was based on all analyses and factors taken, as a whole, and on application of Torreya' own experience and judgment. No one method of analysis should be regarded as critical to the overall conclusion. Accordingly, Torreya believes that its analyses must be considered as a whole, and that selecting portions of its analyses and of the factors considered by it, without considering all analyses and factors, could create a misleading or incomplete view of the evaluation process underlying the Torreya Opinion.

Torreya analyzed the Exchange Ratio using three different methodologies: discounted cash flow analysis, comparable financing ownership analysis and comparable transactions analysis. The results of each of these analyses are summarized below.

Discounted Cash Flow Analysis

A risk-adjusted discounted cash flow, or DCF, analysis is designed to provide insight into the intrinsic value of a business based on its projected earnings and capital requirements as well as the net present value of projected free cash flows. Torreya performed a DCF analysis of Ayala for the purpose of calculating an enterprise equity value Ayala Common Stock on a stand-alone basis based on the estimated present value of the standalone, after-tax free cash flows that Ayala was forecasted to generate during fiscal years ending December 31, 2023 through 2033. For purposes of this analysis, Torreya used risk adjusted projections of free cash flows for fiscal years ending December 31, 2023 through 2033 provided Ayala management (the "Ayala Projections"). Forecasted free cash flows were calculated by taking revenue, subtracting cost of goods sold and operating expenses, adding tax expense (adjusted for Ayala's Net Operating Losses ("NOL") generated to date of $130 million), depreciation and adjusting for changes in net working capital. The Ayala Projections included estimates of revenues for each product in Ayala's pipeline, adjusted by the probability of success specified by management.

($ in mm)	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Free Cash Flow	**(35)**	**(38)**	**(21)**	**(7)**	**27**	**58**	**107**	**132**	**136**	**153**	**162**

The free cash flow analysis assumed a starting net operating loss balance based on Ayala's operating losses incurred to date of $130 million as of December 31, 2022 and forecasts negative cash flow through 2026 of approximately $100 million. To finance these losses, Torreya projected financing fees and other transaction expenses of $10 million. Torreya also assumed a 20% discount on the current share price for each share offered as part of the hypothetical financing. Torreya then discounted the projected free cash flows for fiscal years ending December 31, 2023, through 2033 for Ayala using a discount rate of 12% based on the share price and managements forecast. The DCF analysis resulted in estimated total enterprise value of Ayala of $394 million. While Torreya recognized the implied enterprise value of Ayala indicated by the DCF analysis, Torreya considered (1) that the DCF analysis does not consider market sentiment where approximately 200 US-listed biotech companies are trading below their own cash amounts and (2) the Ayala Projections are not achievable without significant additional funding to bring Ayala through 2026. Ayala ran a full financing process in the first half of 2022 and was unable to find a viable source of any financing to bring Ayala through 2026, leading Ayala to search for a strategic alternative to unlock its intrinsic value.

The DCF analysis, like any other analytical technique used by Torreya, has inherent strengths and weaknesses. The range of valuation indications resulting from any technique, including the DCF analysis, should not be taken in isolation to be Torreya's view of the valuation for Ayala. Accordingly, the valuation range derived from the DCF analysis was not necessarily indicative of Ayala's present or future value.

Advaxis Cash Forecast

Torreya valued Advaxis on the basis of its projected uncommitted cash at closing of $18.2 million. This represents a premium relative to its market capitalization. Torreya deemed that a DCF analysis of Advaxis would not be relevant given Advaxis' clinical programs would not be invested in post-merger beyond the commitments that were in place at that the time of the Merger, and thus the true value of Advaxis to the pro forma company was the amount of uncommitted cash as of deal closing. In a scenario where Advaxis is able to monetize its New Jersey NOLs, its value could be deemed to be higher than $18.2 million. The NJ NOLs estimate was provided by Advaxis management, and were generated based on prior operating losses by Advaxis. Certain of these losses were generated in the state of New Jersey, and prior to the deal announcement, Advaxis received notice from the state of New Jersey that it would be able to "sell" certain of its NOLs for cash, which would thus increase the amount of uncommitted cash Advaxis would have at or soon after the time of Merger closing by approximately $4 million.

Comparable Financing Ownership Analysis

In advance of Torreya's outreach process to parties potentially interested in a strategic transaction, Ayala attempted to raise funding. Two interested parties (each, an "Investor") that proposed to lead a financing engaged in further diligence with Ayala. Both Investors provided term sheets (based on some syndication) that included the proposed terms detailed below, among others:

- Total investment by Investor of $35-$50 million
- Investor would receive Ayala Common Stock at market price for the investment, as well as 5-year warrants with an exercise price set at a 25% premium to the proposed equity financing price
    - Each share of common stock would come with 0.5 warrants
- In addition, two current directors on the Ayala Board would be replaced with directors designated by Investor, with one of the appointed directors becoming Chair of the Board
- Investor would also receive the ability, with agreement, to appoint two additional directors up until June 2024

Although the financing process with both parties failed, Torreya used the term sheets to compare the "closest" available transaction opportunities. Advaxis' uncommitted cash balance at the end of 2022 is projected to be $18.2 million. The analysis shows that in a hypothetical comparable financing for $18.2 million of cash, using the terms provided by the Investors, and assuming a $14.9 million market capitalization of Ayala based on the closing stock price on October 18, 2022, Ayala stockholders would retain between 45-53% of the company (depending on if Ayala's incremental transaction costs were included or not), before giving effect to any potential dilution from warrants in a comparable equity financing. Assuming Advaxis receives an additional $4 million of cash from the sale of New Jersey net operating loss, the hypothetical comparable financing would be for $22.2 million and Ayala stockholders would retain between 40-47% (depending on if Ayala's incremental transaction costs were included in the pro forma company's cash balance upon closing or not). In comparison, as part of this transaction Ayala's stockholders will retain 62.5% ownership of the combined company, which is greater than the ownership percentage implied by any of the financing scenarios.

The additional dilution of the warrants that would be included in an equity financing was not included in the analysis of potential dilution from a comparable financing. If the additional dilution of the warrants associated with an equity financing is taken into account, the ownership of existing Ayala stockholders in a hypothetical comparable financing would decline further.

Comparable Financing Ownership Based on Financing Term Sheets

Advaxis Uncommitted Cash Scenarios	Cash raised [1]	Implied Ayala ownership after an equivalent equity financing
Net of M&A transaction costs [2]	$ 13.0	53%
Net of M&A transaction costs plus NJ NOL[2][3]	$ 17.0	47%
Uncommitted Cash	$ 18.2	45%
Uncommitted cash plus NJ NOL[3]	$ 22.2	40%

(1) Based on Advaxis' cash of $18.2 million.
(2) Assumes $5.2 million of M&A transaction costs.
(3) Assumes an additional $4.0 million of cash received from the state of New Jersey as part of the "sale back" of certain of Advaxis' accumulated net operating losses incurred in the state of New Jersey.

Comparable Transactions Analysis

The first three recent market examples demonstrate that the cash holdings of biotech "cash-shells" drive the value of listed cash-shell mergers in the current environment, especially within public-to-public transactions that limit the negotiating power of the company requiring cash imminently. As shown by the first three examples below, the Merger partner providing the clinical asset(s) ("AssetCo") have received a portion of the pro forma company similar to the percentage of cash that they contributed relative to the total contributed by the Merger partners in total. In the second three examples from 2022, the relative ownership post-merger shows limited correlation to the cash contributed, but in all cases is less than the relative post-merger ownership of the legacy Ayala stockholders in the transaction.

Date	Transaction	AssetCo	AssetCo Cash (m)	AssetCo Cash as % of combined total	AssetCo Ownership %
Mergers where AssetCo cash amount strongly influenced relative ownership post-merger					
Jul-22	Syros-Time	Syros	$ 50	45%	46%
Sep-22	Equillium-Metacrine	Equillium	$ 24	48%	75%
Sep-22	Aceragen-Idera	Aceragen	$ 17	63%	67%
Mergers where AssetCo cash shows limited correlation to relative ownership post-merger					
Jul-22	ARS-Silverback	ARS	$ 25	9%	63%
Apr-22	Cend-Caladrius	Cend	$ 17	27%	50%
Sep-22	Carisma-Sesen	Carisma	$ 38	21%	58%

Note that AssetCo in each of these three transactions is privately owned

In the most recent example, Nasdaq-listed Equillium merged with Metacrine, a recently failed Nasdaq-listed biotech, through the issuance of shares based on "net cash at closing, plus a 25% premium". Further, Equillium paid a 25% premium on cash despite already having a cash balance similar to that of the cash shell. With Equillium trading at a modest premium to cash (rather than a discount), their own cash balance was less relevant to the overall deal dynamic. The Idera / Aceragen and Syros / Tyme transactions are examples that demonstrate that the cash amounts contributed to the pro forma combined company were mirrored by the ownership split.

In the case of the Ayala-Advaxis transaction, at closing, Ayala will likely contribute little-to-none of the pro forma company cash, after giving effect to transaction costs, while receiving 62.5% ownership of the combined company. This ownership of the legacy Ayala stockholders at closing will exceed the implied exchange ratio for the issuance of shares based on the relative cash contribution of the parties in the comparable transactions analysis.

Other Factors

Torreya also considered that should Ayala not find funding of some sort, either through a merger or a private or public financing, Ayala is projected to run out of cash in early 2023 and would likely need to be liquidated, providing little value to stockholders.

Miscellaneous

Other than work associated with this transaction, during the two years preceding the date of the Torreya Opinion, Torreya has not been engaged to provide financial advisory services or other services to Ayala, and Torreya has not received any compensation from Ayala during such period.

Pursuant to Ayala's engagement letter with Torreya, Ayala agreed to pay Torreya a fee of $2.0 million for its services, $50 thousand of which became payable upon signing the engagement letter, $50 thousand of which became payable upon signing of the first term sheet with an M&A partner, $0.5 million became payable upon Torreya informing the Ayala Board that it was prepared to deliver its opinion and $1.4 million that will become payable to Torreya upon completion of the transaction. Ayala also agreed to reimburse Torreya for its reasonable out-of-pocket expenses incurred in connection with its engagement and to indemnify Torreya against certain liabilities relating to or arising out of Torreya's engagement.

Certain Prospective Financial Information of Advaxis; Certain Adjustments by Advaxis to Financial Information of Ayala

As a matter of course, Advaxis does not publicly disclose long-term projections of future financial performance due to among other things, the inherent difficulty of predicting financial performance for future periods and the likelihood that the underlying assumptions and estimates may not be realized. However, in connection with the exploration of strategic alternatives as described in this proxy statement/prospectus, Advaxis management prepared certain non-public, unaudited projections of financial performance for Advaxis reflecting the near-term dissolution of Advaxis and return of cash to Advaxis shareholders (the "Advaxis Projections"), based on its view of the prospects of Advaxis.

The Advaxis Projections did not give effect to any changes or expenses as a result of the Merger or any other effects of the Merger or any impact should the Merger fail to be consummated. The Advaxis Projections were prepared solely for internal use and are subjective in many respects. As a result, there can be no assurance that the forecasted results will be realized or that actual results will not be significantly higher or lower than estimated. The estimates and assumptions underlying the unaudited forecasted financial information involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions that may not materialize and are inherently subject to significant uncertainties and contingencies, all of which are difficult to predict and many of which are beyond Advaxis' control. There can be no assurance that the Advaxis Projections will be realized and actual results may vary materially from those shown.

The prospective financial information included in this proxy statement/prospectus was not prepared with a view toward public dissemination or compliance with published guidelines of the SEC or established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information or generally accepted accounting principles, or GAAP, but, in the view of Advaxis management, was prepared on a reasonable basis, reflected, at the time the prospective financial information was prepared, the best currently available estimates and judgments, and presented, to the best of Advaxis management's knowledge and belief at that time, the expected course of action and the expected future financial performance of Advaxis. However, this information is not fact and should not be relied upon as being necessarily indicative of future results and readers of this proxy statement/prospectus are cautioned not to place undue reliance, if any, on the prospective financial information.

The table below presents a summary of the Advaxis Projections. The summary below is included solely to give Ayala's stockholders access to certain long-term financial analyses and forecasts that were made available to the Advaxis Board and Cantor Fitzgerald for purposes of performing analyses underlying Cantor Fitzgerald's opinion, and is not included in this proxy statement/prospectus to influence an Ayala stockholder's decision whether to vote for the Ayala Merger Proposal or for any other purpose. The inclusion of a summary of the Advaxis Projections in this document does not constitute an admission or representation that the information is material. The inclusion of a summary of the Advaxis Projections should not be regarded as an indication that Advaxis and/or its affiliates, officers, directors, advisors or other representatives consider the Advaxis Projections to be necessarily predictive of actual future events and this information should not be relied upon as such. None of Advaxis and/or its affiliates, officers, directors, advisors or other representatives gives any stockholder of Ayala or any other person any assurance that actual results will not differ materially from the Advaxis Projections. The Advaxis Projections do not take into account any circumstances, transactions or events occurring after the date on which they were prepared. Some or all of the assumptions underlying the Advaxis Projections may have changed since the date the Advaxis Projections were prepared.

ADVAXIS HAS NOT UPDATED AND DOES NOT INTEND TO UPDATE OR OTHERWISE REVISE THE UNAUDITED FORECASTED FINANCIAL INFORMATION TO REFLECT CIRCUMSTANCES EXISTING AFTER THE DATE WHEN MADE OR TO REFLECT THE OCCURRENCE OF FUTURE EVENTS, EVEN IN THE EVENT THAT ANY OR ALL OF THE ASSUMPTIONS UNDERLYING SUCH PROSPECTIVE FINANCIAL INFORMATION ARE NO LONGER APPROPRIATE.

Certain of the measures included in the Advaxis Projections may be considered non-GAAP financial measures. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non- GAAP financial measures as used by Advaxis may not be comparable to similarly titled amounts used by other companies.

Financial measures provided to a financial advisor are excluded from the definition of non-GAAP financial measures and therefore, are not subject to SEC rules regarding disclosures of non-GAAP financial measures, which would otherwise require a reconciliation of a non-GAAP financial measure to a GAAP financial measure. Reconciliations of non-GAAP financial measures were not relied upon by Cantor Fitzgerald for purposes of its financial analysis as described above in "*—Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald*" located elsewhere in this proxy statement/prospectus or by the Advaxis Board in connection with its consideration of the Merger. Accordingly, Advaxis has not provided a reconciliation of the non-GAAP financial measures included in the Advaxis Projections.

For the foregoing and other reasons, readers of this proxy statement/prospectus are cautioned that the inclusion of a summary of the Advaxis Projections in this proxy statement/prospectus should not be regarded as a representation or guarantee that the targets will be achieved nor that they should place undue reliance, if any, on the Advaxis Projections. The Advaxis Projections constitute forward-looking statements and are subject to risks and uncertainties that could cause actual results to differ materially from the projected results. See also "*Cautionary Statement Concerning Forward-Looking Statements*" located elsewhere in this proxy statement/prospectus.

Set forth below is a summary of the Advaxis Projections prepared by Advaxis management and reviewed by Cantor Fitzgerald in undertaking its analysis, which consist of certain operating and financial information relating to Advaxis' business and prospects, including projections for Advaxis through December 31, 2023 reflecting the near-term dissolution of Advaxis and return of cash to Advaxis shareholders.

The projections for Advaxis through December 31, 2023 reflect certain assumptions, including (i) an orderly, phased termination of personnel and the payment of certain severance payments to employees, (ii) the destruction of study materials in October 2022, (iii) the cessation of Advaxis' regulatory functions in September 2023, (iv) the completion of the wind-down of the ADXS-503 program in November 2023, (v) the purchase of a D&O tail insurance policy, (vi) abandonment of all patents, and (vii) receipt of proceeds from the sale of New Jersey net operating losses in December 2022.

	2022			**2023**											
($ in millions)	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total Disbursements	4.3	0.2	0.8	0.6	0.7	0.8	0.3	0.2	0.3	0.2	0.3	1.1	0.2	0.2	1.7
NJ NOL Sale	-	-	4.7	-	-	-	-	-	-	-	-	-	-	-	-
Ending Cash Balance	22.2	22.0	25.9	25.4	24.7	23.9	23.6	23.4	23.1	22.9	22.6	21.5	21.3	21.1	19.4

Adjustments by Advaxis to Certain Summary Projected Financial Information of Ayala

The Ayala projections, as prepared by Ayala management and set forth below under "*The Merger—Certain Prospective Financial Information of Ayala,*" were adjusted by Advaxis management to reflect reductions in projected revenues relating to its assessment of the commercial potential and probability of success for Ayala's lead product candidates, as shown in the table below, for purposes of Cantor Fitzgerald's financial analyses described above in "*The Merger—Opinion of Advaxis' Financial Advisor—Cantor Fitzgerald.*"

($ in millions)	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**
AL101 Revenue	**0**	**0**	**5**	**10**	**23**	**29**	**35**	**37**	**37**	**37**	**37**
AL102 Revenue	**0**	**0**	**0**	**13**	**35**	**75**	**121**	**164**	**200**	**229**	**240**
Total Cost of Goods Sold	0	0	0	1	2	3	6	8	10	12	13
Total Operating Expenses (Including Milestones and Royalties)	37	40	28	32	32	46	48	66	70	78	81
EBIT[(1)]	**(37)**	**(40)**	**(22)**	**(9)**	**24**	**54**	**103**	**127**	**157**	**176**	**184**
Free Cash Flow [(2)]	**(37)**	**(40)**	**(23)**	**(11)**	**16**	**38**	**76**	**96**	**120**	**136**	**144**

(1) EBIT is defined as Ayala's revenues, less cost of goods sold and operating expenses.

(2) Free cash flow is defined as Ayala's EBIT plus tax expense (NOL adjusted) and depreciation and amortization, less increases in net working capital.

Certain Prospective Financial Information of Ayala

As a matter of course, Ayala does not publicly disclose long-term projections of future financial performance due to among other things, the inherent difficulty of predicting financial performance for future periods and the likelihood that the underlying assumptions and estimates may not be realized. However, in connection with the exploration of strategic alternatives as described in this proxy statement/prospectus, Ayala management prepared certain non-public, unaudited projections of financial performance for Ayala for the fiscal years ending December 31, 2023 through 2033, or the Ayala Projections, based on its view of the prospects of Ayala, and risk-adjusted these projections for Ayala's principal programs consisting of (i) AL 101 and AL 102, as described under the "—Opinion of Ayala's Financial Advisor —Torreya Capital, LLC." The Ayala Projections were based on certain internal assumptions about the probability of technical success and regulatory approval, launch timing, epidemiology, pricing, sales ramp, market growth, market share, competition, and other relevant factors relating to the commercialization of Ayala's product candidates.

The Ayala Projections were developed under the assumption of continued standalone operation and did not give effect to any changes or expenses as a result of the Merger or any other effects of the Merger or any impact should the Merger fail to be consummated. The Ayala Projections were prepared solely for internal use and are subjective in many respects. As a result, there can be no assurance that the forecasted results will be realized or that actual results will not be significantly higher or lower than estimated. Since the unaudited forecasted financial information covers multiple years, such information, by its nature, becomes less predictive with each successive year. The estimates and assumptions underlying the unaudited forecasted financial information involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions that may not materialize and are inherently subject to significant uncertainties and contingencies, all of which are difficult to predict and many of which are beyond Ayala's control. The Ayala Projections also reflect assumptions as to certain business decisions that are subject to change. Important factors that may affect actual results and cause the Ayala Projections to not be achieved include, but are not limited to: (1) conditions in the financing markets and Ayala's ability to access sufficient capital; (2) the timing of regulatory approvals and introduction of new products; (3) the market acceptance of new products; (4) the success of clinical testing; (5) the availability of third-party reimbursement; (6) the impact of competitive products and pricing; (7) the effect of regulatory actions; (8) the effect of global economic conditions; (9) changes in applicable laws, rules and regulations; (10) the early development stage of Ayala's product candidates and the corresponding time horizons to reach market and (11) other risk factors described in Ayala's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and Current Reports on Form 8-K, as well as "*Cautionary Statement Concerning Forward-Looking Statements*" located elsewhere in this proxy statement/prospectus. In addition, the Ayala Projections may be affected by Ayala's ability to achieve strategic goals, objectives and targets over the applicable period. Accordingly, there can be no assurance that the Ayala Projections will be realized and actual results may vary materially from those shown.

The prospective financial information included in this proxy statement/prospectus was not prepared with a view toward public dissemination or compliance with published guidelines of the SEC or established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information or generally accepted accounting principles, or GAAP, but, in the view of Ayala's management, was prepared on a reasonable basis, reflected, at the time the prospective financial information was prepared, the best currently available estimates and judgments, and presented, to the best of Ayala management's knowledge and belief at that time, the expected course of action and the expected future financial performance of Ayala. However, this information is not fact and should not be relied upon as being necessarily indicative of future results and readers of this proxy statement/prospectus are cautioned not to place undue reliance, if any, on the prospective financial information.

The tables below present a summary of the Ayala Projections. The summary below is included solely to give Ayala's stockholders access to certain long-term financial analyses and forecasts that were made available to the Ayala Board and Torreya for purposes of performing analyses underlying Torreya's opinion, and is not included in this proxy statement/prospectus to influence an Ayala stockholder's decision whether to vote for the Ayala Merger Proposal or for any other purpose. The inclusion of a summary of the Ayala Projections in this document does not constitute an admission or representation that the information is material. The inclusion of a summary of the Ayala Projections should not be regarded as an indication that Ayala and/or its affiliates, officers, directors, advisors or other representatives consider the Ayala Projections to be necessarily predictive of actual future events and this information should not be relied upon as such. None of Ayala and/or its affiliates, officers, directors, advisors or other representatives gives any stockholder of Ayala or any other person any assurance that actual results will not differ materially from the Ayala Projections. The Ayala Projections do not take into account any circumstances, transactions or events occurring after the date on which they were prepared. Some or all of the assumptions underlying the Ayala Projections may have changed since the date the Ayala Projections were prepared.

AYALA HAS NOT UPDATED AND DOES NOT INTEND TO UPDATE OR OTHERWISE REVISE THE UNAUDITED FORECASTED FINANCIAL INFORMATION TO REFLECT CIRCUMSTANCES EXISTING AFTER THE DATE WHEN MADE OR TO REFLECT THE OCCURRENCE OF FUTURE EVENTS, EVEN IN THE EVENT THAT ANY OR ALL OF THE ASSUMPTIONS UNDERLYING SUCH PROSPECTIVE FINANCIAL INFORMATION ARE NO LONGER APPROPRIATE.

Certain of the measures included in the Ayala Projections may be considered non-GAAP financial measures, including free cash flow. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non- GAAP financial measures as used by Ayala may not be comparable to similarly titled amounts used by other companies.

Financial measures provided to a financial advisor are excluded from the definition of non-GAAP financial measures and therefore, are not subject to SEC rules regarding disclosures of non-GAAP financial measures, which would otherwise require a reconciliation of a non-GAAP financial measure to a GAAP financial measure. Reconciliations of non-GAAP financial measures were not relied upon by Torreya for purposes of its financial analysis as described above in "*—Opinion of Ayala's Financial Advisor—Torreya Capital, LLC*" located elsewhere in this proxy statement/prospectus or by the Ayala Board in connection with its consideration of the Merger. Accordingly, Ayala has not provided a reconciliation of the non-GAAP financial measures included in the Ayala Projections.

For the foregoing and other reasons, readers of this proxy statement/prospectus are cautioned that the inclusion of a summary of the Ayala Projections in this proxy statement/prospectus should not be regarded as a representation or guarantee that the targets will be achieved nor that they should place undue reliance, if any, on the Ayala Projections. The Ayala Projections constitute forward-looking statements and are subject to risks and uncertainties that could cause actual results to differ materially from the projected results. See also "*Cautionary Statement Concerning Forward-Looking Statements*" located elsewhere in this proxy statement/prospectus.

Summary of the Ayala Projections

Set forth below is a summary of the Ayala Projections. The Ayala Projections reflect: (1) Ayala management's assessment of the commercial potential and probability of success for Ayala's lead product candidates, AL101 and AL102; (2) Ayala's existing and future net operating loss, or NOL, carryforwards, estimated using a starting NOL balance as of January 1, 2022 of $130 million; (3) Ayala's estimated cost of goods and operational costs, including research and development and general and administrative costs; (4) a tax rate of 21% for Ayala; (5) estimated royalties and milestone payments for Ayala and (6) capital expenditure and working capital estimates for Ayala.

($ in millions)	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
AL101 Revenue	**0**	**0**	**6**	**13**	**28**	**35**	**43**	**45**	**45**	**45**	**45**
AL102 Revenue	**0**	**0**	**0**	**13**	**37**	**79**	**128**	**173**	**212**	**243**	**255**
Total Cost of Goods Sold	0	0	0	1	2	4	6	9	11	13	14
Total Operating Expenses (Including Milestones and Royalties)	37	40	28	32	32	46	48	66	70	78	81
EBIT[(1)]	**(37)**	**(40)**	**(21)**	**(6)**	**31**	**65**	**117**	**144**	**176**	**198**	**205**
Free Cash Flow [(2)]	**(35)**	**(38)**	**(21)**	**(7)**	**27**	**58**	**107**	**132**	**136**	**153**	**162**

(1) EBIT is defined as Ayala's revenues, less cost of goods sold and operating expenses.

(2) Free cash flow is defined as Ayala's EBIT plus tax expense (NOL adjusted) and depreciation and amortization, less increases in net working capital.

Interests of Advaxis Directors and Executive Officers in the Merger

In considering the recommendation of the Advaxis Board with respect to issuing shares of Advaxis Common Stock in the Merger. The Advaxis stockholders should be aware that Advaxis' directors and executive officers have interests in the Merger that are different from, or in addition to, the interests of Advaxis' stockholders generally. These interests may present them with actual or potential conflicts of interest, and these interests, to the extent material, are described below.

Mr. Kenneth A. Berlin and Dr. Andres A. Gutierrez, M.D., Ph.D. may receive cash severance payments and other benefits pursuant to their respective employment agreements with the total value of these benefits for all of the executives being approximately $3.4 million (collectively, and not individually), including the value of any accelerated vesting of Advaxis equity awards held by those officers.

Additionally, pursuant to the terms of the Merger Agreement:

- Kenneth A. Berlin, Roni Appel, Dr. Samir Khleif and Dr. David Sidransky, members of the Advaxis Board, will continue as directors after the Effective Time, and following the closing of the Merger, Roni Appel, Dr. Samir Khleif and Dr. Sidransky will each be eligible to be compensated as a non-employee director of Advaxis pursuant to the Advaxis compensation policy that is expected to remain in place following the Effective Time.
- Dr. Sidransky is a member of the Ayala Board and is the co-founder of one of Ayala's largest investors.
- Under the Merger Agreement, Advaxis' directors and executive officers are entitled to continued indemnification, expense advancement and insurance coverage.
- The vesting of approximately 208 options granted to Kenneth A. Berlin will accelerate in connection with the closing of the Merger.
- Kenneth A. Berlin, Andres Gutierrez, and Igor Gitelman will continue as executive officers of the combined company after the Merger, and, following the closing of the Merger.

Advaxis intends to provide its Interim Chief Financial Officer, Igor Gitelman, with a one-time bonus equal to thirty percent of his salary upon closing of the Merger.

As of October 31, 2022, the directors and executive officers of Advaxis owned, in the aggregate, less than 1% of the outstanding voting shares of Advaxis Common Stock. The Advaxis Board was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement.

The Advaxis Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the Merger and the Merger Agreement.

Treatment of Advaxis Options

Each option to purchase Advaxis Common Stock that is issued and outstanding at the Effective Time will remain issued and outstanding and such shares will be unaffected by the Merger; provided that the number of shares of Advaxis Common Stock underlying such options, and the exercise prices for such options will be appropriately adjusted if Advaxis obtains stockholder approval of, and implements, a reverse stock split.

The table below shows the outstanding options for each of the named executive officers as of the date hereof.

Name	Number of Vested Options Held	Weighted Average Exercise Price of Vested Options Held	Number of Unvested Options Held	Weighted Average Exercise Price of Unvested Options
Executive Officers				
Kenneth Berlin	1,934	$ 737.09	208(1)	$ 52.80
Andres Gutierrez	1,042	$ 481.31	208	$ 52.80
Igor Gitelman	209	31.20	416	$ 31.20

(1) The vesting of these options will accelerate in connection with the closing of the Merger.

Director Positions Following the Merger

David Sidransky, Roni Appel, and Dr. Samir Khleif are currently non-employee directors of Advaxis and will continue as directors of the combined company after the Effective Time. Kenneth A. Berlin is currently an officer and director of Advaxis and will continue as an officer and director of the combined company.

Indemnification and Insurance

For a discussion of the indemnification and insurance provisions related to the Advaxis directors and officers under the Merger Agreement, please see the section titled "*The Merger Agreement—Indemnification; Directors' and Officers' Insurance*" beginning on page 198 below.

Executive Employment Arrangements

Advaxis has an employment agreement with its President and Chief Executive Officer, Mr. Berlin, effective April 23, 2018 and amended on September 12, 2022. Advaxis also has an employment agreement with its Executive Vice President and Chief Medical Officer, Mr. Gutierrez, effective April 23, 2018. Pursuant to the agreements, in the event the named executive officer's employment is terminated without Just Cause, or if the executive voluntarily resigns with Good Reason, (or if the named executive officer's employment is terminated due to disability (all as defined in their respective employment agreements), and so long as the named executive officer executes a confidential separation and release agreement, in addition to the applicable base salary, plus any expenses that have been earned as of the date of such termination, the named executive officer is entitled to the following severance benefits: (i) 15 and 12 months of base salary payable in equal monthly installments to Mr. Berlin and Mr. Gutierrez, respectively, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, (iii) continued health and welfare benefits for 15 and 12 months to Mr. Berlin and Mr. Gutierrez, respectively, and (iv) full vesting of all stock options and stock awards (with extension of the exercise period for stock options by two years).

In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control (as defined in Mr. Berlin's employment agreement) and ending 18 months after the Change in Control (such period, the "CIC Protection Period"), or if Mr. Berlin voluntarily resigns with Good Reason during the CIC Protection Period, and provided that Mr. Berlin continues to comply with certain covenants set forth in his employment agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Berlin is entitled to the following severance benefits: (i) an amount equal to 2 times the sum of the applicable base salary plus an amount equal to Mr. Berlin's target bonus, payable in a single lump sum within 60 days of the termination, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator is 365, (iii) continued health and welfare benefits for 24 months, and (iv) full vesting and exercisability of all stock options and stock awards.

Limitations of Liability and Indemnification

In addition to the indemnification obligations required by the amended and restated certificate of incorporation and third amended and restated bylaws of Advaxis, Advaxis has offered to enter into indemnification agreements with all directors and has entered into an indemnification agreement with all directors except Samir Khleif. Advaxis has also entered into an indemnification agreement with three of its executive officers, Igor Gitelman, Ken Berlin and Andres Gutierrez. These agreements provide for the indemnification of Advaxis' directors and executive officers for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were agents of Advaxis. Advaxis believes that these amended and restated certificate of incorporation provisions, third amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Interests of Ayala Directors and Executive Officers in the Merger

In considering the recommendation of the Ayala Board with respect to the Merger, Ayala stockholders should be aware that certain members of the Ayala Board and certain executive officers of Ayala may have interests in the Merger that are different from, or are in addition to, interests of Ayala stockholders generally. These interests may present such officers and directors with actual or potential conflicts of interest. The Ayala Board was aware of these interests during its deliberations on the merits of the Merger, in making its decisions in approving the Merger, the Merger Agreement, and the other Transactions, and in deciding to recommend that the Ayala stockholders vote to adopt and approve the Merger Agreement.

Continued Indemnification and Insurance

The Merger Agreement provides that all rights to indemnification by Ayala existing in favor of Ayala's directors and executive officers for their acts and omissions as directors and officers of Ayala occurring prior to the Effective Time, as provided in Ayala's certificate of incorporation and bylaws in effect as of the date of the Merger Agreement), and as provided in any indemnification agreements between Ayala and such persons, in each case as in effect as of the date of the Merger Agreement, will survive the Merger and be observed by the combined company to the fullest extent permitted by Delaware law for a period of six years from the Effective Date.

In addition, Ayala will purchase a six-year "tail" insurance policy for the existing directors' and officers' liability insurance maintained by Ayala, at a premium not to exceed 300% of the annual premiums paid by Ayala for such insurance. The costs of the "tail" policy will be split evenly between Ayala and Advaxis.

Executive Officer Employment Agreements

Each of Ayala's executive officers has entered into an employment agreement under which the executive officer is entitled to severance benefits upon a qualifying termination of employment. Under the terms of their employment agreements, if an executive officer's employment is terminated without "cause" or by the executive officer for "justified reason" (as such terms are defined in the relevant employment agreement), on or within 12 months following a Merger/Sale (as defined in Ayala's 2017 Stock Incentive Plan), then the executive officer will be entitled to receive a cash amount equal to the sum of the executive officer's annual base salary and target annual bonus for the year of termination and accelerated vesting of all of the executive officer's unvested equity awards (the "Special Termination Benefits").

On October 18, 2022, Ayala-Oncology Israel Ltd. ("Ayala-Oncology") entered into a letter agreement with each of Dr. Mamluk and Mr. Maimon, and Ayala entered into a letter agreement with Gary Gordon, Chief Medical Officer of Ayala (collectively, the "Letter Agreements"). The Letter Agreements provide that Dr. Mamluk and Mr. Maimon will terminate employment with Ayala-Oncology as of immediately following the closing of the Merger and, subject to the execution and non-revocation of a waiver and release in favor of Ayala and its affiliates, will be entitled to receive the Special Termination Benefits provided under their respective employment agreements, consisting of a cash payment equal to the sum of their respective annual salary and target annual bonus amounts and accelerated vesting of all unvested equity awards they hold, with the cash severance being paid in equal installment payments in accordance with Ayala-Oncology's normal payroll practices over a 12-month period. The Letter Agreement with Dr. Gordon provides that in the event his employment is terminated without cause or he resigns for justified reason within 12 months following the Merger, subject to the execution and non-revocation of a waiver and release in favor of Ayala and its affiliates, he will be entitled to receive the Special Termination Benefits provided under his employment agreement, consisting of a cash payment equal to the sum of their respective annual salary and target annual bonus amounts and accelerated vesting of all unvested equity awards they hold, with the cash severance being paid in equal installment payments in accordance with Ayala's normal payroll practices over a 12-month period, provided that no demotion in position or reduction in duties or authority in connection with the Merger that is agreed to by Dr. Gordon will provide a basis for a justified reason resignation.

Further, under their respective Letter Agreement, each of Dr. Mamluk, Mr. Maimon and Dr. Gordon have agreed, during a 12-month period following the closing of the Merger, not to transfer any shares of Ayala or Advaxis Common Stock received in connection with their unvested equity awards that accelerate upon a qualifying termination of employment within 12 months following the Merger, other than for the payment of any taxes or exercise price associated with the exercise, vesting or settlement of the accelerated awards.

Treatment of Outstanding Equity Awards

The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) each Ayala Option will be substituted and converted automatically into an Advaxis Replacement Option to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the Effective Time, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the Effective Time, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (ii) each restricted stock unit of Ayala RSU outstanding immediately prior to the Effective Time, whether or not vested, will be substituted and converted automatically into an Adjusted RSU equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the Effective Time by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share. As outstanding shares of Ayala Common Stock, all restricted stock awards ("Ayala Restricted Stock") that are outstanding will be substituted and converted automatically into the right to receive a number of shares of Advaxis Common Stock equal to the Exchange Ratio, provided, however that such stock merger consideration is subject to further adjustment as described in this proxy statement/prospectus. In accordance with the terms of the applicable restricted stock award agreement, these shares of Advaxis Common Stock shall be subject to the terms and conditions applicable to the corresponding Ayala Restricted Stock under, as applicable, Ayala's 2017 Stock Incentive Plan, as amended, and the agreements evidencing grants thereunder, including vesting terms.

The table below sets forth, with respect to each of Ayala's executive officers and directors, the total number of shares of Ayala Options and Ayala Restricted Stock, per individual, expected to be held on the completion of the Merger, assuming (i) the Merger is completed on October 31, 2022 (solely for purposes of the table below) and (ii) the number of equity compensation awards for each executive officer and director on the completion of the Merger is equal to the number of shares of Ayala Common Stock and equity compensation awards that were outstanding as of October 31, 2022. None of Ayala's executive officers and directors is expected to hold Ayala RSUs on completion of the Merger.

Certain equity compensation awards previously made by Ayala to members of its board and its officers will vest in full upon the Effective Time under their original terms. The number of equity compensation awards that will vest solely upon the completion of the Merger are indicated by footnote in the table below. In addition, each executive officer is entitled to accelerated vesting on unvested awards in the event of a qualifying termination, as described in "*Interests of Ayala Directors and Executive Officers in the Merger—Executive Officer Employment Agreements*."

Name	Number of Shares of Ayala Restricted Stock	Number of Ayala Options
Executive Officers		
Roni Mamluk, Ph.D., President and Chief Executive Officer	30,852(1)	47,181(1)
Yossi Maimon, CPA, M.B.A., Chief Financial Officer	10,417(1)	24,562(1)
Gary Gordon, M.D., Ph.D., Chief Medical Officer	9,487	26,257
Directors		
Vered Bisker-Leib, Ph.D., M.B.A.	—	3,981
Murray A. Goldberg	—	7,963
David Sidransky, M.D.	—	4,684
Todd Sone(2)	—	7,963
Robert Spiegel, M.D., F.A.C.P.	—	1,171

(1) Equity compensation award will vest in full upon the completion of the Merger or upon an agreed termination of employment occurring immediately following the Merger.
(2) Mr. Sone resigned from the Ayala Board effective July 28, 2021.

Delisting and Deregistration of Ayala Common Stock

When the Merger is completed, the shares of Ayala Common Stock currently listed on Nasdaq will cease to be listed on Nasdaq and will be de-registered under the Exchange Act.

Restrictions on Sales of Advaxis Common Stock Received in the Merger

The Advaxis Common Stock to be issued in connection with the Merger will be freely transferable under the Securities Act, except for Advaxis Common Stock issued to any holder who may be deemed to be an "affiliate" of Advaxis for purposes of Rule 144 under the Securities Act. Persons who may be deemed to be affiliates include individuals or entities that control, are controlled by, or are under common control with Advaxis and may include the senior management, directors and significant stockholders of Advaxis. Securities held by an affiliate of Advaxis may be resold or otherwise transferred without registration in compliance with the volume limitations, manner of sale requirements, notice requirements and other requirements of Rule 144 under the Securities Act or as otherwise permitted under the Securities Act. This proxy statement/prospectus does not cover resales of Advaxis Common Stock received upon completion of the Merger by any person, and no person is authorized to make any use of this proxy statement/prospectus in connection with a resale.

Regulatory Approvals

The conditions to the closing of the Merger include (i) the effectiveness of the Registration Statement registering the shares of Advaxis Common Stock to be issued in connection with the Merger; (ii) receipt of all required state securities or "blue sky" authorizations for the issuance of such shares of Advaxis Common Stock, except for such authorizations the lack of receipt of which would not reasonably be expected to have a material adverse impact on any of the parties to the Merger Agreement or their respective affiliates.

Anticipated Accounting Treatment

The Merger will be accounted for as a reverse acquisition in accordance with U.S. GAAP. Under this method of accounting, Ayala will be deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectations that, immediately following the Merger (i) Ayala's stockholders are expected to own approximately 62.5% of the voting interests of the combined company immediately following the closing of the Merger; (ii) directors appointed by Ayala will hold more board seats in the combined company than Advaxis; and (iii) Advaxis intends to seek stockholder approval to change its name to "Ayala Pharmaceuticals, Inc." assuming the Merger is approved by Ayala stockholders. Accordingly, for accounting purposes, the Merger will be treated as the equivalent of Ayala issuing stock to acquire the net assets of Advaxis. As a result of the Merger, the net assets of Advaxis will be recorded at their acquisition-date fair value in the financial statements of Ayala and the reported operating results prior to the Merger will be those of Ayala. See the section titled "*Unaudited Pro Forma Condensed Combined Financial Information*" elsewhere in this proxy statement/prospectus for additional information.

Potential Listing of Common Stock of Combined Company

Shares of Advaxis Common Stock are currently quoted on OTCQX under the symbol "ADXS." As of December 9, 2022, the bid price of Advaxis' Common Stock was $1.62 on OTCQX.

Assuming the Merger is approved by Ayala stockholders, Advaxis intends to file an initial listing application with Nasdaq prior to the closing of the Merger, and to undertake the actions necessary to allow the stock of the combined company to be listed on The Nasdaq Capital Market as of the closing of the Merger or promptly thereafter. However, because Advaxis is not currently listed on Nasdaq, the combined company will be required to meet the initial listing standards of The Nasdaq Capital Market applicable to companies seeking to uplist one or more securities from another U.S. market, such as the OTCQX.

Accordingly, Advaxis must meet all the requirements set forth in Rule 5505(a) and at least one of the Standards in Rule 5505(b).

The listing standards of Nasdaq Rule 5505(a) will require Advaxis to have, among other things: (1) a $4.00 per share minimum bid price upon the closing of the Merger; (2) at least 1,000,000 Unrestricted Publicly held Shares; (3) at least 300 Round Lot Holders, and at least 50% of such Round Lot Holders must each hold Unrestricted Securities with a Market Value of at least $2,500; (4) at least three registered and active Market Makers; and (5) a minimum average daily trading volume of 2,000 shares over the 30 trading day period prior to listing, with trading occurring on more than half of those 30 days.

Advaxis must also satisfy at least one of the Rule 5505(b) requirements, which lists an: Equity Standard, Market Value of Listed Securities Standard, and Net Income Standard.

In order to achieve compliance with these listing standards, Advaxis and the combined company will need to undertake certain actions, including Advaxis obtaining the approval of its stockholders, at a special meeting, to undertake a reverse split of the Advaxis Common Stock, which special meeting Advaxis intends to hold at approximately the same time that Ayala holds its meeting to approve the Merger Agreement.

In addition, the combined company expects to need to raise additional capital in order to meeting the listing standards, and to undertake efforts to do so prior to or simultaneously with the closing of the Merger.

If the Nasdaq listing application is ultimately approved, Advaxis anticipates that the Common Stock of the combined company will be uplisted on The Nasdaq Capital Market under the trading symbol "AYRX". There can be no assurance that these efforts to uplist will be successful.

Appraisal Rights and Dissenters' Rights

Under the DGCL, Advaxis stockholders are not entitled to appraisal rights in connection with the Merger.

If the Merger is completed, Ayala stockholders who have not waived such rights are entitled to appraisal rights under Section 262 of the DGCL, referred to as Section 262, provided that they comply with the conditions established by Section 262.

This section is intended to provide a brief summary of the material provisions of the Delaware statutory procedures that a stockholder must follow in order to seek and perfect appraisal rights. However, this summary is not a complete statement of all applicable requirements, and it is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this joint proxy statement/prospectus as Annex F. The following summary does not constitute any legal or other advice, nor does it constitute a recommendation that Ayala stockholders exercise their appraisal rights under Section 262. Failure to follow precisely any of the statutory procedures set forth in Annex F may result in a termination or waiver of appraisal rights.

A record holder of shares of Ayala capital stock who makes the demand described below with respect to such shares, who continuously holds such shares through the Effective time, who submits a written demand for appraisal to Ayala in compliance with the statutory requirements of Section 262, and who does not submit a proxy or vote in favor of the Ayala Merger Proposal or consent thereto in writing will be entitled to an appraisal by the Delaware Court of Chancery of the fair value of his, her or its shares of Ayala capital stock in lieu of the consideration that such stockholder would otherwise be entitled to receive pursuant to the Merger Agreement. All references in this summary of appraisal rights to a "stockholder" or "holders of shares of Ayala capital stock" are to the record holder or holders of shares of Ayala capital stock.

Under Section 262, because the Merger Agreement is to be submitted for adoption at the Ayala Special Meeting, not fewer than 20 days prior to the meeting, Ayala must notify each of the holders of its stock for whom appraisal rights are available that such appraisal rights are available and include in such notice a copy of Section 262. This joint proxy statement/prospectus constitutes such notice to the record holders of Ayala capital stock and a copy of Section 262 is attached to this joint proxy statement/prospectus as Annex F.

Ayala stockholders who desire to exercise their appraisal rights must satisfy all of the conditions of Section 262. Those conditions include the following:

Ayala stockholders electing to exercise appraisal rights must not submit a proxy or vote "for" the Ayala Merger Proposal. Submitting a proxy or voting "for" the Ayala Merger Proposal will result in the waiver of appraisal rights. Also, because a submitted proxy not marked "against" or "abstain" will be voted "for" the Ayala Merger Proposal, the submission of a proxy not marked "against" or "abstain" will result in the waiver of appraisal rights.

A written demand for appraisal of shares of Ayala capital stock must be delivered to Ayala before the taking of the vote on the Ayala Merger Proposal at the Ayala Special Meeting. The written demand for appraisal should specify the Ayala stockholder's name and mailing address, and that such stockholder is thereby demanding appraisal of his, her or its shares of Ayala capital stock. The written demand for appraisal of shares of Ayala capital stock is in addition to and separate from a vote against the Ayala Merger Proposal or an abstention from such vote. Failure to return your proxy, voting against, or abstaining from voting on, the Ayala Merger Proposal will not satisfy your obligation to make a written demand for appraisal. Failure to make a written demand for appraisal prior to the taking of the vote on the Ayala Merger Proposal at the Ayala Special Meeting will constitute a waiver of appraisal rights.

A demand for appraisal must be executed by or for the Ayala stockholder of record, fully and correctly, as such stockholder's name appears on the stock certificate. If the shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, this demand must be executed by or for the fiduciary. If the shares of Ayala capital stock are owned by or for more than one person, as in a joint tenancy or tenancy in common, such demand must be executed by or for all joint owners. An authorized agent, including an agent for two or more joint owners, may execute the demand for appraisal for an Ayala stockholder of record. However, the agent must identify such record holder and expressly disclose the fact that, in exercising the demand, he is acting as agent for such record holder. A person having a beneficial interest in Ayala capital stock held of record in the name of another person, such as a broker or nominee, must act promptly to cause the record holder to follow the steps summarized below in a timely manner to perfect appraisal rights on behalf of the beneficial owners.

An Ayala stockholder who elects to exercise appraisal rights should mail or deliver his, her or its written demand to Ayala, Oppenheimer 4, Rehovot 7670104, Israel, Attention: Chief Financial Officer.

Within 10 days after the Effective Time, Ayala must provide notice of the Effective Time to all Ayala stockholders who have complied with Section 262 and have not voted in favor of the Ayala Merger Proposal.

Within 120 days after the Effective Time, either Ayala or any Ayala stockholder who has complied with the required conditions of Section 262 may file a petition in the Delaware Court of Chancery, with a copy served on Ayala in the case of a petition filed by an Ayala stockholder, demanding a determination of the fair value of the shares of Ayala capital stock held by all Ayala stockholders seeking to exercise appraisal rights. There is no present intent on the part of Ayala to file an appraisal petition, and Ayala stockholders seeking to exercise appraisal rights should not assume that Ayala will file such a petition or that Ayala will initiate any negotiations with respect to the fair value of such shares. Accordingly, Ayala stockholders who desire to have their shares of Ayala capital stock appraised should initiate any petitions necessary for the perfection of their appraisal rights within the time periods and in the manner prescribed in Section 262. Failure to file a petition for appraisal within the time period specified in Section 262 could result in a loss of appraisal rights.

Within 120 days after the Effective Time, any Ayala stockholder who has satisfied the requirements of Section 262 will be entitled, upon written request, to receive from Ayala a statement setting forth the aggregate number of shares of Ayala Common Stock and Ayala preferred stock not voting in favor of the Ayala Merger Proposal and with respect to which demands for appraisal were received by Ayala and the aggregate number of holders of such shares. Such statement must be mailed within 10 days after the Ayala stockholder's request has been received by Ayala or within 10 days after the expiration of the period for the delivery of demands as described above, whichever is later.

If a petition for an appraisal is timely filed and a copy thereof is served upon Ayala, Ayala will then be obligated, within 20 days after such service, to file in the office of the Delaware Register in Chancery (the "Register") a duly verified list containing the names and addresses of all Ayala stockholders who have demanded an appraisal of their shares of Ayala capital stock and with whom agreements as to the value of such shares have not been reached. Upon notice to the Ayala stockholders, as required by the Delaware Court of Chancery, at a hearing on such petition, the Delaware Court of Chancery will determine which Ayala stockholders are entitled to appraisal rights. The Delaware Court of Chancery may require the Ayala stockholders who have demanded an appraisal for their shares of Ayala capital stock and who hold such stock represented by certificates to submit their certificates of stock to the Register for notation thereon of the pendency of the appraisal proceedings; and if any Ayala stockholder fails to comply with such direction, the Delaware Court of Chancery may dismiss the proceedings as to such stockholder. Where proceedings are not dismissed, the Delaware Court of Chancery will appraise the shares of Ayala capital stock owned by such stockholders, determining the fair value of such shares exclusive of any element of value arising from the accomplishment or expectation of the Merger. When the fair value has been determined, the Delaware Court of Chancery will direct the payment of such value upon surrender by those stockholders of the certificates representing their shares of Ayala capital stock. Unless the Delaware Court of Chancery in its discretion determines otherwise for good cause shown, interest from the Effective Time through the date of payment of the judgment will be compounded quarterly and will accrue at 5 percent over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the Effective Time and the date of payment of the judgment.

Although the board of directors of Ayala believes that the merger consideration is fair, no representation is made as to the outcome of the appraisal of fair value as would be determined by the Delaware Court of Chancery, and Ayala stockholders should recognize that such an appraisal could result in a determination of a value higher or lower than, or the same as, the consideration they would receive pursuant to the Merger Agreement. Moreover, Ayala does not anticipate offering more than the merger consideration to any Ayala stockholder exercising appraisal rights and reserves the right to assert in any appraisal proceeding, that, for purposes of Section 262, the "fair value" of a share of Ayala capital stock is less than the merger consideration. In determining "fair value," the Delaware Court of Chancery is required to take into account all relevant factors. In Weinberger v. UOP, Inc., the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered and that "fair price obviously requires consideration of all relevant factors involving the value of a company." The Delaware Supreme Court has stated that in making this determination of fair value, the court must consider market value, asset value, dividends, earnings prospects, the nature of the enterprise and any other facts which could be ascertained as of the date of the Merger which shed any light on the future prospects of the merged corporation. Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the Merger." In Cede & Co. v. Technicolor, Inc., the Delaware Supreme Court stated that such exclusion is a "narrow exclusion that does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In Weinberger, the Delaware Supreme Court also stated that "elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the Merger and not the product of speculation, may be considered." In addition, Delaware courts have decided that the statutory appraisal remedy, depending on factual circumstances, may or may not be a dissenting stockholder's exclusive remedy.

The cost of the appraisal proceeding, which does not include attorneys' or experts' fees, may be determined by the Delaware Court of Chancery and imposed upon the dissenting Ayala stockholder(s) and/or Ayala as the Delaware Court of Chancery deems equitable under the circumstances. Each dissenting Ayala stockholder is responsible for his, her or its attorneys' and expert witness fees and expenses, although, upon application of a dissenting Ayala stockholder, the Delaware Court of Chancery may order that all or a portion of the expenses incurred by any dissenting Ayala stockholder in connection with the appraisal proceeding, including without limitation reasonable attorneys' fees and the fees and expenses of experts, be charged pro rata against the value of all shares of Ayala capital stock entitled to appraisal.

Any Ayala stockholder who has duly demanded appraisal in compliance with Section 262 will not, after the Effective Time, be entitled to vote for any purpose any shares of Ayala capital stock subject to such demand or to receive payment of dividends or other distributions on such shares, except for dividends or distributions payable to Ayala stockholders of record at a date prior to the Effective Time.

At any time within 60 days after the Effective Time, any Ayala stockholder will have the right to withdraw his, her or its demand for appraisal and to accept the terms offered in the Merger Agreement. After this period, an Ayala stockholder may withdraw his, her or its demand for appraisal and receive payment for his, her or its shares as provided in the Merger Agreement only with the consent of Ayala. If no petition for appraisal is filed with the Delaware Court of Chancery within 120 days after the Effective Time, or if any Ayala stockholder otherwise fails to perfect, successfully withdraws, or loses such holder's appraisal rights, then such stockholder's right to appraisal will cease and such stockholder's shares of Ayala capital stock will be deemed to have been converted at the Effective Time into the right to receive the consideration that such Ayala stockholder would otherwise be entitled to receive pursuant to the Merger Agreement. Inasmuch as Ayala has no obligation to file such a petition, any Ayala stockholder who desires a petition to be filed is advised to file it on a timely basis. Any Ayala stockholder may withdraw such stockholder's demand for appraisal by delivering to Ayala a written withdrawal of his, her or its demand for appraisal and acceptance of the merger consideration, except that (i) any such attempt to withdraw made more than 60 days after the Effective Time will require written approval of Ayala and (ii) no appraisal proceeding in the Delaware Court of Chancery will be dismissed as to any Ayala stockholder who commenced or joined such proceeding as a named party without the approval of the Delaware Court of Chancery, and such approval may be conditioned upon such terms as the Delaware Court of Chancery deems just.

Failure by any Ayala stockholder to comply fully with the procedures described above and set forth in Annex F to this joint proxy statement/prospectus may result in the loss of such stockholder's appraisal rights. In view of the complexity of exercising appraisal rights under Delaware law, any Ayala stockholder considering exercising these rights should consult with legal counsel.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER

The following is a general discussion of material U.S. federal income tax consequences of the Merger to U.S. Holders (as defined below) of Ayala Common Stock that exchange their Ayala Common Stock for Advaxis Common Stock in the Merger. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the IRS, in each case as in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a U.S. Holder. Ayala has not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the Merger. This discussion assumes that the Merger will be consummated in accordance with the Merger Agreement and as further described in this joint proxy statement/prospectus. This discussion is not a complete description of all of the tax consequences of the Merger and, in particular, does not address any tax consequences arising under the unearned income Medicare contribution tax on net investment income or the alternative minimum tax, nor does it address any tax consequences arising under the laws of any state, local or non-U.S. jurisdiction, or under any U.S. federal laws other than those pertaining to the income tax.

This discussion applies only to U.S. Holders of shares of Ayala Common Stock who hold such shares as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). Further, this discussion does not purport to address all aspects of U.S. federal income taxation that may be relevant to U.S. Holders of Ayala Common Stock in light of their particular circumstances and does not apply to U.S. Holders of Ayala Common Stock subject to special treatment under the U.S. federal income tax laws including, without limitation:

- banks, insurance companies and other financial institutions;
- tax-exempt and governmental organizations;
- partnerships, S corporations and other pass-through entities (and investors therein);
- regulated investment companies and real estate investment trusts;
- controlled foreign corporations and passive foreign investment companies;
- brokers and dealers in stocks, securities, commodities, or currencies;
- traders in securities that elect to apply a mark-to-market method of accounting;
- persons who acquired Ayala Common Stock pursuant to the exercise of employee stock options, through a tax qualified retirement plan or otherwise as compensation;
- persons who actually or constructively own more than 1% of the outstanding stock of Ayala;
- persons whose functional currency is not the U.S. dollar;
- persons who hold Ayala Common Stock as part of a hedge, straddle, constructive sale, conversion, or other integrated transaction;
- U.S. expatriates; and
- persons holding Ayala Common Stock who exercise dissenters' rights.

For purposes of this discussion, the term "U.S. Holder" means a beneficial owner of Ayala Common Stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or entity treated as a corporation for U.S. federal income tax purposes, organized under the laws of the United States, any state thereof or the District of Columbia;
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) or (ii) has made a valid election to be treated as a United States person for U.S. federal income tax purposes; or
- an estate, the income of which is subject to U.S. federal income tax regardless of its source.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds Ayala Common Stock, the tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Any entity treated as a partnership for U.S. federal income tax purposes that holds Ayala Common Stock and any partners in such partnership should consult their tax advisors regarding the tax consequences of the Merger to them.

THE FOLLOWING DISCUSSION DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE POTENTIAL TAX CONSEQUENCES OF THE MERGER. ALL HOLDERS OF AYALA COMMON STOCK SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF THE MERGER, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S., AND OTHER TAX LAWS.

U.S. Federal Income Tax Consequences of the Merger to U.S. Holders of Ayala Common Stock

The Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Code. The completion of the Merger is, however, not conditioned on the Merger qualifying as a "reorganization" within the meaning of Section 368(a) of the Code or upon the receipt of an opinion of counsel to that effect. No assurance can be given that the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code. Neither Advaxis nor Ayala intends to obtain a ruling from the IRS with respect to the tax consequences of the Merger. If the IRS were to successfully challenge whether the Merger qualifies as a "reorganization," the tax consequences would differ materially from those described in this joint proxy statement/prospectus as discussed below under "— *Tax Consequences if the Merger Fails to Qualify as a Reorganization*."

Assuming that the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code, generally, a U.S. Holder of Ayala Common Stock that exchanges their Ayala Common Stock for Advaxis Common Stock in the Merger:

- will not recognize any gain or loss upon the exchange of Ayala Common Stock for Advaxis Common Stock in the Merger, except with respect to cash received in lieu of fractional shares of Advaxis Common Stock (as discussed below);
- will have a tax basis in the Advaxis Common Stock received in the Merger (including fractional shares of Advaxis Common Stock for which cash is received) equal to the tax basis of the Ayala Common Stock surrendered in exchange therefor;
- will have a holding period for the Advaxis Common Stock received in the Merger (including fractional shares of Advaxis Common Stock for which cash is received) that includes its holding period for its Ayala Common Stock surrendered in exchange therefor.

If holders of Ayala Common Stock acquired different blocks of Ayala Common Stock at different times or at different prices, any gain will be determined separately with respect to each block of Ayala Common Stock, and such holders' basis and holding period in such holders' Advaxis Common Stock may be determined with reference to each block of Ayala Common Stock exchanged therefor. Any such holders should consult their tax advisors regarding the manner in which Advaxis Common Stock received in the exchange should be allocated among different blocks of Ayala Common Stock and with respect to identifying the bases or holding periods of the particular shares of Advaxis Common Stock received in the Merger.

Cash in Lieu of Fractional Shares

A U.S. Holder that receives cash in lieu of a fractional share of Advaxis Common Stock in the Merger will generally be treated as having received the fractional share pursuant to the Merger and then as having exchanged such fractional share with Advaxis for cash, and will generally recognize capital gain or loss measured by the difference between the cash received for such fractional share of Advaxis Common Stock and the U.S. Holder's tax basis in the fractional share of Advaxis Common Stock. Such capital gain or loss will generally be long-term capital gain or loss if the holding period for such fractional share of Advaxis Common Stock is more than one year. The deductibility of capital losses is subject to limitations.

Tax Consequences if the Merger Fails to Qualify as a Reorganization

If the Merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code, a U.S. Holder generally would recognize gain or loss for U.S. federal income tax purposes on each share of Ayala Common Stock surrendered in the Merger in an amount equal to the difference between the fair market value, at the time of the Merger, of the Advaxis Common Stock received in the Merger (including any cash received in lieu of a fractional share of Advaxis Common Stock) and such U.S. Holder's tax basis in the share of Ayala Common Stock surrendered in the Merger. Gain or loss must be calculated separately for each block of Ayala Common Stock exchanged by such U.S. Holder if such blocks were acquired at different times or for different prices. Any gain or loss recognized generally would be capital gain or loss, and generally would be long-term capital gain or loss if the U.S. Holder's holding period in a particular block of Ayala Common Stock is more than one year at the Effective Time. Long-term capital gain of certain non-corporate taxpayers, including individuals, generally is taxed at reduced U.S. federal income tax rates. The deductibility of capital losses is subject to limitations. A U.S. Holder's tax basis in Advaxis Common Stock received in the Merger would be equal to the fair market value thereof as of the Effective Time, and such U.S. Holder's holding period in such Advaxis Common Stock would begin on the day following the Merger.

Information Reporting and Backup Withholding

U.S. Holders may be subject to information reporting and backup withholding of U.S. federal income tax with respect to any cash received in the Merger, including any cash received in lieu of fractional shares of Advaxis Common Stock. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and certifies that it is not subject to backup withholding on IRS Form W-9 or is otherwise exempt from backup withholding and provides proof of the applicable exemption. Backup withholding is not an additional tax and any amounts withheld will be allowed as a refund or credit against the U.S. Holder's U.S. federal income tax liability, if any, provided that such U.S. Holder timely furnishes the required information to the IRS.

THE ABOVE DISCUSSION OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSTRUED AS, TAX ADVICE. ALL HOLDERS OF AYALA COMMON STOCK SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES, OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S., OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached to this proxy statement/prospectus as Annex A and is incorporated by reference into this proxy statement/prospectus. The Merger Agreement has been attached to this proxy statement/prospectus to provide you with information regarding its terms. It is not intended to provide any other factual information about Advaxis, Ayala or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement.

The Merger Agreement contains representations and warranties that Advaxis and Merger Sub, on the one hand, and Ayala, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Advaxis and Ayala do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Advaxis or Ayala, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Advaxis, and Merger Sub and Ayala, and are modified by the disclosure schedules.

General

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Advaxis formed by Advaxis in connection with the Merger under the laws of the state of Delaware, will merge with and into Ayala, with Ayala surviving as a wholly owned subsidiary of Advaxis.

Merger Consideration

At the Effective Time:

- each issued and outstanding share of common stock of Ayala (including restricted stock issued by Ayala under its 2017 Stock Incentive Plan and excluding certain shares of Ayala Common Stock that may be cancelled pursuant to the terms and conditions of the Merger Agreement) shall by virtue of the Merger and without any action on the part of the holder thereof, be automatically converted into the right to receive a number of shares of Advaxis Common Stock equal to the Exchange Ratio, which was 0.1874 shares of Advaxis Common Stock as of the date of the Merger Agreement, and may be adjusted at the closing of the Merger based on the formula set forth in the Merger Agreement and described further below, and shall thereafter be cancelled and cease to exist;

- each share of common stock, par value $0.01 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be automatically and without further action converted into and become one validly issued, fully paid and non-assessable ordinary share of common stock, par value $0.01 per share, of the surviving company of the Merger;

- each option to purchase shares of Ayala Common Stock that is outstanding and unexercised immediately prior to the Effective Time will automatically and without any action on the part of Advaxis, Ayala or the holder thereof, be converted into an option to purchase (A) that number of shares of Advaxis Common Stock (rounded down to the nearest whole share) equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such option immediately prior to the Effective Time by (ii) the Exchange Ratio, (B) at a per share exercise price equal to the quotient obtained by dividing (i) the exercise price per share of Ayala Common Stock at which such option was exercisable immediately prior to the Effective Time by (ii) the Exchange Ratio (rounding the resulting exercise price up to the nearest whole cent). The terms and conditions applicable to the Ayala Options, including any restrictions on the exercise thereof will continue following the conversion and the term, exercisability and other provisions of such options will generally remain unchanged;

- each Ayala warrant that is outstanding and unexercised immediately prior to the Effective Time shall be treated in accordance with its terms; and

- each Ayala RSU that is outstanding immediately prior to the Effective Time will, automatically and without any action on the part of the Advaxis, Ayala or the holder thereof, be converted into an Adjusted RSU for (A) such number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU by (ii) the Exchange Ratio (rounding the resulting number of shares down to the nearest whole number of shares of Advaxis Common Stock). The terms and conditions applicable to the Ayala RSUs, including any restrictions on the exercise thereof will continue following the conversion and the term, exercisability and other provisions of such options will generally remain unchanged.

- The Exchange Ratio is subject to customary equitable adjustment in the event that the outstanding shares of Advaxis Common Stock and/or Ayala Common Stock, as applicable, have been changed into, or exchanged for, a different number of shares or a different class of shares during the period from the date of the Merger Agreement until the closing.

No fractional shares of Advaxis Common Stock will be issuable pursuant to the Merger, and no certificates or scrip representing any such fractional shares shall be issued. The Exchange Agent (as defined below), acting as agent for the holders of the shares of Ayala Common Stock otherwise entitled to receive fractional shares of Advaxis Common Stock, will aggregate all fractional shares of Advaxis Common Stock that would otherwise have been required to be distributed and cause them to be sold in the open market for the accounts of such holders. Each holder of shares of Ayala Common Stock who would otherwise have been entitled to receive a fraction of a share of Advaxis Common Stock shall receive, in lieu thereof, cash, rounded to the nearest whole cent and without interest, in an amount equal to the proceeds from such sale by the Exchange Agent, if any, less any brokerage commissions or other fees, transfer taxes or other out-of-pocket transaction costs, as well as a proportional amount of any expenses of the Exchange Agent incurred from the sale of such fractional shares of Advaxis Common Stock.

The Merger Agreement provides that, at the closing, Advaxis will deposit with an exchange agent that is mutually acceptable to Advaxis and Ayala (the "Exchange Agent") (i) evidence of book entry shares representing the non-certificated shares of Advaxis Common Stock issuable in connection with the Merger, and (ii) cash sufficient to make payments in lieu of fractional shares.

The Merger Agreement provides that, promptly (and in any event within five business days) after the Effective Time, the Exchange Agent shall mail to each record holder of (i) shares of Ayala Common Stock represented by a certificate (a "Certificate") (or affidavit of loss, if applicable) or (ii) each book-entry account representing any uncertificated shares of Ayala Common Stock ("Uncertificated Shares") a letter of transmittal and instructions for surrendering such Certificates (or affidavit of loss, if applicable) or Uncertificated Shares to the Exchange Agent. Upon surrender of a Certificate (or affidavit of loss, if applicable) to the Exchange Agent or, with respect to Uncertificated Shares, receipt of an "agent's message" in customary form (or such other evidence, if any, as the Exchange Agent may request) by the Exchange Agent, the holder will be entitled to receive in exchange:

- the non-certificated shares of Advaxis Common Stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement;

- cash in lieu of any fractional shares of Advaxis Common Stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and
- dividends or other distributions, if any, declared or made with respect to Advaxis Common Stock with a record date after the Effective Time.

At the Effective Time, all holders of shares of Ayala Common Stock that were issued and outstanding immediately prior to the Effective Time will cease to have any rights as shareholders of Ayala. In addition, no transfer of shares of Ayala Common Stock after the Effective Time will be registered on the stock transfer books of Ayala.

If any Certificate has been lost, stolen or destroyed, in order for the person claiming such Certificate to be lost, stolen or destroyed to receive the shares of Advaxis Common Stock, cash in lieu of fractional shares and/or dividends or other distributions to which such person would otherwise be entitled pursuant to the terms of the Merger Agreement, such person will have to (i) make an affidavit of that fact, and (ii) if required by Advaxis or the Exchange Agent, post a bond in such reasonable amount as Advaxis or the Exchange Agent, as applicable, may direct as indemnity against any claim that may be made against Advaxis or the Exchange Agent, as applicable, with respect to such lost, stolen or destroyed Certificate.

From and after the Effective Time, until it is surrendered, each Certificate or Uncertificated Share will be deemed to represent only the right to receive shares of Advaxis Common Stock and cash in lieu of fractional shares. Advaxis will not pay dividends or other distributions on any shares of Advaxis Common Stock to be issued in exchange for any unsurrendered Certificate or Uncertificated Share until such Certificate (or affidavit of loss in lieu thereof) or Uncertificated Share is surrendered as provided in the Merger Agreement.

Treatment of Ayala Options

At the Effective Time, each option to purchase shares of Ayala Common Stock that is outstanding and unexercised immediately prior to the Effective Time will, automatically and without any action on the part of the Advaxis, Ayala or the holder thereof, cease to represent a right to acquire shares of Ayala Common Stock, and be converted into an option to purchase Advaxis Common Stock. From and after the Effective Time, each such option may be exercised for such number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to the option by the (ii) Exchange Ratio (rounding the resulting number of shares down to the nearest whole number of shares of Advaxis Common Stock). The per share exercise price of the converted option will be determined by dividing the existing exercise price of the Ayala Option by the Exchange Ratio (which is subject to customary equitable adjustment in the event that the outstanding shares of Advaxis and/or Ayala, as applicable, have been changed into, or exchanged for, a different number of shares or a different class of shares during the period from the date of the Merger Agreement until the closing) and rounding that result up to the nearest whole cent. The terms and conditions applicable to the Ayala Option, including any restrictions on the exercise thereof will continue following the conversion and the term, exercisability and other provisions of such options will generally remain unchanged.

Treatment of Ayala RSUs

At the Effective Time, each Ayala RSU that is outstanding immediately prior to the Effective Time will, automatically and without any action on the part of the Advaxis, Ayala or the holder thereof, be converted into an Adjusted RSU for (A) such number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU by (ii) the Exchange Ratio (rounding the resulting number of shares down to the nearest whole number of shares of Advaxis Common Stock). The terms and conditions applicable to the Ayala restricted stock units, including any restrictions on the exercise thereof will continue following the conversion and the term, exercisability and other provisions of such options will generally remain unchanged.

Treatment of Ayala Warrants

At the Effective Time, each Ayala warrant that is outstanding and unexercised immediately prior to the Effective Time shall be treated in accordance with its terms.

Under the terms of the warrants to purchase Ayala Common Stock (the "Ayala Common Warrants"), upon the effective time of the Merger, the Ayala Common Warrants will become warrants to purchase Advaxis Common Stock. The Holders of the Ayala Common Warrants shall have the right to receive, upon exercise of their Ayala Common Warrants, the number of shares of Advaxis Common Stock equal to the number of shares of Ayala Common Stock issuable upon exercise of the Ayala Common Warrants multiplied by the Exchange Ratio, which is what the holders would have received had the holders exercised their Ayala Common Warrants prior to the closing of the Merger.

Under the terms of the pre-funded warrants to purchase Ayala Common Stock (the "Ayala Pre-Funded Warrants"), upon the effective time of the Merger, the Ayala Pre-Funded Warrants shall automatically be net exercised in accordance with their terms.

Directors and Officers of Advaxis Following the Merger

Effective immediately following the Effective Time, the Advaxis Board will consist of five designees selected by Ayala and two designees selected by Advaxis. The composition of the Advaxis Board following the Effective Time in the aggregate is expected to satisfy the requisite independence requirements, as well as the sophistication and independence requirements for the required committees, pursuant to Nasdaq listing requirements. It is anticipated that after the Effective Time, the Advaxis Board will be the following:

- David Sidransky, M.D.
- Vered Bisker-Leib, Ph.D.
- Robert Spiegel, M.D.
- Murray A. Goldberg
- Kenneth A. Berlin
- Roni A. Appel
- Samir N. Khleif

It is anticipated that the executive officers of Advaxis upon the consummation of the Merger will be:

Name	Title
Kenneth A. Berlin	President and Chief Executive Officer
Igor Gitelman	Interim Chief Financial Officer
Andres A. Gutierrez, M.D., Ph.D.	Chief Medical Officer

Advaxis Special Meeting for Amendments to the Certificate of Incorporation of Advaxis and to the Stock Incentive Plan of Advaxis

On December 2, 2022, Advaxis filed a preliminary proxy statement for a special meeting of Advaxis stockholders (the "Advaxis Special Meeting") to (1) approve an amendment to Advaxis' Amended and Restated Certificate of Incorporation (the "Advaxis Charter") to effect a reverse stock split of Advaxis Common Stock at a ratio to be determined by the Advaxis Board within a range of one-for-two to one-for-ten (or any number in between), without reducing the authorized number of shares of the Advaxis Common Stock, to be effected in the sole discretion of the Advaxis Board at any time within one year of the date of the Advaxis Special Meeting without further approval or authorization of Advaxis' stockholders; (2) approve an amendment to the Advaxis Charter to change the corporate name from "Advaxis, Inc." to "Ayala Pharmaceuticals, Inc."; (3) approve an amendment to Advaxis' 2015 Incentive Plan (the "2015 Incentive Plan") to increase the total number of shares authorized for issuance thereunder from 79,165 shares to 1,579,165 shares and to increase certain other maximum number of awards that may be granted annually; and (4) consider and vote upon an adjournment of the Advaxis Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2, and 3. For the avoidance of doubt, the Advaxis Special Meeting shall be separate and apart from the Ayala Special Meeting, and the approval of the matters to be voted on at the Advaxis Special Meeting is not a condition to the consummation of the Merger.

If the Advaxis reverse stock split proposal is approved at the Advaxis Special Meeting and the reverse stock split is implemented, the shares of Advaxis Common Stock received by Ayala stockholders as consideration in the Merger will be split accordingly. There can be no assurance that the Advaxis reverse stock split will be approved.

Conditions to the Completion of the Merger

Each party's obligation to complete the Merger is subject to the satisfaction or waiver (to the extent permitted by applicable legal requirements) by each of the parties, at or prior to the Merger, of various conditions, which include the following:

- the Registration Statement must have become effective in accordance with the provisions of the Securities Act and no stop order suspending the effectiveness of the Registration Statement has been issued and no proceedings for that purpose have been initiated or threatened;
- no governmental entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any law or judgment (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins or otherwise prohibits the consummation of the Merger;
- the Merger Agreement shall have been adopted by the affirmative vote of the holders of a majority of the outstanding shares of Ayala Common Stock present in person or by proxy and entitled to vote thereon at the Ayala Special Meeting (the "Ayala Stockholder Approval");
- any necessary state securities or "blue sky" filings or notices shall have been made and any required authorizations shall have been received for the issuance of shares of Advaxis Common Stock in the Merger (except for any such filings or notices that would not be reasonably expected to have a material adverse impact on any of the parties to the Merger Agreement or their respective affiliates).

In addition, each party's obligation to complete the Merger is further subject to the satisfaction or waiver by that party of the following additional conditions:

- (i) each of the representations and warranties of the other party other than the Ayala Fundamental Representations and the Advaxis Fundamental Representations (as defined below) shall be true and correct (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth in the Merger Agreement) as of the date of the Merger Agreement and as of the date of the closing of the Merger as though made on and as of the closing date (except to the extent in either case that such representations and warranties speak as of another date, in which case as of such date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth in the Merger Agreement), individually or in the aggregate, has not had and would not reasonably be expected to have a material adverse effect on the other party, (ii) the representations and warranties of the other party related to organizational documents, organization, authority to enter into the Merger Agreement and brokers shall be true and correct in all material respects as of the date of the Merger Agreement and as of the date of the closing of the Merger as though made on and as of the closing date (except to the extent in each case that such representations and warranties speak as of another date, in which case as of such date), and (iii) the representations and warranties of the other party related to capitalization (such representations and warranties referenced in clauses (ii) and (iii) by Ayala, the "Ayala Fundamental Representations" and such representations and warranties referenced in clauses (ii) and (iii) by Advaxis, the "Advaxis Fundamental Representations") shall be shall be true and correct in all respects except for *de minimis* inaccuracies as of the date of the Merger Agreement and as of the date of the closing of the Merger as though made on and as of the closing date (except to the extent in either case that such representations and warranties speak as of another date, in which case as of such date).

- there shall not have occurred any material adverse effect on the other party that is continuing;

- the other party must have performed or complied in all material respects with all covenants and obligations in the Merger Agreement required to be performed or complied with by it on or before the consummation of the Merger; and

- the other party to the Merger Agreement must have delivered a customary closing certificate to such party certifying that the closing conditions related to the accuracy of representations and warranties, lack of material adverse effect and compliance with covenants have been satisfied.

The Merger Agreement provides that the following events shall not be considered a material adverse effect to Ayala:

- general business or economic conditions generally affecting the industry in which Ayala and its subsidiaries operate;

- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters and health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof);

- changes in financial, banking or securities markets;

- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles (or interpretations thereof);

- any change in the stock price or trading volume of Ayala Common Stock;

- any failure by Ayala to meet internal or analysts' expectations or projections; or

- the announcement of the Merger Agreement or the pendency of the other Transactions.

provided, that (i) any effect causing or contributing to the events described in the fifth and sixth bullets above may be taken into account in determining whether there has been, or would reasonably be expected to be, a material adverse effect to Ayala (unless such effects are otherwise included in the events listed above), and (ii) any event referred to in the first, second, third and fourth bullets above may be considered a material adverse effect to Ayala to the extent disproportionately affecting Ayala and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Ayala and its subsidiaries operate.

The Merger Agreement provides that the following events shall not be considered a material adverse effect to Advaxis:

- general business or economic conditions generally affecting the industry in which Advaxis and its subsidiaries operate;
- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters and health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof);
- changes in financial, banking or securities markets;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles (or interpretations thereof);
- any change in the stock price or trading volume of Advaxis Common Stock;
- any failure by Advaxis to meet internal or analysts' expectations or projections; or
- the announcement of the Merger Agreement or the pendency of the other Transactions;

provided, that (i) any effect causing or contributing to the events described in the fifth and sixth bullets above may be taken into account in determining whether there has been, or would reasonably be expected to be, a material adverse effect to Advaxis (unless such effects are otherwise included in the events listed above), and (ii) any event referred to in the first, second, third and fourth bullets above may be considered a material adverse effect to Advaxis to the extent disproportionately affecting Advaxis and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Advaxis and its subsidiaries operate.

Representations and Warranties

The Merger Agreement contains customary representations and warranties of Advaxis, Merger Sub and Ayala for a transaction of this type relating to, among other things:

- organizational documents
- due organization; subsidiaries
- capitalization
- authority; binding nature of the Merger Agreement
- non-contravention; consents
- SEC filings; financial statements

- absence of changes
- absence of undisclosed liabilities
- title to assets (with respect to Ayala only)
- legal proceedings; orders
- contracts
- employee and labor matters; benefit plans
- environmental matters (with respect to Ayala only)
- taxes
- intellectual property (with respect to Ayala only)
- regulatory matters
- insurance; real estate (with respect to Ayala only)
- registration statement/proxy statement/prospectus
- transactions with affiliates
- brokers and finders
- opinion of financial advisor
- anti-bribery (with respect to Ayala only)
- ownership of common stock
- ownership and operations of Merger Sub (with respect to Advaxis and Merger Sub only)

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the Merger, but their accuracy forms the basis of certain of the conditions to the obligations of Advaxis and Ayala to complete the Merger.

No Solicitation

The Merger Agreement provides that, except as described below, each of Advaxis and Ayala will not, and it will cause it and its subsidiaries' officers, directors, employees, investment bankers, attorneys, accountants and other advisors, agents or representatives not to, directly or indirectly:

- solicit, initiate, induce, encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (as defined below);
- participate in any discussions or negotiations or cooperate in any way with any person regarding any proposal or offer the consummation of which would constitute an Acquisition Proposal;

- provide any non-public information or data concerning it or any of its subsidiaries to any person in connection with any proposal, the consummation of which would constitute an Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating an Acquisition Proposal;

- enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to an Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to an Acquisition Proposal;

- adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (including by approving any transaction, or approving any person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any person (other than the other party and its subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or its organizational or other governing documents; or

- resolve, publicly propose or agree to do any of the foregoing actions.

Each of Advaxis and Ayala also agreed that it shall, and shall cause its subsidiaries and representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any person conducted prior to the date of the Merger Agreement with respect to any Acquisition Proposal, or proposal that could reasonably be expected to lead to an Acquisition Proposal, and shall promptly terminate access by any such person to any physical or electronic data rooms relating to any such Acquisition Proposal. Each of Advaxis and Ayala also agreed to deliver a notice to any person it entered into a confidentiality agreement with, end any discussions and require the return or destruction of any confidential information. Each of Advaxis and Ayala also agreed to enforce any standstill agreement entered into with any other person.

An "Acquisition Proposal" means with respect to Advaxis or Ayala, any proposal (other than a proposal or offer by the other party or any of its Affiliates) for:

- any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a person or "group" (as defined in the Exchange Act, as amended, and the rules promulgated thereunder) of persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 20% of the outstanding shares of any class of voting securities of such party;

- issuance or acquisition of securities representing more than 20% of the outstanding shares of any class of voting securities of such party;

- any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of such party and of its subsidiaries that constitute or account for (x) more than 20% of the consolidated net revenues of such party, consolidated net income of such party or consolidated book value of such party; or (y) more than 20% of the fair market value of the consolidated assets of such party; or

- any liquidation or dissolution of such party.

However, prior to the time the Ayala Stockholder Approval is obtained, each party may (i) subject to certain conditions, provide access to nonpublic information regarding such party or any of its subsidiaries to, and (ii) may engage or participate in discussions or negotiations with, any third party in response to an unsolicited, written bona fide Acquisition Proposal first received after the date of the Merger Agreement (and which has not been withdrawn), if:

- such Acquisition Proposal did not result from a breach of the non-solicitation provisions of the Merger Agreement described above with respect to such Acquisition Proposal;
- such party has provided prior written notice to the other party of the identity of the person submitting such Acquisition Proposal and its intention to engage or participate in any discussions or negotiations with any such person; and
- such party's board of directors determines in good faith, after consultation with its outside legal counsel and outside financial advisors, that such Acquisition Proposal either (x) constitutes or would reasonably be expected to result in a "Superior Proposal" (as defined below) and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable laws.

Each of Ayala and Advaxis agree to promptly (and in any event within 24 hours), notify the other party (orally and in writing) if (i) such party receives any offers or inquiries with respect to an Acquisition Proposal or that could reasonably be expected to lead to an Acquisition Proposal, (ii) any non-public information is requested from such party in connection with any Acquisition Proposal or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to an Acquisition Proposal are sought to be initiated or continued with such party (which notification shall include certain required information and ongoing notice obligations as further specified in the Merger Agreement).

Each party agreed that it and its subsidiaries would not enter into a confidentiality agreement with any person that would prohibit it from providing confidential information to the other party pursuant to the terms of, or otherwise complying with its obligations under the non-solicitation provision of, the Merger Agreement; and that it would not provide any information to any other person pursuant to any confidentiality agreement entered into prior to the date of the Merger Agreement unless such person agreed to waive any provision that would prohibit such party from providing confidential information to the other party pursuant to the terms of the Merger Agreement.

A "Superior Proposal" means, with respect to Advaxis or Ayala, any bona fide, binding, written Acquisition Proposal on terms which the board of Advaxis or Ayala, as applicable, determines in its good faith judgment, after consultation with outside financial advisors and outside counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the person or group of persons making the proposal, and, if consummated, would result in a transaction more favorable to such party's stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the other Transactions and the time likely to be required to consummate such Acquisition Proposal); provided that for purposes of the definition of "Superior Proposal", the references to "20%" in the definition of Acquisition Proposal shall be deemed to be references to "50%."

No Ayala Change in Recommendation or Ayala Alternative Acquisition Agreement

Except as provided below, the board of directors of Ayala and each committee thereof may not (i) withhold, withdraw, qualify or modify (or publicly propose or resolve to withhold, withdraw, qualify or modify), in a manner adverse to Advaxis, its recommendation to Ayala stockholders to adopt the Merger Agreement (the "Ayala Board Recommendation") or approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Acquisition Proposal or make or authorize the making of any public statement (oral or written) that has the substantive effect of such a withdrawal, qualification or modification, or remove the Ayala Board Recommendation from or fail to include the Ayala Board Recommendation in this proxy statement/prospectus (each, an "Ayala Change in Recommendation") or (ii) cause or permit Ayala or any of its subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement as permitted by the Merger Agreement) relating to or that could reasonably be expected to lead to any Acquisition Proposal or requiring Ayala (or that would require or could reasonably be expected to require Ayala) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by the Merger Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the other Transactions (an "Ayala Alternative Acquisition Agreement").

Exceptions to No Ayala Change in Recommendation and Ayala Alternative Acquisition Agreement

Notwithstanding the foregoing, upon receipt of an unsolicited written Acquisition Proposal in compliance with the terms of the Merger Agreement, the board of directors of Ayala may make an Ayala Change in Recommendation and enter into an Ayala Alternative Acquisition Agreement prior to the receipt of the Ayala Stockholder Approval if:

- the board of directors of Ayala determined in good faith, in consultation with outside financial advisors and outside legal counsel, that such Acquisition Proposal constitutes a Superior Proposal;
- Ayala provided Advaxis with four business days' written notice, which notice shall contain certain required information as further specified in the Merger Agreement;
- prior to making such Ayala Change in Recommendation, Ayala engaged in good faith negotiations with Advaxis, and took into account any changes to the terms of the Merger Agreement proposed in writing by Advaxis; and
- the board of directors of Ayala determined in good faith, in consultation with outside financial advisors and outside legal counsel, that, in light of such Superior Proposal and taking into account any revised terms proposed in writing by Advaxis, such Superior Proposal continues to constitute a Superior Proposal and, after consultation with outside legal counsel, that the failure to make sure Ayala Change in Recommendation with be inconsistent with the directors' fiduciary duties under applicable law.

Notwithstanding the foregoing, the board of directors of Ayala may make an Ayala Change in Recommendation upon the occurrence of an Intervening Event (as defined below) prior to receipt of the Ayala Stockholder Approval if:

- Ayala provided Advaxis with four Business Days' written notice, which notice shall contain certain required information as further specified in the Merger Agreement; and
- Ayala engaged in good faith negotiations with Advaxis, and took into account any changes to the terms of the Merger Agreement proposed in writing by Advaxis; and
- the board of directors of Ayala determined in good faith, in consultation with outside financial advisors and outside legal counsel, that, in light of such Intervening Event and taking into account any revised terms proposed in writing by Advaxis, that the failure of the board of directors of Ayala to make an Ayala Change in Recommendation would be inconsistent with the directors' fiduciary duties under applicable law.

"Intervening Event" means any event or development that has a material effect on Ayala and its subsidiaries taken as a whole, occurring or arising after the date of the Merger Agreement that (i) was not known to, or reasonably foreseeable by, the board of directors of Ayala prior to the execution of the Merger Agreement, which event, occurrence, fact, condition, change, development or effect becomes known to, or reasonably foreseeable by, the board of directors of Ayala prior to the receipt of the Ayala Stockholder Approval and (ii) does not relate to (A) an Acquisition Proposal made to Ayala or (B) (1) any changes in the market price or trading volume of Ayala or Advaxis, (2) the Ayala or Advaxis stockholder meetings, failing to meet or exceeding published or unpublished revenue or earnings projections, in each case in and of itself, (3) any events or developments relating to Advaxis or any of its affiliates, (4) any event or development generally affecting the industries in which Ayala or Advaxis operate or in the economy generally or other general business, financial or market conditions, (5) any change in any applicable law, (6) any event, occurrence, result and/or development with respect to the product candidates AL101 or AL102 or (7) any event or development to the extent directly resulting from the announcement or pendency of, or any actions required to be taken by the Ayala or Advaxis (or refrained to be taken by Ayala or Advaxis) pursuant to the Merger Agreement or the consummation of the other Transactions.

No Advaxis Alternative Acquisition Agreement

Except as provided below, the board of directors of Advaxis and each committee thereof may not approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Acquisition Proposal or cause or permit Advaxis or any of its subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement as permitted by the Merger Agreement) relating to or that could reasonably be expected to lead to any Acquisition Proposal or requiring Advaxis (or that would require or could reasonably be expected to require Advaxis) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by the Merger Agreement or that would otherwise materially impede, interfere with or be inconsistent with, other Transactions (a "Advaxis Alternative Acquisition Agreement").

Exception to No Advaxis Alternative Acquisition Agreement

Notwithstanding the foregoing, upon receipt of an unsolicited written Acquisition Proposal in compliance with the terms of the Merger Agreement, the board of directors of Advaxis may enter into an Advaxis Alternative Acquisition Agreement prior to receipt of the Ayala Stockholder Approval if:

- the board of directors of Advaxis determined in good faith, in consultation with outside financial advisors and outside legal counsel, that such Acquisition Proposal constitutes a Superior Proposal;
- Advaxis provided Ayala with four Business Days' written notice, which notice shall contain certain required information as further specified in the Merger Agreement;
- Advaxis engaged in good faith negotiations with Ayala, and took into account any changes to the terms of the Merger Agreement proposed in writing by Ayala; and
- the board of directors of Advaxis determined in good faith, in consultation with outside financial advisors and outside legal counsel, that, in light of such Superior Proposal and taking into account any revised terms proposed in writing by Ayala, such Superior Proposal continues to constitute a Superior Proposal.

Meetings of Stockholders

Unless the Merger Agreement is terminated in accordance with the terms of the Merger Agreement, Ayala is obligated under the Merger Agreement to establish the Record Date for, duly call, give notice of and use its reasonable best efforts to hold The Ayala Special Meeting for the purposes of adopting and approving the Merger Agreement. The Ayala Special Meeting will be held as promptly as practicable, and in any event within forty-five (45) days after the declaration of effectiveness of the Registration Statement, of which this proxy statement/prospectus is a part.

Advaxis may establish a record date for, duly call, give notice of and hold a special meeting of its stockholders for the purpose of adopting an amendment to Advaxis' certificate of incorporation to implement a reverse stock split and amend the name of Advaxis to "Ayala Pharmaceuticals, Inc." and the Parent Stock Plans (as defined in the Merger Agreement).

Covenants; Conduct of Business Pending the Merger

Ayala agreed that during the period from the date of the Merger Agreement to the earlier of the termination of the Merger Agreement in accordance with its terms and the Effective Time (the "Interim Period"), it will, and cause each of its subsidiaries to, use commercially reasonable efforts to conduct its business in the ordinary course of its normal operations and in accordance with past practices, except as (i) set forth in the disclosure schedules delivered by Ayala pursuant to the Merger Agreement (the "Ayala Disclosure Schedules"), (ii) expressly contemplated or permitted by the Merger Agreement, (iii) required by applicable law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect employee health and safety, (B) to respond to third-party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable law, directive or guideline from any governmental entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as consented to in writing by Advaxis, which consent shall not be unreasonably withheld, delayed or conditioned. Ayala also agreed that, subject to certain limited exceptions, without the consent of Advaxis, it will not, and will not cause or permit any of its subsidiaries to, during the Interim Period (except as set forth in the Ayala Disclosure Schedules, expressly permitted by or required in accordance with the Merger Agreement or as required by applicable laws):

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Ayala or in connection with the payment of the exercise price and/or withholding taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the 2017 Ayala Stock Incentive Plan in accordance with the terms of such award in effect on the date of the Merger Agreement);

- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Ayala or any of its subsidiaries (except for shares of Ayala Common Stock issued upon the valid exercise or conversion of outstanding Ayala Options or Ayala warrants or settlement of Ayala RSUs); (B) any option, warrant or right to acquire any capital stock or any other security, other than stock options granted to employees and service providers in the ordinary course of its normal operations and in accordance with past practices which are included in the calculation of the Exchange Ratio; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Ayala or any of its subsidiaries;

- except as required to give effect to anything in contemplation of the closing, amend any of the organizational documents of Ayala of any of its subsidiaries, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the other Transactions;

- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

- (A) lend money to any person (except for the advancement of expenses to employees, directors and consultants in the ordinary course of its normal operations and in accordance with past practices), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of transaction expenses, make any capital expenditure in excess of one hundred ten percent (110%) of the budgeted capital expenditure amounts set forth in Ayala's operating budget delivered to Advaxis concurrently with the execution of the Merger Agreement (the "Ayala Budget");

- other than as set forth in the Ayala Disclosure Schedules, required by applicable laws or the terms of any Ayala employee benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any Ayala employee benefit plan, other than in the ordinary course of its normal operations and in accordance with past practices; (B) cause or permit any Ayala employee benefit plan to be amended in any material respect, other than in the ordinary course of its normal operations and in accordance with past practices; (C) increase the amount of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the ordinary course of its normal operations and in accordance with past practices or (D) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $150,000 per year (other than ordinary course replacement of departed employees or officers during the Interim Period);

- recognize any labor union or labor organization, except as otherwise required by applicable laws or after prior written consent of Advaxis (which consent shall not be unreasonably withheld, delayed or conditioned);

- enter into any material transaction other than in the ordinary course of its normal operations and in accordance with past practices;

- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any lien with respect to such assets or properties, except in the ordinary course of its normal operations and in accordance with past practices;

- sell, assign, transfer, license, sublicense or otherwise dispose of any material Ayala intellectual property, other than pursuant to non-exclusive licenses in the ordinary course of its normal operations and in accordance with past practices;

- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of its normal operations and in accordance with past practices, the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of its normal operations and in accordance with past practices of not more than seven months), or adopt or change any material accounting method in respect of taxes;

- other than amendments to contracts related to the company's desmoid programs to the extent necessary to comply with the Ayala Budget, enter into, materially amend or terminate any Ayala material contract;

- except as otherwise set forth in the Ayala Budget and for the incurrence or payment of any transaction expenses, other than in the ordinary course of its normal operations and in accordance with past practices, make any expenditures, incur any liabilities or discharge or satisfy any liabilities, in each case, in amounts that exceed the aggregate amount of the Ayala Budget by $150,000;

- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the other Transactions; or
- agree, resolve or commit to do any of the foregoing.

Advaxis agreed that during the Interim Period, it will, and cause each of its subsidiaries to, use its commercially reasonable efforts to conduct its business in the ordinary course of its normal operations and consistent with past practices, except as (i) set forth in the disclosure schedules delivered by Advaxis pursuant to the Merger Agreement (the "Advaxis Disclosure Schedules"), (ii) expressly contemplated or permitted by the Merger Agreement, (iii) as required by applicable laws, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary (A) to protect employee health and safety, (B) to respond to a third-party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable law, directive or guideline from any governmental entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as consented to in writing by Ayala, which consent shall not be unreasonably withheld, delayed or conditioned. Advaxis also agreed that, subject to certain limited exceptions, without the consent of Ayala, it will not, and will not cause or permit any of its subsidiaries to, during the Interim Period (except as set forth in the Advaxis Disclosure Schedules, expressly permitted by or required in accordance with the Merger Agreement or as required by applicable laws):

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Advaxis or in connection with the payment of the exercise price and/or withholding taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Advaxis equity compensation plans in accordance with the terms of such award in effect on the date of this Agreement);
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Advaxis or Merger Sub (except for shares of Advaxis Common Stock issued upon the valid exercise or conversion of outstanding Advaxis options or Advaxis warrants); (B) any option, warrant or right to acquire any capital stock or any other security, other than stock options granted to employees and service providers in the ordinary course of its normal operations and in accordance with past practices which are included in the calculation of the Exchange Ratio; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Advaxis or Merger Sub;
- except as required to give effect to anything in contemplation of the closing, amend any of Advaxis' or its subsidiaries' organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the other Transactions;
- other than Merger Sub, form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

- (A) lend money to any person (except for the advancement of expenses to employees, directors and consultants in the ordinary course of its normal operations and in accordance with past practices), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of transaction expenses, make any capital expenditure in excess of one hundred ten percent (110%) of the budgeted capital expenditure amounts set forth in Advaxis' operating budget delivered to Ayala concurrently with the execution of this Agreement (the "Advaxis Budget");

- other than as required by the terms of any Advaxis employee benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any Advaxis employee benefit plan, other than in the ordinary course of its normal operations and in accordance with past practices; (B) cause or permit any Advaxis employee benefit plan to be amended in any material respect; (C) increase the amount of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees or (D) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $150,000 per year (other than ordinary course replacement of departed employees or officers during the Interim Period);

- recognize any labor union or labor organization, except as otherwise required by applicable laws;

- enter into any material transaction;

- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any lien with respect to such assets or properties;

- sell, assign, transfer, license, sublicense or otherwise dispose of any material intellectual property rights that are owned or purported to be owned by Advaxis or its subsidiaries, or exclusively licensed or purported to be exclusively licensed to Advaxis or its subsidiaries;

- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of its normal operations and in accordance with past practices the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of its normal operations and in accordance with past practices of not more than seven months), or adopt or change any material accounting method in respect of taxes;

- enter into, materially amend or terminate any Advaxis material contract;

- except as set forth in the Advaxis Budget and for the incurrence or payment of any transaction expenses, make any expenditures, incur any liabilities or discharge or satisfy any liabilities, in each case, in amounts that exceed the aggregate amount of the Advaxis Budget by $150,000;

- other than as required by law or GAAP, take any action to change accounting policies or procedures;

- initiate or settle any legal proceeding;

- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the other Transactions; or
- agree, resolve or commit to do any of the foregoing.

Regulatory Approvals and Related Matters

Each of Advaxis and Ayala has agreed:

- that each party will cooperate with the other party and use reasonable best efforts to file, as soon as practicable after the date of the Merger Agreement, all notices, filings, submissions and other documents required to be filed by such party with any governmental entity with respect to the Merger or any of the other Transactions, and to submit promptly any information requested by such governmental entity;
- that each party shall give the other party prompt notice of the commencement or known threat of commencement of any legal proceeding by or before any governmental entity with respect to the Merger or any of the other Transactions, keep the other party reasonably informed as to the status of any such legal proceeding or threat, and in connection with any such legal proceeding, permit authorized representatives of the other party to be present at each meeting or conference relating to any such legal proceeding and to have access to and be consulted in connection with any document, opinion or proposal made or submitted to any governmental entity in connection with any such legal proceeding;
- that each party shall use reasonable best efforts to take, or cause to be taken, all actions necessary to consummate the Merger and make effective the other Transactions. Without limiting the generality of the foregoing, each party: (i) shall make all filings (if any) and give all notices (if any) required to be made and given by such party in connection with the Merger and the other Transactions; (ii) shall use reasonable best efforts to obtain each consent (if any) required to be obtained (pursuant to any applicable law or contract, or otherwise) by such party in connection with the Merger or any of the other Transactions; and (iii) shall use reasonable best efforts to lift any restraint, injunction or other legal bar to the Merger;
- each party shall, upon request by the other, promptly furnish the other with all information concerning itself, its subsidiaries, directors, officers and shareholders and such other matters as may be reasonably necessary or advisable in connection with the Registration Statement, of which this proxy statement/prospectus is a part, this proxy statement/prospectus and any other statement, filing, notice or application made by or on behalf of Advaxis, Ayala or any of their respective subsidiaries to any third party and/or any governmental entity in connection with the other Transactions; and
- that each party shall promptly furnish the other with copies of notices or other communications received by Advaxis or Ayala, as the case may be, or any of their respective subsidiaries from any third party and/or any governmental entity with respect to the other Transactions, other than immaterial communications.

Indemnification; Directors' and Officers' Insurance

The Merger Agreement provides that Ayala will purchase, prior to the Effective Time, a six year "tail policy" for the existing policy of directors' and officers' liability insurance maintained by Ayala as of the date of the Merger Agreement, at a premium not to exceed 300% of the annual premiums currently paid by Ayala for such insurance. The Merger Agreement further provides that all rights to indemnification by Ayala in favor of the directors and officers of Ayala as of the date of the Merger Agreement with respect to acts or omissions occurring prior to the Effective Time, as provided in Ayala's organizational documents and in any indemnification agreements between Ayala and such persons, shall survive the Merger and be observed by the surviving company of the Merger for a period of six years following the Effective Time, in each case to the fullest extent permitted by Delaware law.

Stock Exchange De-Listing and De-Registration

The Merger Agreement provides that Ayala shall take all actions necessary to permit the shares of Ayala Common Stock and any other security issued by Ayala or any of its subsidiaries and listed on The Nasdaq Global Market to be de-listed and de-registered under the Exchange Act, as amended, as soon as possible following the Effective Time.

Other Agreements

Each of Advaxis and Ayala has agreed to:

- during the Interim Period, promptly notify the other party in writing of any event, condition, fact or circumstance that would reasonably be expected to make the timely satisfaction of any condition to closing of the Merger impossible or unlikely or, in the case of Ayala, that has had or could reasonably be expected to have or result in a material adverse effect to Ayala;

- during the Interim Period, promptly advise the other party in writing of (i) any claim asserted or legal proceeding commenced, or, to the party's knowledge, either: (A) with respect to a governmental entity, overtly threatened; or (B) with respect to any other person, threatened in writing, in each case against, relating to, involving or otherwise affecting any of the other Transactions; (ii) any knowledge of any notice from any person alleging that the consent of such person is or may be required in connection with the Merger or any of the other Transactions; and (iii) any other material legal proceeding or material claim threatened, commenced or asserted against or with respect to any party or its respective subsidiaries;

- subject to certain conditions, afford the other party's representatives reasonable access (at the requesting party's cost) under the supervision of appropriate personnel of the other party, during normal business hours during the period prior to the Effective Time, to the other party's, and each of its subsidiaries' employees, properties, assets, books, records and contracts and, during such period, each of Advaxis and Ayala shall, and shall cause each of its subsidiaries to, furnish promptly to the other all information concerning its or any of its subsidiaries' capital stock, business and personnel as may reasonably be requested by the other;

- use its reasonable best efforts to, and cause its subsidiaries to, cause the Merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code, as amended; and

- during the Interim Period following the initial joint press release with respect to the Merger and the other Transactions, consult with each other prior to making any press releases or other public announcements concerning the Merger and any filings with any governmental entity, subject to certain exceptions.

Termination

The Merger Agreement may be terminated at any time before the Effective Time, whether before or after the Ayala Stockholder Approval has been obtained (except as otherwise set forth in the Merger Agreement), as set forth below:

- by mutual written consent of Advaxis and Ayala; or
- by either the Advaxis or Ayala, if (a) the Merger shall not have been consummated by 11:59 p.m. (eastern standard time) on April 18, 2023, (b) if a governmental authority shall have issued a final and non-appealable permanent restraining order, permanent injunction or other similar permanent order which has the effect of permanently restraining, enjoining or otherwise prohibiting consummation of the Transactions, or (c) the Ayala Stockholder Approval was not obtained at the Ayala Special Meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the adoption of the Merger Agreement was taken, in each of (a), (b) and (c) where the terminating party's material breach of the Merger Agreement is not the cause of, or has resulted in, the failure of such condition;
- by Ayala, if:
    - prior to the Effective Time, Advaxis breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of Ayala's conditions to closing the other Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the terms of the Merger Agreement; provided, that Ayala shall not have the right to terminate the Merger Agreement pursuant to this provision if Ayala is then in material breach of any of its representations, warranties or covenants contained the Merger Agreement or agreements under the Merger Agreement;
    - prior to obtaining the Ayala Stockholder Approval, Advaxis materially breaches or fails to perform its non-solicitation covenant, or enters into an Acquisition Proposal; or
    - prior to obtaining the Ayala Stockholder Approval, Ayala's board of directors authorizes Ayala to enter into an Acquisition Proposal constituting a Superior Proposal and Ayala enters into an Acquisition Proposal constituting a Superior Proposal;
- by Advaxis, if:
    - prior to the Effective Time, Ayala breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of Advaxis' conditions to closing the other Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the terms of the Merger Agreement; provided, that Advaxis shall not have the right to terminate the Merger Agreement pursuant to this provision if Advaxis is then in material breach of any of its representations, warranties or covenants contained the Merger Agreement or agreements under the Merger Agreement;

- prior to obtaining the Ayala Stockholder Approval, (i) the Ayala Board makes an Ayala Change in Recommendation, (ii) Ayala fails to include the Ayala Board Recommendation in this proxy statement/prospectus, (iii) Ayala materially breaches or fails to perform its non-solicitation covenant, or (iv) Ayala enters into an Acquisition Proposal; or

- prior to obtaining the Ayala Stockholder Approval, Advaxis' board of directors authorizes Advaxis to enter into an Acquisition Proposal constituting a Superior Proposal and Advaxis enters into an Acquisition Proposal constituting a Superior Proposal.

Termination Fee

The Merger Agreement provides that the payment of a $600,000 termination fee will be payable:

- by Ayala to Advaxis if (a) prior to obtaining the Ayala Stockholder Approval, Advaxis terminates the Merger Agreement due to (I) the board of directors of Ayala having made an Ayala Change in Recommendation, (II) Ayala's failure to include the Ayala Board Recommendation in this proxy/prospectus, (III) Ayala's entry into a competing Acquisition Proposal or (IV) Ayala's material breach or failure to perform in any material respect its obligations with respect to its non-solicitation covenant; (b) prior to obtaining the Ayala Stockholder Approval, Ayala terminates the Merger Agreement due to the board of directors of Ayala's authorization, to the extent permitted by its non-solicitation covenant, of Ayala's entry into a Superior Proposal and, concurrently with Ayala's termination of the Merger Agreement, Ayala enters into such Superior Proposal; or (c) after the date of the Merger Agreement, (I) a competing Acquisition Proposal is made to Ayala and becomes publicly known prior to the meeting of Ayala shareholders to adopt the Merger Agreement and such proposal is not withdrawn at the time of such meeting, (II) the Merger Agreement is terminated by Ayala or Advaxis due to a failure to obtain the Ayala Stockholder Approval or by Advaxis due to Ayala's failure to satisfy the condition to the Merger regarding the accuracy of Ayala's representations and warranties or compliance with its covenants and (III) within 12 months after such termination, Ayala enters into an Ayala Alternative Acquisition Agreement pursuant to a competing Acquisition Proposal; or

- by Advaxis to Ayala if (a) prior to obtaining the Ayala Stockholder Approval, Ayala terminates the Merger Agreement due to (I) Advaxis' entry into a competing Acquisition Proposal or (II) Advaxis' material breach or failure to perform in any material respect its obligations with respect to its non-solicitation covenant; (b) prior to obtaining the Ayala Stockholder Approval, Advaxis terminates the Merger Agreement due to the board of directors of Advaxis' authorization, to the extent permitted by its non-solicitation covenant, of Advaxis' entry into a Superior Proposal and, concurrently with Advaxis' termination of the Merger Agreement, Advaxis enters into such Superior Proposal.

Specific Performance

The parties to the Merger Agreement acknowledged and agreed that irreparable damage would occur and that the parties would not have any adequate remedy at law if any provision of the Merger agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. The parties accordingly agreed that shall each party be entitled to an injunction or injunctions, specific performance and other equitable relief to prevent breaches of the Merger agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each party waived any requirement for the security or posting of any bond in connection with such remedy), in addition to any other remedy to which they are entitled at law or in equity. The parties further agreed not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that Ayala or Advaxis otherwise have an adequate remedy at law. The parties acknowledged that the agreements contained in this provision of the Merger Agreement are an integral part of the other Transactions, and that, without these agreements, the parties would not have entered into the Merger Agreement.

Expenses

Except as described under the heading "*—Termination Fee*", whether or not the Merger is consummated, all costs and expenses incurred in connection with the Merger Agreement and the other Transactions will be paid by the party incurring such expense.

Amendment

The Merger Agreement may be amended by an instrument in writing signed by the parties at any time, except that after the Merger Agreement has been adopted and approved by the stockholders of a party, no amendment which by law requires further approval by the stockholders of such party shall be made without such further approval.

Governing Law

The Merger Agreement is governed by the laws of the State of Delaware.

Voting and Support Agreements

In connection with execution of the Merger Agreement, Advaxis entered into Voting Agreements with each of (a) aMoon, and (b) IBF I, pursuant to which each such party agreed, among other things, to vote their respective beneficially owned shares of Ayala Common Stock (i) in favor of (1) the adoption of the Merger Agreement and the approval of the Merger and the other Transactions, and (2) any proposal to adjourn or postpone the stockholders meeting of Ayala called to approve such matters to the extent permitted or required under the Merger Agreement; and (ii) against (1) any Acquisition Proposal made to Ayala, except as expressly permitted by the Merger Agreement, (2) any merger agreement or merger (other than the Merger Agreement and the Merger), consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by Ayala, in each case except as expressly permitted by the Merger Agreement, and (3) any proposal, action or agreement that would reasonably be expected to (A) materially delay or postpone, prevent or otherwise impair the Merger or the other Transactions, (B) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of Ayala under the Merger Agreement, (C) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of such party under the Voting Agreement, (D) result in any of the conditions set forth in Section 6 of the Merger Agreement not being fulfilled or (E) except as expressly contemplated by the Merger Agreement, change in any manner the dividend policy or capitalization of, including the voting rights of any class of capital stock of, Ayala. The Voting Agreements will terminate upon the earliest to occur of (x) the mutual agreement of Advaxis and the stockholder party to such Voting Agreement, (y) the Effective Time; and (z) the date on which the Merger Agreement is terminated in accordance with its terms. The Voting Agreements provide that, in the event of a Company Change in Recommendation (as defined in the Merger Agreement), the number of shares of Ayala's capital stock subject to the Voting Agreements shall only be 30% of Ayala's total current outstanding voting power, and the number of shares of Ayala's capital stock of each of Israel Biotech Fund I, L.P. and aMoon subject to the Voting Agreements shall be reduced proportionately based on the number of shares of Ayala's capital stock of subject thereto.

The foregoing description of the Voting Agreement does not purport to be complete and is qualified in its entirety by the full text of the forms of Voting Agreements, which are attached hereto as Annex D and Annex E, respectively.

Executive Officers

The following table provides information on our current executive officers.

Name	Age	Position
Kenneth Berlin	58	President and Chief Executive Officer
Igor Gitelman	46	Interim Chief Financial Officer and Vice President of Finance
Andres Gutierrez	61	Chief Medical Officer and Executive Vice President

Kenneth Berlin. Mr. Berlin has served as our President and Chief Executive Officer and a member of our Board of Directors since April 2018. Mr. Berlin served as our Interim Chief Financial Officer from September 2020 to May 2022. Prior to joining Advaxis, Mr. Berlin served as President and Chief Executive Officer of Rosetta Genomics from November 2009 until April 2018. Prior to Rosetta Genomics, Mr. Berlin was Worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. At Veridex he grew the organization to over 100 employees, launched three cancer diagnostic products, led the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from an R&D entity to a commercial provider of oncology diagnostic products and services. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. From 2001 until 2004 he served as Vice President, Licensing and New Business Development in the pharmaceuticals group, and from 2004 until 2007 served as Worldwide Vice President, Franchise Development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California Los Angeles School of Law. Mr. Berlin's experience in life science companies, as well as his business experience in general, qualify him to service as our director.

Igor Gitelman. Mr. Gitelman has served as the Company's Interim Chief Financial Officer since May of 2022, VP of Finance since November 2020 and Chief Accounting Officer since February 2021. Before joining the Company, Mr. Gitelman served as CFO Executive Financial Consultant for Accu Reference Medical Labs, a clinical diagnostic laboratory. Before that, from February 2017 through November 2018, Mr. Gitelman served as a chief accounting officer of Cancer Genetics, Inc., a drug discovery, preclinical oncology, and immuno-oncology services company. Prior to that, Mr. Gitelman served as an Assistant to Vice President (AVP) of Finance and Tax at clinical diagnostic laboratory, BioReference Laboratories, Inc., from October 2005 to October 2016. During this time at BioReference Laboratories, Inc., Mr. Gitelman held various positions of increasing responsibility managing the company's internal audit function, SEC financial reporting, tax and corporate finance functions.

Andres Gutierrez, M.D., Ph.D. Dr. Gutierrez has served as our Executive Vice President and Chief Medical Officer since April 2018. Prior to joining Advaxis, Dr. Gutierrez served as Chief Medical Officer for Oncolytics Biotech, Inc. from November 2016 to April 2018. Prior to Oncolytics, Dr. Gutierrez was Chief Medical Officer at SELLAS Life Sciences Group from November 2015 to September 2016 and was Medical Director, Early Development Immuno-Oncology at BMS from October 2012 to November 2015, where he oversaw the development of translational and clinical development of immuno-oncology programs in solid tumors and hematological malignancies. Earlier, Dr. Gutierrez was Medical Director for several biotechnology companies, including Sunesis Pharmaceuticals, BioMarin Pharmaceutical, Proteolix and Oculus Innovative Sciences, leading key programs with talazoparib and carfilzomib, among others. Prior to Oculus, he served as Director of the Gene & Cell Therapy Unit at the National Institutes of Health in Mexico City and as a consultant physician at the Hospital Angeles del Pedregal.

Independence of Advaxis' Board of Directors

Each of our incumbent non-employee directors is independent in accordance with the definition set forth in the rules of The Nasdaq Stock Market LLC, though our shares of common stock are not currently listed on that exchange. Each nominated member of each of our Board committees is an independent director under the Nasdaq standards applicable to such committees. The Board considered the information included in transactions with related parties as outlined below along with other information the Board considered relevant, when considering the independence of each director.

Leadership Structure of Advaxis' Board of Directors

On May 27, 2015, David Sidransky was appointed Chairman and continues to serve as Chairman. Dr. Sidransky's experience in life science companies, as well as his scientific knowledge, his history with our Company and his own history of innovation and strategic thinking, qualify him to serve as our Chairman. Additionally, on April 23, 2018, Kenneth Berlin was appointed President and Chief Executive Officer and named a member of our board of directors. Mr. Berlin's knowledge of industry standards and his experience in industry operations and his leadership experience complements Dr. Sidransky's scientific knowledge.

While we do not have a formal policy regarding the separation of our principal executive officer and chairman of our board of directors, we believe the current structure is in the best interest of the Company at this time. Further, this structure demonstrates to our employees, customers and stockholders that we are under strong leadership, with multiple skills and sets the tone for managing our operations. This leadership structure promotes strategic development and execution, timely decision-making and effective management of our resources. We believe that we are well served by this structure.

Role of Advaxis' Board of Directors in Risk Oversight

Advaxis' board of directors has an active role in overseeing our risk management and is responsible for discussing with management and the independent auditors our major financial risk exposures, the guidelines and policies by which risk assessment and management is undertaken, and the steps management has taken to monitor and control risk exposure. The board of directors regularly engages in discussions of the most significant risks that we are facing and how those risks are being managed. Advaxis' board of directors believes that its work, and the work of the Chairman and the principal executive officer, enables the board of directors to effectively oversee our risk management function.

Meetings of Advaxis' Board of Directors

All directors who served as directors at the time attended our 2021 and 2022 Annual Meetings of Stockholders. Directors are expected, but not required, to attend the Annual Meeting of Stockholders. We will encourage, but will not require, our directors to attend our next Annual Meeting of Stockholders. Each director attended at least 75% of the aggregate of (1) the total number of board of directors' meetings and (2) the total number of meetings of the committee(s) of which he was a member, if any. Our board of directors holds meetings at least quarterly. Our board of directors held 15 meetings during fiscal year 2021, four of which were regularly scheduled and 11 were special meetings.

Executive Compensation

The Compensation Committee of the Board has responsibility for establishing, implementing and continually monitoring adherence with the Company's compensation philosophy. The Compensation Committee seeks to ensure that the total compensation paid to the executives is fair, reasonable and competitive. Our named executive officers for fiscal 2022 are Mr. Berlin, Mr. Gitelman and Dr. Gutierrez.

The following table summarizes all compensation for each of the last two fiscal years (ending October 31, 2022) awarded to, earned by or paid to our Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s)	Option Award(s) (1)	All Other Compensation (2)	Total
Kenneth Berlin	2022	$ 643,427	$ -	$ -	$ -	$ 60,341	$ 703,768
President, Chief Executive Officer	2021	$ 569,670	$ -	$ -	$ -	$ 55,728	$ 625,398
Igor Gitelman (3)	2022	$ 299,985	$ -	$ -	$ -	$ 42,224	$ 342,209
Interim Chief Financial Officer and Vice President of Finance	2021	$ 259,135	$ -	$ -	$ 15,777	$ 38,733	$ 313,645
Andres Gutierrez	2022	$ 494,944	$ -	$ -	$ -	$ 38,683	$ 533,627
Senior VP, Chief Medical Officer	2021	$ 438,208	$ -	$ -	$ -	$ 33,824	$ 472,032

(1) Reflects the aggregate grant date fair value of stock options determined in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 7 to the Company's financial statements.

(2) All Other Compensation is more fully described in the table under "All Other Compensation – Supplemental" below.

(3) Mr. Gitelman has been the Company's Chief Accounting Officer since February 2021, and was named Interim Chief Financial Officer on May 1, 2022.

All Other Compensation – Supplemental

Name and Principal Position	Fiscal Year	Health Insurance Premiums $	Life and AD&D Insurance $	Matching Contributions to 401(k) Plan $	Other $	Total $
Kenneth Berlin	2022	35,179	536	24,026	600	60,341
President, Chief Executive Officer	2021	32,526	696	21,906	600	55,728
Igor Gitelman	2022	35,179	536	5,909	600	42,224
Interim Chief Financial Officer and Vice President of Finance	2021	29,442	665	8,049	577	38,733
Andres Gutierrez	2022	35,179	536	2,368	600	38,683
Senior VP, Chief Medical Officer	2021	32,526	698	-	600	33,824

Employment Agreements with Named Executive Officers

The Company appointed Mr. Berlin as President and Chief Executive Officer, effective April 23, 2018. The Company and Mr. Berlin entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon ninety (90) days' written notice. The employment agreement provides that Mr. Berlin will receive a base salary of $576,493 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and he is eligible for an annual bonus targeted at 55% of his base salary based on achievement of performance goals in the discretion of the Compensation Committee. Mr. Berlin also received a one-time lump-sum bonus equal to $150,000 that was paid within fifteen (15) days following the effective date of the agreement. Mr. Berlin also received 625 stock options and 208 restricted stock units, which vest in equal instalments over the first three years of his employment. In May 2020, Mr. Berlin received an additional 625 stock options.

The Company appointed Mr. Gitelman as Chief Accounting Officer, effective February 11, 2021. Mr. Gitelman does not have an employment agreement with the Company. In November 2020, Mr. Gitelman received 625 stock options.

The Company appointed Mr. Gutierrez as Executive Vice President and Chief Medical Officer, effective April 23, 2018. The Company and Mr. Gutierrez entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon ninety (90) days' written notice. The employment agreement provides that Mr. Gutierrez will receive a base salary of $443,456 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and eligible for an annual bonus based on achievement of performance goals at the discretion of the Compensation Committee. Mr. Gutierrez also received a one-time lump-sum bonus equal to $40,000 that was paid within the first ninety (90) days following the effective date of the agreement. Mr. Gutierrez also received 208 stock options, which vest annually on the first three anniversaries of his employment as an equity incentive award. In May 2020, Mr. Gutierrez received an additional 625 stock options.

In the event Mr. Gutierrez employment is terminated without Just Cause, or if he voluntarily resigns with Good Reason, or if his employment is terminated due to disability (all as defined in their respective employment agreements), and so long as he executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, he is entitled to the following severance benefits: (i) twelve months of base salary payable in in equal monthly installments, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, (iii) continued health and welfare benefits for 12 months, and (iv) full vesting of all stock options and stock awards (with extension of the exercise period for stock options by two years).

On September 12, 2022, the Company and Mr. Berlin entered into Amendment No. 1 to his employment agreement to revise certain terms related to if he was terminated without Just Cause or he terminated his employment for Good Reason. In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control and ending after the CIC Protection Period, or if Mr. Berlin voluntarily resigns with Good Reason, during the CIC Protection Period, and provided that Mr. Berlin continues to comply with certain covenants set forth in his employment agreement, in addition to the applicable base salary and any earned but unpaid bonus for the prior fiscal year, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Berlin is entitled to the following severance benefits: (i) an amount equal to 2 times the sum of the applicable base salary plus an amount equal to Mr. Berlin's target bonus, payable in a single lump sum within sixty (60) days of the termination, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator is 365, (iii) continued health and welfare benefits for 24 months, and (iv) full vesting and exercisability of all stock options and stock awards. Amendment No. 1 further provides, that in the event Mr. Berlin's employment were terminated without Just Cause, or he terminated his employment for Good Reason, other than during the CIC Protection Period, he would receive equal monthly installments of 1.25 times his applicable Base Salary (increased from 1.0 times), and that he would receive this amount for 15 months rather than 12. In addition, the number of months for which he would receive continued health and welfare benefits in this circumstance is increased from 12 months to 15 months. Mr. Berlin is also entitled to a bonus payment for the year in which his employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination.

The named executive officer employment agreements contain customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table summarizes all outstanding equity awards held by our named executive officers at fiscal year-end. The market or payout value of unearned shares, units or rights that have not vested equals $1.86, which was the closing price of Advaxis' common shares on OTCQX on October 31, 2022 and for performance based restricted stock units presumes that the target performance goals are met.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Value of Shares or Units of Stock That Have Not Vested ($)
Kenneth Berlin	625	-(1)	1,944.00	4/23/2028	-	-
	267	-(2)	648.00	11/5/2028	-	-
	625	-(3)	24.80	10/24/2029	-	-
	417	208(4)	52.80	5/4/2030	-	-
Igor Gitelman	209	416(6)	31.20	11/16/2030	-	-
Andres Gutierrez	208	-(5)	1,944.00	4/23/2028	-	-
	104	-(2)	648.00	11/05/2028	-	-
	313	-(3)	24.80	10/24/2029	-	-
	417	208(4)	52.80	5/4/2030	-	-

(1) Of these options, one-third vested on December 31, 2018, one-third vested on April 23, 2020, and the award was fully vested on April 23, 2021.

(2) Of these options, one-third vested on November 5, 2019, one-third vested on November 5, 2020, and the award was fully vested on November 5, 2021.

(3) Of these options, one-third vested on October 24, 2020, one-third vested on October 24, 2021, and the award was fully vested on October 24, 2022.

(4) Of these options, one-third vested on May 4, 2021, one-third vested on May 4, 2022, and the award will be fully vested on May 4, 2023.

(5) Of these options, one-third vested on April 23, 2019, one-third vested on April 23, 2020, and the award was fully vested on April 23, 2021.

(6) Of these options, one-third vested on November 16, 2021, one-third vested on November 16, 2022, and the award will be fully vested on November 16, 2023.

Potential Payments Upon Termination or Change-in-Control

Termination of Employment

As described above under "Employment Agreements with Named Executive Officers," the Company has entered into employment agreements with two of the named executive officers that provide for certain severance payments and benefits in the event the named executive officer's employment with the Company is terminated under certain circumstances.

In addition, upon a Change in Control of the Company, unvested equity awards held by two of the executive officers will be accelerated as follows: (i) outstanding stock options and other awards in the nature of rights that may be exercised shall become fully vested and exercisable, (ii) time-based restrictions on restricted stock, restricted stock units and other equity awards shall lapse and the awards shall become fully vested, and (iii) performance-based equity awards, if any, shall become vested and shall be deemed earned based on an assumed achievement of all relevant performance goals at "target" levels, and shall payout pro rata to reflect the portion of the performance period that had elapsed prior to the Change in Control.

The table below shows the estimated value of benefits to each of the named executive officers if their employment had been terminated under various circumstances as of October 31, 2022. The amounts shown in the table exclude accrued but unpaid base salary, unreimbursed employment-related expenses, accrued but unpaid vacation pay, and the value of equity awards that were vested by their terms as of October 31, 2022.

	Involuntary Termination without a Change in Control ($)	Involuntary Termination in connection with a Change in Control ($)	Death ($)	Disability ($)	Termination for Cause; Voluntary Resignation ($)
Kenneth Berlin					
Cash severance	870,144(1)	2,157,996(5)	-	870,144(1)	-
Bonus	382,863(7)	382,863(2)	382,863(2)	382,863(7)	-
Health benefits	45,813(3)	73,701(6)	-	45,813(3)	-
Value of equity Acceleration	-(4)	-(4)	-(4)	-(4)	-
Total	1,298,820	2,614,120	382,863	1,298,820	-
Andres Gutierrez					
Cash severance	535,473(1)	535,473(5)	-	535,473(1)	-
Bonus	214,189(7)	214,189(2)	214,189(7)	214,189(7)	-
Health benefits	36,651(3)	36,651(6)	-	36,651(3)	-
Value of equity Acceleration	-(4)	-(4)	-(4)	—(4)	-
Total	786,313	786,313	214,189	786,313	-
Igor Gitelman					
Cash severance	-	-	-	-	-
Bonus	-	-	-	-	-
Health benefits	-	-	-	-	-
Value of equity Acceleration	-	-	-	-	-
Total	-	-	-	-	-

(1) For Mr. Berlin, reflects severance payment equal to 1.25 times base salary payable in equal monthly instalments for 15 months. For Mr. Gutierrez, reflects severance payment equal to one times base salary payable in equal monthly instalments for 12 months.

(2) Reflects pro rata bonus determined by multiplying the target bonus amount for the year in which the termination occurs by a fraction, the numerator of which is the number of calendar days the executive is employed during such year and the denominator of which is 365. Because the amounts reflected in the table assume the named executive officer's employment was terminated on October 31, 2022 (the last day of the 2022 fiscal year), the amounts reflected are not pro-rated.

(3) For Mr. Berlin, reflects the Company's cost of continued health coverage at active employee rates for 15 months. For Mr. Gutierrez, reflects the Company's cost of continued health coverage at active employee rates for 12 months.

(4) Reflects the value of unvested in-the-money stock options that vest upon the designated event.

(5) For Mr. Berlin, reflects two times the sum of his base salary and target bonus, payable in equal monthly installments for 24 months. For Mr. Gutierrez, equals one times base salary, payable in equal monthly installments for 12 months.

(6) Reflects the full cost of continued health coverage at active employee rates for 24 months for Mr. Berlin and 12 months for Mr. Gutierrez.

(7) Represents a bonus payment equal to the executive's target bonus.

ADVAXIS DIRECTOR COMPENSATION

For fiscal year 2021, non-employee directors received an annual cash retainer of $395,000 for board of directors' services, and the Chairman of the board of directors and the Vice Chairman of the board of directors received larger annual cash retainers of $105,000 and $87,500, respectively. Non-employee directors received additional annual retainers for serving on board of directors' committees, as follows: $15,000 for Audit Committee Chair; $15,000 for Compensation Committee Chair; $7,500 for Audit Committee member; $7,500 for Compensation Committee member; $10,000 for Nominating and Corporate Governance Chair; $10,000 for Research and Development Chair; $5,000 for Nominating and Corporate Governance member; and $5,000 for Research and Development member. On May 4, 2020, each non-employee director was granted 163 stock options. Of these options, one-third vest on May 4, 2021, one-third vest on May 4, 2022, and the final third will vest on May 4, 2023. The Compensation Committee annually reviews and makes recommendations to the board of directors regarding compensation and benefits for non-employee directors. As part of its annual review, the Compensation Committee regularly engages an independent compensation consultant to provide competitive market data and advice regarding non-employee director compensation.

The following table sets forth information regarding the compensation earned for service on Advaxis' board of directors for fiscal year 2021 by Advaxis' directors who were not also its employees. Kenneth A. Berlin, Advaxis' President and Chief Executive Officer, is also a member of Advaxis' board of directors, but did not receive any additional compensation for service as a director in fiscal year 2021. The compensation for Mr. Berlin as an executive officer is set forth above under "Advaxis Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($) [1]	Option Awards ($) [2]	Total ($)
Dr. David Sidransky	105,000	-	105,000
Dr. James Patton	87,500	-	87,500
Roni A. Appel	62,500	-	62,500
Richard J. Berman	72,500	-	72,500
Dr. Samir N. Khleif	67,500	-	67,500

(1) Represents the annual retainers paid in cash for director services in fiscal year 2021.

(2) Reflects the aggregate grant date fair value of stock options determined in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 9 to the Company's audited financial statements contained herein.

AYALA DIRECTOR COMPENSATION

The following section provides information with respect to the compensation of each director of Ayala who will serve as a director of the combined company. No executive officers of Ayala will serve as an executive officer of the combined company.

Non-Employee Director Compensation Program

Ayala maintains a Non-Employee Director Compensation Program under which each non-employee director receives the following amounts for their services on Ayala's board of directors:

- Upon the director's initial election or appointment to Ayala's board of directors,
- an option to purchase 8,750 shares of Ayala's Common Stock for each director other than the chair of the board of directors;
- an option to purchase 17,500 shares of Ayala's Common Stock for the chair of the board of directors;
- If the director has served on Ayala's board of directors for at least six months as of the date of an annual meeting of stockholders and will continue to serve as a director immediately following such meeting,
- an option to purchase 6,250 shares of Ayala's Common Stock for each director other than the chair of the board of directors;
- an option to purchase 12,500 shares of Ayala's Common Stock for the chair of the board of directors;
- An annual director fee of $25,000;
- If the director serves as chair of the board of directors or on a committee of Ayala's board of directors, an additional annual fee as follows:
- Chair of the board of directors: $20,000;
- Chair of the audit committee: $10,000;
- Audit committee member other than the chair, $5,000
- Chair of the compensation committee, $10,000;
- Compensation committee member other than the chair, $5,000;
- Chair of the nominating and corporate governance committee, $10,000; and
- Nominating and corporate governance committee member other than the chair, $5,000.

Director fees under the program are payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, provided that the amount of each payment is prorated for any portion of a quarter that a director is not serving on Ayala's board.

Stock options granted to Ayala's non-employee directors under the program have an exercise price equal to the fair market value of Ayala's Common Stock on the date of grant and expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment vest in 36 substantially equal monthly installments following the date of grant. The stock options granted annually to directors vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vest in full upon the occurrence of a change in control.

2021 Director Compensation Table

The following table sets forth information concerning the compensation earned by Ayala's non-employee directors during the year ended December 31, 2021.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Vered Bisker-Leib, Ph.D.	35,000	44,983	79,983
Murray A. Goldberg	40,000	44,983	84,983
David Sidransky, M.D.	65,000	89,965	154,965
Robert Spiegel, M.D.	32,500	44,983	77,483

(1) Amounts reflect the full grant-date fair value of stock options granted during 2021 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. Ayala provides information regarding the assumptions used to calculate the value of all option awards made to Ayala's non-employee directors in Note 8 to Ayala's audited consolidated financial statements included in this proxy statement/prospectus.

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2021 by each non-employee director who was serving on the board as of such date. None of Ayala's non-employee directors held any stock awards as of December 31, 2021.

Name	Options Outstanding at Fiscal Year End
Vered Bisker-Leib, Ph.D.	15,000
Murray A. Goldberg	36,250
David Sidransky, M.D.	12,500
Robert Spiegel, M.D.	36,250

ADVAXIS' BUSINESS

General

Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria* monocytogenes, or *Lm*, Technology antigen delivery products based on a platform technology that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, the Company's product candidates have the potential to optimize the clinical impact of checkpoint inhibitors while having a generally well-tolerated safety profile. The Company's passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline which is directed towards improving treatment options for cancer patients and increasing shareholder value.

Advaxis is focused on multiple antigen delivery products which are in various stages of clinical development. All of the Company's products are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex, or MHC, I and II pathways, due to its active phagocytosis by Antigen Presenting Cells, or APCs. Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potently stimulate the immune system.

Through a license from the University of Pennsylvania and through its own development efforts, Advaxis has exclusive access to a proprietary formulation of attenuated *Lm* that we call *Lm* Technology. *Lm* Technology is designed to optimize this natural system, and one of the keys to the enhanced immunogenicity of *Lm* Technology is the *tLLO*-fusion protein, which is made up of tumor associated antigen, or TAA, fused to a highly immunogenic bacterial protein that triggers potent cellular immunity. The *tLLO*-fusion protein is also designed to help reduce immune tolerance in the TME and to promote antigen spreading, thereby improving activity in the TME. Multiple copies of the *tLLO*-fusion protein within each construct may increase antigen presentation and TME impact.

As the field of immunotherapy continues to evolve, the flexibility of the *Lm* Technology platform has allowed Advaxis to develop highly innovative products. To date, *Lm* Technology has demonstrated preclinical synergy with multiple checkpoint inhibitors, co-stimulatory agents and radiation therapy. The safety profile of all *Lm* Technology constructs seen to date across over 470 patients has been generally predictable and manageable, consisting mostly of mild to moderate flu-like symptoms that have been transient and associated with infusion.

The Advaxis Corporate Strategy and Strategic Considerations

Our strategy is to advance the *Lm* Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. We are currently conducting clinical studies of *Lm* Technology immunotherapies in non-small cell lung cancer and early prostate cancer. We are working with, or are in the process of identifying, collaborators and potential licensees for these programs and others for first-generation *Lm* immunotherapies like ADXS-HPV for HPV-associated cancer and ADXS-HER-2 for pediatric osteosarcoma.

Advaxis is currently mainly concentrating on its disease-focused, hotspot/"off-the-shelf" neoantigen-directed therapies called ADXS-HOT. ADXS-HOT is a program that leverages the Company's proprietary *Lm* technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-associated antigens that also commonly occur in specific cancer types.

We expect that we will continue to invest exclusively in the HOT construct ADXS-504 in early prostate cancer through an ongoing Investigator Sponsored Trial (IST) at Columbia University in NYC. Additionally, we are seeking partners and/or licensees for our programs. The study with ADXS-503 immunotherapy in non-small cell lung cancer will be stopped for the difficulty in enrolling patients. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

In October 2022, we announced that we had entered into the Merger Agreement with Ayala Pharmaceuticals. ("Ayala"), pursuant to which Ayala is to merge with and into Ayala Ltd. ("Merger Sub"), a direct, wholly-owned subsidiary of Ayala, with Advaxis continuing as the surviving company and a wholly-owned subsidiary of Ayala (the "Merger").

***Lm* Technology and the Immunotherapy Landscape**

The challenge of cancer immunotherapy has been to find the best overall balance between efficacy and side effects when mobilizing the body's immune system to fight against cancer. The development of immune checkpoint inhibitors was a significant step forward, particularly with anti-PD-1 therapies, and brought with it impressive clinical activity in many different types of cancers, including melanoma, lung, head and neck and urothelial cancers. However, a literature review published in *Science* in 2018 noted that anti-PD-1 monotherapy response rates are only in the 15-25% range, and rise to ≥50% only in selected groups of patients with desmoplastic melanoma, Merkel carcinoma or tumors with mismatch-repair deficiency. Development of secondary resistance with disease progression is yet another common limitation of these therapies. Therefore, for most cancer patients, there is room for improvement. Checkpoint inhibitors can expand existing cancer fighting cells that may already be present in low numbers and support their activity against cancer cells, but if the right cancer-fighting cells are not present, checkpoint inhibitors may not provide clinical benefit. Similarly, there are many mechanisms of immune tolerance that are distinct from the checkpoints which may also be blocking the immune system from fighting cancer. Based on both pre-clinical and early clinical data, Advaxis believes that checkpoint inhibitors, when combined with treatments such as *Lm* Technology, can have an amplified anti-tumor effect. *Lm* Technology incorporates several complementary elements that include innate immune stimulation, potent generation of cancer-targeted T cells, ability to boost immunity through multiple treatments, enhancing lymphocyte infiltration into tumors, reduction of non-checkpoint mediated immune tolerance within the tumor microenvironment, and promotion of antigen spreading which may amplify the effects of treatment. These results provide rationale for further testing of *Lm* Technology agents alone and in combination with checkpoint inhibitors.

Traditional cancer vaccines were another development within immunotherapy and have a history beginning over 30 years ago. Unfortunately, these vaccines have largely been unsuccessful for a variety of potential reasons. These include poor selection of targets, imbalanced antigen presentation by inclusion of certain immune enhancing agents (adjuvants), failure to consider the blocking actions of immune tolerance, and choice of vaccine vectors. In some cases, patients may develop neutralizing antibodies, preventing further treatments. In contrast to traditional cancer vaccines, *Lm* Technology takes advantage of a natural pathway in the immune system that evolved to protect us against *Listeria* infections, that also happens to generate the same type of immunity that is required when fighting cancer. The live but weakened (attenuated) bacteria stimulate a balanced concert of innate immune triggers and present the tumor antigen target precisely where it needs to be able to generate potent cancer fighting cells from within the immune system itself. The multitude of accompanying signals serves to broadly mobilize most of the immune system in support of fighting what seems to be a *Listeria* infection, and is then "re-directed" against cancer cell targets. Additionally, the unique intracellular lifecycle of *Listeria* avoids the creation of neutralizing antibodies, thereby allowing for repeat administration as a chronic therapy with a sustained enhancing of tumor antigen-specific T cell immunity.

Looking back on the last two decades, there have been promising technology advancements to harness and activate killer T cells against cancers and every day more is learned about the interplay between immunity and cancer that can lead to improved treatments. However, there are still significant unmet needs in the immunotherapy landscape that Advaxis feels *Lm* Technology may be able to address and complement. Specifically, *Lm* Technology has the potential to optimize and expand checkpoint inhibitor activity in combination. It also avoids many of the limitations of previous cancer vaccine attempts by tapping into the pathway reserved for defense against *Listeria* infection while incorporating the best cancer targets science can identify, including neoantigens that result from mutations in the cancer. Moreover, these immunotherapies could be effectively used as adjuvant therapies for patients who have had clinical response to radical therapy, in order to prevent emergence of new metastases and disease progression. To date, *Lm* Technology products have a manageable safety profile, do not generate neutralizing antibodies lending themselves to retreatments, and most of the products are designed to be immediately available for treatment without the complication and expense of modifying a patient's own cells in a laboratory.

***Lm* Technology: An optimized *Listeria* -based antigen delivery system**

Advaxis' *Listeria* -based immunotherapies are designed for antigen delivery through a process of insertion of multiple copies of the proprietary *tLLO*-fusion protein into each extrachromosomal protein expression and secretion plasmid that makes and secretes the target protein right inside the patient's antigen presenting cells to initiate and/or boost their immune response. The *tLLO*-fusion protein approach was developed at the University of Pennsylvania as an improvement over insertion of a single copy of the target gene, as an ACT-A (or other *Lm* peptide) fusion, within the bacterial genome for four key reasons:

1. Multiple copies of the DNA in the plasmids per bacteria can result in larger amounts of *tLLO* -fusion protein being expressed simultaneously, versus a single copy. This is designed to improve antigen presentation and immunologic priming and increases the number of T cells generated for a particular treatment.

2. *tLLO* expressed on plasmids (with or without a tumor target protein attached) has been shown preclinically to reduce numbers and immune suppressive function of Tregs and myeloid-derived suppressor cells, or MDSCs, in the tumor microenvironment. Presented preclinical data demonstrates that Tregs are destroyed as soon as five days after the first *Lm* Technology treatment and that suppressive M2 tumor-associated macrophages, or TAMs, are replaced by M1 macrophages which support antigen presentation and adoptive immunity.

3. The extrachromosal DNA plasmids themselves also contain CpG sequence patterns that trigger TLR-9, which confers additional innate immune stimulation beyond a *Listeria* without the plasmids.

4. The multiple copies of bacterial DNA plasmids (up to 80-100 per bacteria) confers additional stimulation of the STING receptor within APC's which has been associated with enhancing anti-cancer immunity in patients.

Clinical Pipeline

Advaxis is focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products. Advaxis is currently winding down or has wound down clinical studies of *Lm* Technology immunotherapies in four program areas:

- Non-small cell lung cancer (ADXS-503)
- Human Papilloma Virus ("HPV")-associated cancers
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these clinical program areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. The Phase 1/2 study with ADXS-PSA ± pembrolizumab in metastatic castration-resistant prostate cancer patients was closed on January 25, 2021. The MEDI Phase 2 combo study (AZ) with AXAL ± durvalumab in Cervical and Head and Neck Cancer and the AIM2CERV Phase 3 clinical trial with ADXS-HPV (AXAL) in cervical cancer were closed on August 22, 2019 and June 11, 2021, respectively. The study with personalized neoantigen-directed therapies (ADXS-NEO) was closed on May 22, 2020 and the NEO program-IND inactivation request was submitted to the FDA on May 10, 2021. On October 18, 2022, Advaxis announced that it would begin the orderly wind down of its ADXS-503 product in the 4Q 2022 to focus on the Ayala product line and its other products.

While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these program areas, our license agreements continue with OS Therapies, LLC, for ADXS-HER2, and with GBP for the exclusive license for the development and commercialization of ADXS-HPV or AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

Advaxis Pipeline of Product Candidates

Disease-focused hotspot/'off -the-shelf' neoantigen therapies (ADXS-HOT)

Advaxis is creating a new group of immunotherapy constructs for major solid tumor cancers that combines our optimized *Lm* Technology vector with promising targets designed to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that will target somatic mutations, or hotspots; cancer testis antigens, or CTAs; and oncofetal antigens, or OFAs. These three types of targets form the basis of the ADXS-HOT program because they are designed to be more capable of generating potent, tumor-specific, and high-strength killer T cells, versus more traditional over-expressed native sequence tumor associated antigens. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT products will combine many of the potential high avidity targets that are expressed in all patients with the target disease into one "off-the-shelf," ready-to-administer treatment. The ADXS-HOT technology has a strong intellectual property, or IP, position, with potential protection into 2037, and an IP filing strategy providing for broad coverage opportunities across multiple disease platforms and combination therapies. Advaxis entered into an agreement with Columbia University Irving Medical Center in April 2021 to fund a phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study started early in 3Q 2021 and is the first clinical evaluation of ADXS-504, Advaxis' off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer.

Nearly 248,530 men in the United States will be diagnosed with prostate cancer in 2021. It has been estimated that ~135,000 new cases undergo radical prostatectomy (RP) or radiotherapy (RT). Of these cases, 20–40% of pts with RP and 30–50% with RT will experience rising prostate specific antigen (PSA) levels following local therapy (BCR) within 10 years, a condition known as biochemical recurrence (BCR). BCR is not typically associated with imminent death, and biochemical progression may occur over a prolonged period. Clinicians treating men with BCR thus face a difficult set of decisions in attempting to delay the onset of metastatic disease and death while avoiding over-treating patients whose disease may never affect their overall survival or quality of life.

The phase 1 open-label study is evaluating the safety and tolerability of ADXS-504 monotherapy, administered via infusion, in 9-18 patients with biochemically recurrent prostate cancer, i.e., those with elevation of prostate-specific antigen (PSA) in the blood after radical prostatectomy or radical radiotherapy (external beam or brachytherapy) and who are not currently receiving androgen ablation therapy. The study will also evaluate if the body's immune system can control the prostate cancer following treatment with ADXS-504 monotherapy.

HPV-Related Cancers

The Company conducted several studies evaluating axalimogene filolisbac, or AXAL, for HPV-related cancers. AXAL is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV.

In June 2019, the Company announced the closing of its AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. Company estimates showed that the remaining cost to complete the AIM2CERV trial ranged from $80 million to $90 million, and initial efficacy data was not anticipated for at least three years. Therefore, results from the clinical trial were not the basis for the decision to close the study, nor was safety as the trial recently underwent its third Independent Data Monitoring Committee (IDMC) review with no safety issues noted. The Company has unblinded the AIM2CERV clinical data generated to date and currently has no plans to present it at any medical conference as the data set is incomplete and inconclusive. The Company's clinical study report of the AIM2CERV Phase 3 study was completed on January 3, 2022 and submitted to the FDA.

In 2014, Advaxis granted Global BioPharma, or GBP, an exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries. GBP is responsible for all development and commercial costs and activities associated with the development in their territories.

Other HPV Program Licensing Agreements

Biocon Limited, or Biocon, our co-development and commercialization partner for AXAL in India and key emerging markets, filed a MAA for licensure of this immunotherapy in India.

Especificos Stendhal SA de CV, or Stendhal, the Company's co-development and commercialization partner for AXAL in Mexico, Brazil, Colombia and other Latin American countries, agreed to pay $10 million in support payment towards the expense of AIM2CERV over the duration of the trial, contingent upon Advaxis achieving annual project milestones, pursuant to a Co-Development and Commercialization Agreement, or the Stendhal Agreement. The Company was in arbitration proceedings with Stendhal. For more information, see Note 11, "*Contingencies—Legal Proceedings*" of the "*Notes to Consolidated Financial Statements*" included in Item 8.

Knight Therapeutics Inc., or Knight, holds an exclusive license to commercialize AXAL in Canada, as well as other product candidates.

Personalized Neoantigen-directed Therapies (ADXS-NEO)

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system and stimulating a T cell response against cancerous cells. In October 2019, the Company announced that it has dosed its last patient in Part A, in monotherapy, and does not intend to continue into Part B, in combination with a checkpoint inhibitor. As a result, Advaxis has closed this study. The Company has completed the clinical study report from Part A of the ADXS-NEO study and the NEO program-IND inactivation request has been submitted to FDA.

Prostate Cancer (ADXS-PSA)

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men and is the second leading cause of cancer death in men, behind only lung cancer. More than 160,000 men are estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 deaths each year. Unfortunately, in about 10-20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer, or CRPC, which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC, or mCRPC, occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen, PSA, level. This stage of prostate cancer has an average survival of 9-13 months, is associated with deterioration in quality of life, and has few therapeutic options available.

Recent data regarding checkpoint inhibitor monotherapy has shown some antitumor activity that provides disease control in a subset of patients with bone predominant mCRPC previously treated with next generation hormonal agents and docetaxel. Data from the KEYNOTE-199 trial in bone predominant-mCRPC patients treated with KEYTRUDA®, or pembrolizumab, was updated at the ASCO GU meeting in 2019. In this trial, the total stable disease/disease stabilization rate was 39% with no responses reported so far, and only one patient with ≥50% decrease in the post-baseline PSA value. It is hypothesized that the limited activity in mCRPC may be due to 1) the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment and 2) the presence of an immunosuppressive tumor micro-environment, or TME. The combination therapy with agents—like *Lm* constructs—that induce T cell infiltration within the tumor and decrease negative regulators in the TME may improve performance of checkpoints in prostate cancer.

Lm Technology constructs demonstrated the ability to induce anti-tumor T cell responses and T cell infiltration in the TME and to reduce the number and suppressive function of Tregs and MDSCs in the TME. For example, destruction of Tregs in the TME has been documented as soon as five days after dosing *Lm* constructs in models. This reduction of immune suppression in the tumors has been attributed to our proprietary *tLLO*-fusion peptides expressed by multiple copies of the plasmids in each bacteria. Because of all these effects, it is hypothesized that *Lm* constructs can turn "cold prostate tumors" into "hot tumors" that better respond to checkpoint inhibitors. Advaxis believes that the combination of ADXS-PSA, its immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC.

Advaxis has entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA®, Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (KEYNOTE-046). ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of 1×10^9 cfu (n=7) and successfully escalated to higher dose levels of $5x10^9$ cfu (n=3) and $1x10^{10}$ cfu (n=3) without achieving a maximum tolerated dose. TEAEs noted at these higher dose levels were generally consistent with those observed at the lower dose level (1×10^9 cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The Recommended Phase II Dose of ADXS-PSA monotherapy was determined to be $1x\ 10^9$ cfu based on a review of the totality of the clinical data. This dose was used in combination with 200mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in the study was completed in January 2017.

At the final data cutoff of September 16, 2019, median overall survival for 37 patients in the combination arm was 33.6 months (95% CI, range 15.4-33.6 months). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research Annual Meeting in April 2019, where median overall survival was 21.1 months in the combination arm. The combination of ADXS-PSA with KEYTRUDA®, might be associated with prolonged OS in this population, particularly in patients with unmet medical needs like visceral metastasis (16.4 months, range 4.0 - not reached) and those with prior docetaxel (16 months, range 6.4-34.6). The majority of TEAEs consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well-tolerated to date, with no additive toxicity observed. The Company presented these new data at the ASCO Genitourinary Cancers Symposium in San Francisco, CA. on February 2020 and the final results were published in the peer-reviewed journal "The Oncologist" in 2022. Advaxis has also completed the clinical study report for the ADXS-PSA study. The Company is currently seeking potential partners regarding opportunities to expand or advance this mCRPC program.

Other Lm Technology Products

HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to published literature, up to 60% of osteosarcomas are HER2 positive, and this overexpression is associated with poor outcomes for patients. ADXS-HER2 is an *Lm* Technology antigen delivery product candidate designed to target HER2 expressing solid tumors including human and canine osteosarcoma. ADXS-HER2 has received FDA and EMA ODD for osteosarcoma and has received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

A phase 1B dose escalation study of ADXS31-164 in subjects with HER-2 expressing tumors was completed, and the database lock was completed in November 2018. Overall, ADXS31-164 IV infusion at the dose of 1×10^9 CFU appeared to be safe and well tolerated in 12 subjects treated and evaluable. No objective responses were observed in this late stage heavily pre-treated patient cohort. The results of this study were primarily intended to describe the safety and tolerability of ADXS31-164. This study was not intended to contribute to the evaluation of the effectiveness of ADXS31-164 for the treatment of patients with a history of HER2 expressing tumors. Advaxis has completed the clinical study report and it has been transferred along with the ADXS31-164 program-IND to OS Therapies, as described below.

In September 2018, the Company announced that it had granted a license to OS Therapies, LLC, or OS Therapies, for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, OS Therapies, in collaboration with the Children's Oncology Group, will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. In December 2020 and January 2021, we received an aggregate of $1,415,000 from OS Therapies upon achievement of the $1,550,000 funding milestone set forth in the license agreement. In April 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and received the amount due from OS Therapies of $1,375,000 in May 2021. For more information, see Note 10, "*Licensing Agreements*" of the "*Notes to Consolidated Financial Statements*" included in Item 8.

Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement, or Aratana Agreement, with Aratana Therapeutics, Inc., or Aratana, where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture, or USDA. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana is currently conducting an extended field study which is a requirement for full USDA licensure. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to Advaxis in the amount of $1,000,000 upon signing of the Aratana Agreement. Aratana will also pay Advaxis: (a) up to $36.5 million based on the achievement of milestone relating to the advancement of products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union, or E.U., in all four therapeutic areas and up to an additional $15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all products for use in non-human animal health applications, or the Aratana Field, (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a product-by-product and country-by-country basis from first commercial sale of a product in a country until the later of (a) the 10th anniversary of first commercial sale of such product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates. In fiscal year 2019, the Company received approximately $8,000 in royalty revenue from Aratana. Additionally, in July 2019, Aratana announced that their shareholders approved a merger agreement with Elanco Animal Health, or Elanco, whereby Elanco is now the majority shareholder of Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

Corporate Information

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were a publicly-traded “shell” company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among Advaxis, the stockholders of Advaxis and us. As a result of the Share Exchange, Advaxis became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006, our stockholders approved the reincorporation of our company from Colorado to Delaware by merging the Colorado entity into our wholly-owned Delaware subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002 and the Company was listed on The Nasdaq Capital Market (“Nasdaq”) in 2014. In December 2021, the Company was delisted from Nasdaq and accepted onto the OTCQX.

Our principal executive offices are located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852, and our telephone number is (609) 452-9813. We maintain a corporate website at www.advaxis.com which contains descriptions of our technology, our product candidates and the development status of each drug. We make available free of charge through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and Current Reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. The SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is http://www.sec.gov.

Intellectual Property

Protection of our intellectual property is important to our business. We have a robust patent portfolio that protects our product candidates and *Lm* -based immunotherapy technology. Currently, we own or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with University of Pennsylvania, or Penn, Merck, National Institute of Health, or NIH, and/or Augusta University. We aggressively prosecute and defend our patents and proprietary technology. Our patents and applications are directed to the compositions of matter, use, and methods thereof, of our *Lm*-LLO immunotherapies for our product candidates, including AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2. We have and may continue to abandon prosecuting certain patents that are not strategically aligned with the direction of the Company.

Our approach to the intellectual property portfolio is to create, maintain, protect, enforce and defend our proprietary rights for the products we develop from our immunotherapy technology platform. We endeavor to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines. Issued patents which are directed to AXAL, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2021 and 2032. Issued patents directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 outside of the United States, will expire in 2032. Issued patents directed to our *Lm* -based immunotherapy platform in the United States, will expire between 2021 and 2031. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2021 and 2033.

We have pending patent applications directed to our product candidates AXAL, ADXS-PSA, ADXS-HER2, and ADXS-HOT that, if issued would expire in the United States and in countries outside of the United States between 2021 and 2037. We have pending patent applications directed to methods of using of our product candidates AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2 directed to the following indications and others: prostate cancer and her2/neu-expressing cancer, that, if issued would expire in the United States and in countries outside of the United States between 2021 and 2037, depending on the specific indications.

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

Any patent applications which we have filed or will file or to which we have or will have license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our products or technology, or may be subsequently circumvented, invalidated, narrowed, or found unenforceable. Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to successfully defend a patent challenge or to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a materially adverse effect on our business. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for, or useful to, the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and methods could be limited or prohibited.

The Drug Development Process

The product candidates in our pipeline are at various stages of clinical development. The path to regulatory approval includes multiple phases of clinical trials in which we collect data that will ultimately support an application to regulatory authorities to allow us to market a product for the treatment, of a specific type of cancer. There are many difficulties and uncertainties inherent in research and development of new products, resulting in high costs and variable success rates. Bringing a drug from discovery to regulatory approval, and ultimately to market, takes many years and significant costs.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an IRB for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the product candidate's safety, purity, and potency for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with cGMPs and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or managed on behalf of these companies by Clinical Research Organizations, or CROs. The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the study sponsor and implemented by study investigators. Clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Additionally, some clinical trials are overseen by an independent data safety monitoring board, which reviews data and advises the study sponsor on study continuation. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND.

Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain clinical outcomes in the participants.

Phase 1. Phase 1 clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate. They typically involve testing an investigational new drug on a limited number of patients. Phase 1 studies determine a drug's basic safety, maximum tolerated dose, mechanism of action and how the drug is absorbed by, and eliminated from, the body. Typically, cancer therapies are initially tested on late-stage cancer patients.

Phase 2. Phase 2 clinical trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 clinical trials gather preliminary data on effectiveness (where the drug works in people who have a certain disease or condition) and to determine the common short-term side effects and risks associated with the drug. If Phase 2 clinical trials show that an investigational new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to evaluate the investigational new drug in Phase 3 studies.

Phase 3. Phase 3 clinical trials are typically controlled multi-center trials that involve a larger number of patients to ensure the study results are statistically significant. The purpose is to confirm effectiveness and safety on a large scale and to provide an adequate basis for physician labeling. These trials are generally global in nature and are designed to generate clinical data necessary to submit an application for marketing approval to regulatory agencies. Typically, two Phase 3 trials are required for product approval. Under limited circumstances, however, approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

The FDA may also consider additional kinds of data in support of a BLA, such as patient experience data and real-world evidence. For genetically targeted populations and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Reports regarding clinical study progress must be submitted to the FDA and IRB on an annual basis. Additional reports are required if serious adverse events or other significant safety information is found. Certain reports may also be required to be submitted to the IBC. Investigational biologics must additionally be manufactured in accordance with cGMPs, imported in accordance with FDA requirements, and exported in accordance with the requirements of the receiving country as well as FDA.

Additionally, under the Pediatric Research Equity Act, or PREA, BLAs or BLA supplements for a new active ingredient, dosage form, dosage regimen, or route of administration, unless subject to the below requirement for molecularly targeted cancer products, must contain data to assess the safety and effectiveness of the product in all relevant pediatric subpopulations. The FDA may, however, grant deferrals or full or partial waivers of this requirement. PREA does not apply to orphan designated products approved solely for the orphan indication.

If a product is intended for the treatment of adult cancer and is directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, even if the product has orphan designation, the application sponsors must submit, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. Like PREA, FDA may grant deferrals or waivers of some or all of this data requirement.

Certain gene therapy studies are also subject to the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. The NIH Guidelines include the review of the study by a local institutional committee called an institutional biosafety committee, or IBC. The IBC assesses the compliance of the research with the NIH Guidelines, assesses the safety of the research and identifies any potential risk to public health or the environment.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. These include guidance regarding preclinical studies; chemistry, manufacturing, and controls; the measurement of product potency; how FDA will determine whether a gene therapy product is the same as another product for the purpose of the agency's orphan drug regulations; and long term patient and clinical study subject follow up and regulatory reporting.

To lessen the burden of subjects being required to travel to the clinic for an onsite visit during the *Lm* surveillance phase of the studies, the *Lm* surveillance period was reduced to 1 year instead of 3 years based on an agreement with the FDA in November 2020.

Biologic License Application (BLA). During clinical trials, companies usually also complete additional preclinical studies. Companies further develop additional information about the product candidate's physical characteristics and finalize the cGMP manufacturing process. The results of the clinical trials using biologics are submitted to the FDA as part of a BLA. Following the completion of Phase 3 studies, if the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of the investigational biologic, the sponsor submits a BLA to the FDA requesting marketing approval. The application is a comprehensive filing that includes the results of all preclinical and clinical studies, information about the product's composition, and the sponsor's plans for manufacturing, packaging, labeling and testing the investigational new product

Subject to certain exceptions, the BLA must be accompanied by a substantial user fee at the time of the first submission. FDA has 60 days from its receipt of a BLA to determine whether the application is sufficiently complete for filing and for a substantive review. If the FDA determines that the NDA is incomplete, the FDA may refuse to file the application, in which case the applicant must address the FDA identified deficiencies before refiling. After the BLA is accepted for filing, the FDA reviews the application to determine whether the product meets FDA's approval standards. The FDA aims to complete its review within ten months of the 60-day filing date. For products that present significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions FDA aims to complete its review within 6 months of the 60-day filing date. The FDA, however, does not always meet its review goal. The review goal date may also be extended if FDA requests or the sponsor provides additional information regarding the application. As part of the approval process, FDA will typically inspect one or more clinical sites, as well as the facility or the facilities at which the product is manufactured to ensure GCP and cGMP compliance.

FDA may also refer an application for review by an independent advisory committee. Specifically, for a product candidate for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. While FDA is not bound by the recommendation of an advisory committee, it does carefully consider the committee's recommendations.

After evaluating the application, FDA may issue an approval letter, authorizing product marketing, or a Complete Response Letter, or CRL, indicating that the application is not ready for approval. The CRL describes the application's deficiencies and conditions that must be met for product approval. If a CRL is issued, the applicant may resubmit the application, addressing the deficiencies, withdraw the application, or request a hearing. Even with submission of additional information, the FDA ultimately may decide that the application is not approvable.

If approval is granted, the FDA may limit the indications for use, including the indicated population, require contraindications, warnings or precautions be included in the product labeling, including black box warnings, or may not approve label statements necessary for successful commercialization. FDA may also require, or companies may conduct, additional clinical trials following approval, called Phase 4 studies, which can confirm or refute the effectiveness of a product candidate, and can provide important safety information. FDA may also require the implementation of a REMS which may include requirements for a medication guide or patient package insert, a communication plan on product risks, or other elements to assure safe use.

After approval, some types of changes to the approved product, such as adding new indications or label claims, which may themselves require further clinical testing, or changing the manufacturing process are subject to further FDA review and approval. FDA can also require the implementation REMS or the conduct of phase 4 studies after product approval.

Government Regulations

General

Government authorities in the United States and other countries extensively regulate, among other things, the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of biopharmaceutical and drug products. In the United States, the FDA subjects drugs to rigorous review under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations.

Orphan Drug Designation

Under the ODA, the FDA may grant ODD, to a drug or biological product intended to treat a rare disease or condition, which means a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States will be recovered from domestic sales of the product. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity.

The benefits of ODD can be substantial, including research and development tax credits, grants and exemption from user fees. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. Moreover, if there is no other product that the FDA considers to be the same product that is approve for the orphan indication, the orphan designated product is eligible for 7 years of orphan market exclusivity once the product is approved. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. Other applicants, however, may receive approval of different products for the orphan indication or the same product for a different indication during the orphan exclusivity period. In order to qualify for these incentives, a company must apply for designation of its product as an "Orphan Drug" and obtain approval from the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

We currently have ODD with the FDA for AXAL for treatment of anal cancer (granted August 2013), HPV-associated head and neck cancer (granted November 2013); and treatment of Stage II-IV invasive cervical cancer (granted May 2014). We also have ODD with the FDA for ADXS-HER2 for the treatment of osteosarcoma (granted May 2014).

In Europe, the Committee for Orphan Medicinal Products, COMP, has issued a positive opinion on the application for ODD of AXAL for the treatment of anal cancer (December 2015) and on the application for ODD of ADXS-HER2 for osteosarcoma (November 2015).

Expedited Review and Approval Programs for Serious Conditions

Four core FDA programs are intended to facilitate and expedite development and review of new biologics to address unmet medical need in the treatment of serious or life-threatening conditions: Fast Track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to avail ourselves of any and all of these programs as applicable to our products.

FDA is required to facilitate the development, and expedite the review, of products that are intended for the treatment of a serious or life-threatening disease or condition, and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new biologic product candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. If Fast Track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. FDA may also initiate review of sections of a Fast Track product's BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted.

Under FDA's accelerated approval programs, FDA may approve a product for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

Under the provisions of the FDA Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Another expedited pathway is the Regenerative Medicine Advanced Therapy, or RMAT, designation. Qualifying products must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. The product must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the product has the potential to address an unmet need for such disease or condition. Advantages of the RMAT designation include all the benefits of the Fast Track and breakthrough therapy designation programs, including early interactions with the FDA. These early interactions may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including biologics, are required to register and submit certain clinical trial information within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, Trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years, depending on the circumstances, after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Coverage, Pricing and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under certain federal governmental healthcare programs, such as Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. In the United States, the process for determining whether a third-party payor will provide coverage for a biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. With respect to biologics, third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost sharing obligation imposed on patients. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of a product. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable a manufacturer to maintain price levels sufficient to realize an appropriate return on its investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product does not ensure that other payors will also provide coverage for the medical product, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and is a time-consuming process.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, in addition to questioning safety and efficacy. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country (particularly in the EEA where it is illegal to impede such imports from elsewhere within the EEA).

Other Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including CMS, the HHS Office of Inspector General and HHS Office for Civil Rights, other divisions of the HHS and the Department of Justice.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

The AKS prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the FCA, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Several biopharmaceutical, medical device and other healthcare companies have been prosecuted under the FCA and civil monetary penalty laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved (e.g., or off-label), and thus non-covered, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Claims which include items or services resulting from a violation of the federal AKS are false or fraudulent claims for purposes of the FCA.

Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under these laws.

HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The Affordable Care Act, or the ACA, imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year and the reported information is publicly made available on a searchable website.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, although it is unclear that we would be considered a "business associate" in the normal course of our business. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

Similar state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extend Medicaid rebates to Medicaid managed care plans, provide for mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. With the President Trump administration and current Congress, there will likely be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their lawsuit was dismissed by a federal judge in California on July 18, 2018. In addition, CMS has recently finalized regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills, and may do so again in the future, designed to repeal or repeal and replace portions of the ACA.

While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to repeal and replace elements of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027, unless additional Congressional action is taken.

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The Blueprint contains certain measures that HHS is already working to implement. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Non-U.S. Regulation

Before our products can be marketed outside the United States, they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The time spent in gaining approval varies from that required for FDA approval, and in certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

Collaborations, Partnerships and Agreements

Collaborations, partnerships and agreements are a key component of Advaxis' corporate strategy. As a clinical stage biotechnology company without sales revenue, partnerships are an essential part of the ongoing strategy. Additionally, the evolution of the field of immunotherapy has resulted in combination treatments becoming ubiquitous; ongoing clinical studies and agreements with many of the leading, large oncology pharmaceutical companies helps validate that *Lm* Technology may play a key role in the cancer treatment protocols of the future.

Our collaborators and partners include Merck, OS Therapies, Biocon, Global BioPharma, Knight, and others. For more information, see Note 10, "*Licensing Agreements*" of the "*Notes to Consolidated Financial Statements*" included in Item 8.

We entered into an exclusive worldwide license agreement with Penn, on July 1, 2002 with respect to the innovative work of Yvonne Paterson, Ph.D., Associate Dean for Research at the School of Nursing at Penn, and former Professor of Microbiology at Penn, in the area of innate immunity, or the immune response attributed to immune cells, including dendritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically (subject to certain U.S. government rights). This agreement was amended and restated as of February 13, 2007, and, thereafter, has been amended from time to time.

This license, unless sooner terminated in accordance with its terms, terminates upon the latter of (a) the expiration of the last to expire of the Penn patent rights; or (b) twenty years after the effective date of the license. Penn may terminate the license agreement early upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to us.

The license provides us with the exclusive commercial rights to the patent portfolio developed by Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our Common Stock. In addition, Penn is entitled to receive a non-refundable initial license fee, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the amended licensing agreement, Penn is entitled to receive 2.5% of net sales in the territory. Should annual net sales exceed $250 million, the royalty rate will increase to 2.75%, but only with respect to those annual net sales in excess of $250 million. Additionally, Penn will receive tiered sales milestone payments upon the achievement of cumulative global sales ranging between $250 million and $2 billion, with the maximum aggregate amounts payable to Penn in the event that maximum sales milestones are achieved is $40 million. Notwithstanding these royalty rates, upon first in-human commercial sale (U.S. & E.U.), we have agreed to pay Penn a total of $775,000 over a four-year period as an advance minimum royalty, which shall serve as an advance royalty in conjunction with the above terms. In addition, under the license, we are obligated to pay an annual maintenance fee of $100,000 commencing on December 31, 2010, and each December 31st thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to us and we are obligated to reimburse Penn for all attorney's fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Upon first regulatory approval in humans (US or EU), Penn will be entitled to a milestone payment of $600,000. Furthermore, upon the achievement of the first sale of a product in certain fields, Penn will be entitled to certain milestone payments, as follows: $2.5 million will be due upon the first in-human commercial sale (US or EU) of the first product in the cancer field and $1.0 million will be due upon the date of first in-human commercial sale (US or EU) of a product in each of the secondary strategic fields sold.

Manufacturing

cGMPs, are the standards identified to conform to requirements by governmental agencies that control authorization and licensure for manufacture and distribution of biologic products for either clinical investigations or commercial sale. GMPs identify the requirements for procurement, manufacturing, testing, storage, distribution and the supporting quality systems to ensure that a drug product is safe for its intended application. cGMPs are enforced in the United States by the FDA, under the authorities of the Federal Food, Drug and Cosmetic Act and its implementing regulations and use the phrase "current good manufacturing practices" to describe these standards.

Each of Advaxis' wholly owned product candidates is manufactured using a platform process, with uniform methods and testing procedures. This allows for an expedited pathway from construct discovery to clinical product delivery, while helping to keep cost of goods low.

Advaxis has entered into agreements with multiple third-party organizations, or CMOs, to handle the manufacturing, testing, and distribution of product candidates. These organizations have extensive experience within the biologics space and with the production of clinical and commercial GMP supplies.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development expenses. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including: BioNtech, Moderna, Gritstone, BMS, AstraZeneca, Merck, Neon Therapeutics, et al., each of which is pursuing cancer vaccines and/or immunotherapies.

Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential immunotherapies or of competitors' products may be an important competitive factor. Accordingly, the speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, administration, reliability, acceptance, availability, price and patent position.

Experience and Expertise

Our management team has extensive experience in oncology development, including contract research, development, manufacturing and commercialization across a board range of science, technologies, and process operations. We have built internal capabilities supporting research, clinical, medical, manufacturing and compliance operations and have extended our expertise with collaborations.

Employees

As of October 31, 2022, we had 15 employees, 14 of which were full time employees. Of our full-time employees, 1 holds a Ph.D. degree. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

Properties

Advaxis' principal office is located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852. We will continue to rent necessary offices and laboratories to support our business. Advaxis believes that its facilities are sufficient to meet its current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

Advaxis is not subject to any material legal proceedings.

AYALA'S BUSINESS

Overview

Ayala is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers. Ayala's current portfolio of product candidates, AL101 and AL102, targets the aberrant activation of the Notch pathway using gamma secretase inhibitors, or GSIs. Gamma secretase is the enzyme responsible for Notch activation and, when inhibited, turns off the Notch pathway activation. Aberrant activation of the Notch pathway has long been implicated in multiple solid tumor and hematological cancers and has often been associated with more aggressive cancers. In cancers, Notch is known to serve as a critical facilitator in processes such as cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, all of which contribute to a poorer patient prognosis. AL101 and AL102 are designed to address the underlying key drivers of tumor growth, and Ayala's initial Phase 2 clinical data of AL101 and AL102 suggest that Ayala's approach may address shortcomings of existing treatment options. Ayala believes that its novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from rare and aggressive cancers.

Ayala's product candidates, AL101 and AL102, are being developed as potent, selective, small molecule GSIs. Ayala obtained an exclusive, worldwide license to develop and commercialize AL101 and AL102 from BMS in November 2017. BMS evaluated AL101 in three Phase 1 studies involving more than 200 total subjects and AL102 in a single Phase 1 study involving 36 subjects with various cancers who had not been prospectively characterized for Notch activation, and to whom Ayala refers as unselected subjects. While these Phase 1 studies did not report statistically significant overall results, clinical activity was observed across these studies in cancers in which Notch has been implicated as a tumorigenic driver.

AL102, is being developed as an oral GSI for the treatment of desmoid tumors. AL102 is being evaluated in the Phase 2/3 RINGSIDE trial for the treatment of desmoid tumors, which could potentially be used as a registrational trial, and has received Fast Track designation for progressing desmoid tumors from the FDA. Desmoid tumors are rare, disfiguring and often debilitating types of soft tissue tumors. Desmoid tumors have an annual incidence of approximately 1,700 patients in the United States. There are currently no therapies approved by the FDA for patients with desmoid tumors. Given the slowly progressive nature of the disease, Ayala believes these patients will be best served by an oral therapy. BMS conducted a Phase 1 study of AL102 in 36 subjects with heavily pretreated unselected solid tumors. While this Phase 1 study did not report statistically significant overall results, the study included one subject with desmoid tumors who was observed to have stable disease, or SD, for over six months. In a separate Phase 1 study of AL101, three subjects with desmoid tumors were included. Two of these subjects had a partial response, or PR, and continued treatment in a post-trial expanded access protocol. Both maintained their responses, and one subject had SD. These results were published in *Current Oncology* in September 2021. Ayala believes that GSIs have the potential to treat patients with desmoid tumors based on the data Ayala has obtained to date.

The Phase 2/3 RINGSIDE trial is designed to evaluate the efficacy, safety and tolerability of AL102 in adult and adolescent patients with desmoid tumors. Part A of the study is an open-label study (Phase 2) and, in February 2022, completed the enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102 of 1.2 mg once daily, 2 mg twice weekly, and 4 mg twice weekly, with initial follow up to evaluate safety, tolerability and tumor volume by MRI after 16 weeks in order to determine the optimal dose. On September 12, 2022, Ayala announced interim results from Part A of the RINGSIDE Pivotal Phase 2/3 trial and the selection of 1.2 mg once daily as the dose to be tested in Part B (the Phase 3 portion of the study). As of the cut-off date of July 14, 2022, 28 patients were evaluable for tumor volume and 29 were evaluable for Response Evaluation Criteria in Solid Tumors 1.1, or RECIST, a commonly used set of measures for evaluating the response of solid tumors to treatment, with a scan at base line and at least one additional scan at week 16. Twelve subjects had follow up MRI scans at week 28 and one patient had a scan at week 40. One patient had a PR per RECIST at week 16, confirmed at week 28. Three additional unconfirmed PRs were observed, two at week 28 and one at week 40. Continuous tumor volume reduction was observed over time in all patients that underwent two or more MRI scans. At week 16, there were nine evaluable patients for RECIST in the selected dose of 1.2 mg once daily with one PR observed, confirmed at week 28. The remaining eight patients had stable disease, of which seven patients had a tumor reduction. At week 28, there were three patients evaluable for RECIST in the selected dose of 1.2 mg once daily with one confirmed and one unconfirmed PR and one stable disease with all patients showing tumor reduction and deepening of tumor shrinkage since previous scan. At the selected dose of 1.2 mg once daily, at week 16 there were nine evaluable patients for tumor volume change with seven patients experiencing tumor volume reduction. At week 28, there were three evaluable patients for volume change in the selected dose of 1.2 mg once daily with all three patients experiencing continuous tumor shrinkage. AL102 was generally well tolerated at all doses. Most adverse events were grade 1 or 2 and included mainly diarrhea. No grade 4 or 5 events were observed and only low rates of grade 3 events were observed. At the selected dose of 1.2 mg once daily, three out of the 14 patients (21.4%) experienced grade 3 events. Ovarian dysfunction was observed in about 22% of women with childbearing potential (N=23). At the end of Part A, all patients will be eligible to enroll into an open label extension study at the selected dose where long-term efficacy and safety will be monitored. The effect of food on absorption of AL102 was also evaluated in Part A and results showed that food restrictions were not needed. Ayala is advancing Part B (the Phase 3 portion) of the RINGSIDE study with a selected dose of 1.2 mg once daily and enrolling patients in the open-label extension study at the same dose. Part B of the study will be a double-blind placebo-controlled study enrolling up to 156 patients with progressive disease, randomized between AL102 or placebo.

Ayala is currently evaluating AL101 as a monotherapy in an open-label Phase 2 clinical trial for the treatment of R/M ACC, for patients bearing Notch-activating mutations. Ayala refers to this trial as the ACCURACY trial. Ayala uses next-generation sequencing, or NGS, to identify patients with Notch-activating mutations, an approach that Ayala believes will enable Ayala to target the patient population with cancers that it believes are most likely to respond to and benefit from AL101 treatment. Ayala chose to initially target R/M ACC based on Ayala's differentiated approach, which is comprised of: data generated in a Phase 1 study of AL101 in unselected, heavily pretreated subjects conducted by BMS, Ayala's own data generated in patient-derived xenograft models, Ayala's bioinformatics platform and its expertise in the Notch pathway.

ACC is a rare malignancy of the secretory glands, most commonly of the salivary glands. It has an annual incidence of approximately 3,400 patients in the United States, approximately 1,700 of whom are R/M ACC patients. There are currently no FDA-approved therapies for patients with R/M ACC. Based on scientific literature and Ayala's bioinformatics research, Ayala estimates that 18% to 22% of R/M ACC patients have Notch-activating mutations. These Notch patients have a significantly worse prognosis, with estimated overall median survival rates roughly four times shorter than patients without Notch-activating mutations. According to published data from 31 Phase 2 clinical trials in ACC conducted since 2005 using a variety of treatment modalities, these treatments showed limited or no clinical activity in unselected ACC subjects. The objective response rates, or ORRs, in 30 of these trials, ranged from 0% to 20%, with a 47% ORR observed in one trial conducted in China. In 15 of the 31 trials, a 0% ORR was observed. ORR includes subjects who displayed either a CR or PR.

Ayala is currently conducting its ongoing Phase 2 ACCURACY trial for the treatment of R/M ACC in subjects with progressive disease and Notch-activating mutations. As of April 14, 2022, 87 subjects were enrolled and 77 were evaluable for efficacy, including 41 subjects in the 4mg cohort, and 36 in the 6mg cohort. No confirmed responses were observed, and the disease control (PR+SD) rate across both dose cohorts was 69% (53/77). In the 4mg cohort, there were 6 PRs and, in the 6mg cohort, there were 3 PRs. All 87 treated patients in the AL101 experienced treatment-emergent adverse events, or TEAEs. Grade 3/4 adverse events occurred in 54 patients (62.1%) and 49 experienced at least one serious TEAE (56.3%). There were nine deaths (10.3%) resulting from TEAEs.

If approved, Ayala believes that AL101 has the potential to become the first FDA-approved therapy for patients with R/M ACC and to address the unmet medical need of these patients. AL101 was granted ODD for the treatment of ACC in May 2019 and Fast Track designation in February 2020 for the treatment of R/M ACC. In the second quarter of 2020, Ayala commenced dosing of patients in its ACCURACY trial for the treatment of R/M ACC with Notch-activating mutations at the higher dose of 6 mg. Ayala reported initial data from this trial in 2022.

As part of Ayala's efforts to focus its resources on its more advanced programs and studies, it is focusing its efforts on the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC.

Ayala's product candidates have been or are being evaluated in clinical trials at leading oncology centers across the United States, including MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center and Massachusetts General Hospital, and in centers in Canada, Israel and Europe.

Ayala's History and Team

Ayala was founded in November 2017 when Ayala acquired an exclusive, worldwide license to AL101 (previously called BMS-906024) and AL102 (previously called BMS-986115), from BMS. Ayala has assembled a team with extensive experience in building and operating clinical and commercial organizations, particularly in oncology and rare diseases. Ayala's President and Chief Executive Officer, Roni Mamluk, Ph.D., has extensive experience in the biopharmaceutical industry and has led Ayala's business since its inception. Ayala's Chief Medical Officer, Gary Gordon, M.D., Ph.D., is an oncologist with clinical research experience from John Hopkins School of Medicine and in oncology drug development roles at AbbVie, Inc. Dr. Gordon was involved in the development and commercialization plans for venetoclax, celecoxib and veliparib. Members of Ayala's management team have held leadership positions at companies that have successfully discovered, acquired, developed and commercialized therapies for a range of rare diseases and cancers, including Chiasma Inc., Adnexus Therapeutics, Inc., AbbVie Inc., Abbott Laboratories, Protalix Biotherapeutics, Inc. and Teva Pharmaceutical Industries Ltd.

Ayala's Strategy

Ayala's goal is to develop and commercialize therapies that improve treatment outcomes for patients with aggressive cancers. The key elements of Ayala's strategy are:

- ***Rapidly advance the clinical development of AL102 for the treatment of desmoid tumors.*** Ayala is currently conducting its pivotal Phase 2/3 RINGSIDE study, which could potentially be used as a registrational study, and where it has completed enrollment for Part A, evaluating AL102 for the treatment of desmoid tumors. Ayala is advancing Part B of the RINGSIDE study with a selected dose of 1.2 mg once daily and enrolling patients in the open-label extension study at the same dose. AL102 has received Fast Track designation for progressing desmoid tumors from the FDA. There are currently no FDA-approved therapies for patients with desmoid tumors. Ayala also intends to evaluate other indications in which it believes AL102 could potentially deliver substantial benefits to patients.

- ***Rapidly advance the clinical development of AL101 for the treatment of R/M ACC.*** Ayala is currently conducting its Phase 2 ACCURACY trial of AL101 for the treatment of R/M ACC. Ayala's interim data from both the 4mg and 6mg dosing groups of its clinical trial showed encouraging initial signs of activity. Ayala expects to report further results from this trial in a medical conference in the second half of 2022. AL101 was granted ODD in May 2019 for the treatment of ACC and Fast Track designation in February 2020 for the treatment of R/M ACC. If approved, Ayala believes that AL101 has the potential to become the first FDA-approved therapy for patients with R/M ACC. Ayala may also seek regulatory approval of AL101 for the treatment of R/M ACC selectively in other territories.

- ***Commercialize Ayala's product candidates, if approved, to address the unmet medical need of underserved patient populations with rare and aggressive cancers.*** Ayala intends to commercialize its product candidates, if approved, by building its own specialized sales and marketing organization initially in the United States. Ayala believes its target market can be addressed by a small number of dedicated marketing and medical sales specialists covering specialized oncologists treating the target patient population. Ayala may also selectively pursue strategic collaborations with third parties to maximize the commercial potential of its product candidates, if approved.

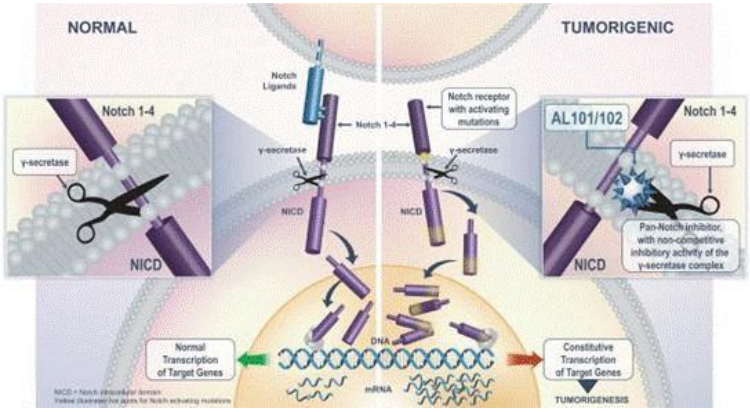
- ***Evaluate strategic collaborations to maximize the potential of Ayala's portfolio.*** Ayala is continuously evaluating opportunities to expand its portfolio of product candidates through in-licensing, acquisition and other collaboration opportunities to jointly develop product candidates and maximize the value of Ayala.

Ayala's Product Candidates

The Role of the Notch Pathway

The Notch pathway has long been implicated in multiple solid tumor and hematological cancers, and often has been associated with more aggressive cancers. Notch receptors serve as critical facilitators in processes such as cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, which all contribute to a poorer prognosis. Humans have four Notch receptors, known as Notch 1, 2, 3 and 4, as well as five transmembrane-bound ligands. Different forms of cancer are associated with different types of Notch mutations.

Normal and Tumorigenic Signaling of Notch



As seen on the left side of the above graphic, normal Notch receptor signaling is initiated by the binding of a ligand expressed on an adjacent cell, which triggers a conformational change, permitting cleavage of the Notch receptor by the g-secretase complex. As seen on the right side of the above graphic, this cleavage releases the Notch intracellular domain, or NICD, which then translocates to the cell nucleus, interacts with transcription complexes and promotes the transcription of downstream target genes that regulate critical cell functions. This pathway activation is terminated by the degradation of NICD. Activating mutations in the Notch receptor lead to accumulation of the NICD and hyper-activation of the pathway, resulting in excess NICD. Hyper-activation of the Notch pathway promotes cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, which are each hallmarks of cancer.

Ayala's Potent and Selective Investigational Gamma Secretase Inhibitors

Ayala is developing targeted therapies designed to address the underlying key drivers of tumor growth in patients where GSI inhibition of the Notch pathway may lead to clinical benefit. Ayala's current portfolio of product candidates targets the aberrant activation of the Notch pathway with GSIs. Gamma secretase is the enzyme responsible for Notch activation and, when inhibited, blocks the expression of Notch gene targets by blocking the final cleavage step required for Notch activation, thereby "turning off" the aberrant activation of the Notch pathway. Ayala has designed its GSIs to selectively inhibit all four Notch receptors.

Ayala's Bioinformatics Platform

Ayala has developed a proprietary bioinformatics platform to analyze NGS data and identify patients in whom Notch is a tumorigenic driver. Ayala applies its big-data analysis capabilities to identify and confirm patients with Notch-activating mutations who are likely sensitive to GSIs.

The first step in Ayala's bioinformatics process is to gather evidence from literature and identify indications in which Notch is a known tumorigenic driver. Ayala then confirms there are a requisite number of patients with Notch alterations in a specific indication using its proprietary database to integrate genetic information from thousands of unidentified patients. Ayala couples these methods with its analysis of patient-derived xenograft, or PDX, models, which allow Ayala to assess the sensitivity of the tumors *in vivo* with Notch-activating mutations, for certain indications.

Ayala's bioinformatics platform includes:

- Ayala Cancer Omics Research Database, or ACORD, which is used to collate NGS data and integrate Notch-activating mutations from approximately 250,000 patients with over 400 different forms of cancer and harbors approximately 27,000 unique Notch alterations. Ayala continues to expand ACORD by gaining access to additional sources of NGS data and scientific literature. Ayala believes that it possesses the largest database of Notch-activating mutations.

- Open source and proprietary algorithms integrated into a dedicated software platform, resulting in over 20 specialized data processing pipelines. These algorithms transform DNA and RNA sequences into searchable parameters, including which cancers harbor potential Notch-activating mutations. A systems biology approach is then applied to explore pathways involved in drug resistance and inform the design of Ayala's future clinical trial designs and to consider potential treatment combinations and responses to GSI.

Ayala's scientists continue to utilize unique capabilities in bioinformatics and functional biology to create a Notch-focused patient identification engine that it believes will result in the discovery of additional patients with currently undetected Notch-activating mutations.

Expanding Ayala's Addressable Patient Population

In addition to the well-known scientific literature supporting Notch's tumorigenic role in various forms of cancer, Ayala is developing its bioinformatics platform to potentially discover additional genetic alterations not currently covered in commercially available genetic screening panels. Currently available NGS tests only cover certain areas of Notch genes on the DNA level, however, Ayala believes that there is no single test that covers all four Notch genes on the DNA and RNA level. As a result, these tests are able to detect only a subset of the patients with Notch-activating mutations. In order to develop a diagnostic test that can detect the full breadth of Notch-activating mutations on both the DNA and RNA level, Ayala plans to collaborate with leading diagnostics companies to improve the testing capabilities for Notch-activating mutations. For example, Ayala has a collaboration agreement with Tempus to use their assays to assist with patient selection for Ayala's future clinical trials and detect a wider range of Notch gene rearrangements than commercially available NGS tests.

Ayala estimates that there are up to 12,000 newly diagnosed patients annually across the United States, Europe and Japan who have Notch pathway activation in the indications that it is currently targeting.

Ayala's Novel Approach: AL101 and AL102

Differentiated GSI for the Treatment of Rare Cancers

AL101 and AL102 are potent and selective small molecule GSIs designed to inhibit the aberrant activation of the Notch pathway. In preclinical studies and three Phase 1 studies conducted by BMS, tumor responses were observed in cancers Ayala is initially targeting and where Notch is known to be an important tumorigenic driver. Ayala's further investigation using PDX models provided additional evidence supporting its targeted patient population development approach.

In preclinical studies, both AL101 and AL102 inhibited all four Notch genes at low concentrations, when compared to other GSIs either currently or previously under development as illustrated in the below graphic.

Comparative Inhibitory Potency of Five GSIs in a Notch Luciferase Reporter Assay

Inhibition of Constitutive Notch Signaling: IC50 (nM)1

	AL101 (BMS-906024)	AL102 (BMS-986115)	Niro-gacestat[2] (PF-03084014)	RO-4929097[3]	MK-0752[4]
Notch1	1.6	6.1	13	3.8	354
Notch2	0.7	2.9	15	4.4	403
Notch3	3.4	8.1	17	22	955
Notch4	2.9	4.4	16	12	874

(1) Luciferase reporter-based assay, inhibition of constitutive Notch signaling.

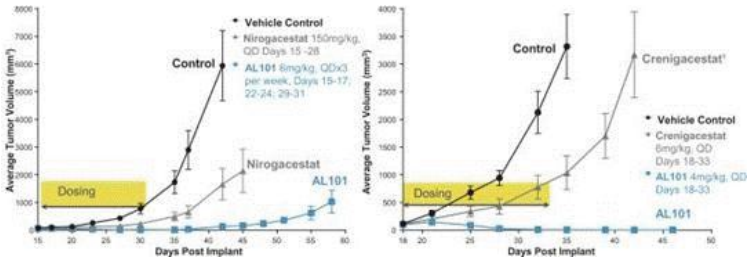
(2) Nirogacestat is being developed by SpringWorks Therapeutics, Inc.

(3) RO-4929097 was developed by F. Hoffmann-La Roche Ltd. and is not under active development.

(4) MK-0752 was developed by Merck & Co., Inc. and is not under active development.

The Notch cell-based transactivation assay was based on the ability of the released NICD to function as a transcription factor with other nuclear factors. Luciferase reporter activity provided a measure of the antagonism of Notch transcriptional activity. HeLa cervical cancer cells were transiently cotransfected with plasmids containing truncated Notch 1-4 receptors and a luciferase reporter vector. The cells were tested for Notch-activity in the absence or presence of GSIs at increasing concentrations. These data represent the GSI concentration inhibiting luciferase assay by 50%, or IC50. Lower concentrations correlate to more potent GSIs. As highlighted in the above graphic, AL101 and AL102 generally reached IC50 across all four Notch receptors at concentrations lower than other GSIs either currently or previously under development, which displayed the potency of AL101 and AL102 and supported the continued clinical development of these product candidates.

Effect on Tumor Growth in T-ALL Mouse Model



Tumor volume data are Mean ± SEM for 7-8 mice per treatment arm.

(1) Crenigacestat is being developed by Celgene Corporation, which was acquired by BMS.

Furthermore, as shown in the graphs above, AL101's stronger inhibition of tumor growth was observed in T-ALL mouse models when compared to other GSI molecules. Ayala believes that AL101 and AL102, if approved, are GSIs with the potential to address the unmet medical need for patients with rare and aggressive tumors.

Ayala's Novel Approach: AL102

Overview

AL102 is being developed as a potent, selective and oral GSI. Ayala obtained an exclusive, worldwide license to develop and commercialize AL102 from BMS in November 2017. Ayala is initially developing AL102 for the treatment of desmoid tumors.

The FDA has agreed, based on data from AL101 and AL102 studies including durable responses observed in patients with Desmoid tumors, to proceed with a Phase 2/3 pivotal study which can potentially be used as a registrational study. Part A of the study is an open-label study and, in February 2022, completed the enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102: 1.2 mg once daily, 2 mg twice weekly, and 4 mg twice weekly with initial follow up to evaluate safety, tolerability and tumor volume by MRI after 16 weeks in order to determine the optimal dose. On September 12, 2022, Ayala announced interim results from Part A of the RINGSIDE Pivotal Phase 2/3 trial. Ayala is advancing Part B of the RINGSIDE study with a selected dose of 1.2 mg once daily and enrolling patients in the open-label extension study at the same dose. AL102 has received Fast Track designation for progressing desmoid tumors from the FDA.

AL102 for the Treatment of Desmoid Tumors

Disease Background

Desmoid tumors, also called aggressive fibromatosis, are rare connective tissue neoplasms with an annual incidence of approximately 1,700 patients in the United States, and arise in the extremities, abdominal wall, mesenteric root, and chest wall. An estimated 7% to 15% of desmoid tumors present in the head and neck. They do not metastasize, but often aggressively infiltrate neurovascular structures and vital organs resulting in pain, loss of function, organ dysfunction, and death.

Desmoid tumors are typically diagnosed in patients between 15 and 60 years of age, more often in young adults, with a two- to three-fold female predominance and no significant racial or ethnic predilection.

Current Treatment Landscape

Although surgery and radiation remain the primary therapies for desmoid tumors, there are no treatment options for some patients given the diffuse nature of the tumor in some tissues. Surgery and radiation suffer from additional shortcomings including the morbidity associated with resection, disfigurement and/or functional impairment, post-operative complications and frequent recurrences. Aggressive adjuvant radiation therapy and surgical resection with wide margins of normal tissue may improve rates of post-surgical recurrence, which can occur in up to 72% of patients.

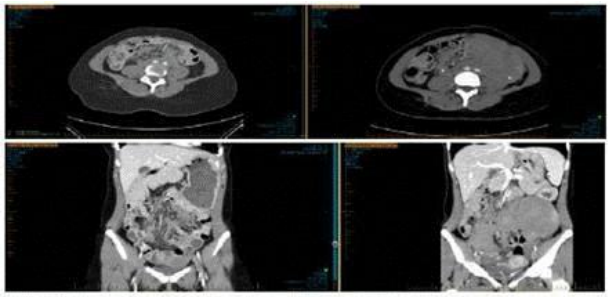
There are no FDA-approved systemic therapies for the treatment of unresectable, recurrent or progressive desmoid tumors and there is no currently accepted standard of care. Since current treatment responses are insufficient and not durable, there is an unmet medical need for the treatment of recurrent or progressive tumors (systemic therapy). Given the high recurrence and progression rates and lack of effective treatment options, Ayala believes that there is a sizeable patient population with desmoid tumors with a high unmet medical need.

Clinical Evidence of GSI Activity in Desmoid Tumors

Based on data from multiple clinical evaluations, including data from three patients with desmoid tumors evaluated in a Phase 1 study of AL101 conducted by BMS, Ayala believes that GSIs have the potential to address the shortcomings associated with existing treatment options for patients with desmoid tumors. In the Phase 1 study of AL101, PRs were observed in two subjects with desmoid tumors and SD was observed in another subject with desmoid tumors. In addition, three subjects, including two subjects from the Phase 1 study of AL101, entered into an expanded access program. Two case studies of adult patients with desmoid tumors treated with AL101 were published in *Current Oncology*.

The data included in the case studies were based on earlier Phase 1 results and compassionate use of AL101 in desmoid tumors. Both patients evaluated in these case studies, Case One and Case Two, presented with substantial tumor burden and symptomatic and life-threatening disease due to disease bulk and location. Both patients achieved long-lasting PRs with AL101 treatment with a maximum decrease in tumor size from baseline of 41% after approximately 1 year (55 weeks) of treatment in Case One, and a maximum decrease in tumor size from baseline of 60% after about 1.6 years (82 weeks) of treatment in Case Two. With continued monitoring, one patient was able to discontinue AL101 after 4.6 years of treatment, while maintaining a PR, and the other patient has maintained a PR at a reduced AL101 dose.

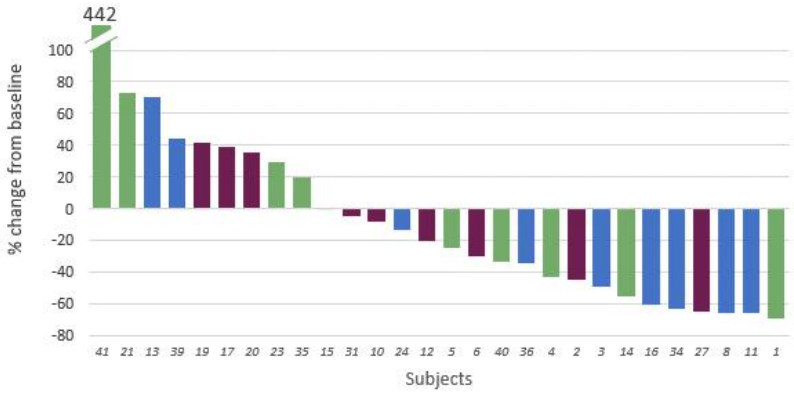
Below are scans from a patient who achieved a PR and following the end of the BMS study opted to continue into an expanded access program



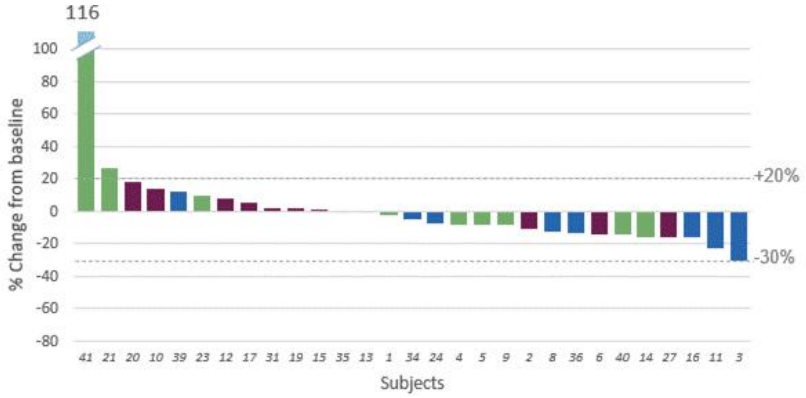
Phase 2/3 Pivotal Study of AL102

Ayala is currently conducting its Phase 2/3 RINGSIDE pivotal study, which could potentially be used as a registrational trial, in adult and adolescent patients with desmoid tumors. The study's primary endpoint is progression free survival, or PFS, with secondary endpoints including, ORR, duration of response, or DOR, and patient reported Quality of Life measures. In February 2022, Part A of the study completed enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102: 1.2 mg once daily, 2 mg twice weekly, and 4 mg twice weekly with initial follow up to evaluate safety, tolerability and tumor volume by MRI after 16 weeks in order to determine the optimal dose. On September 12, 2022, Ayala announced interim results from Part A of the RINGSIDE Pivotal Phase 2/3 trial. As of the cut-off date of July 14, 2022, 28 patients were evaluable for tumor volume and 29 were evaluable for RECIST with a scan at base line and at least one additional scan at week 16. Twelve subjects had follow up MRI scans at week 28 and one patient had a scan at week 40. One patient had a PR per RECIST at week 16, confirmed at week 28. Three additional unconfirmed PRs were observed, two at week 28 and one at week 40. Continuous tumor volume reduction was observed over time in all patients that underwent two or more MRI scans. At week 16, there were nine evaluable patients for RECIST in the selected dose of 1.2 mg once daily with one PR observed, confirmed at week 28. The remaining eight patients had stable disease, of which seven patients had a tumor reduction. At week 28, there were three patients evaluable for RECIST in the selected dose of 1.2 mg once daily with one confirmed and one unconfirmed PR and one SD with all patients showing tumor reduction and deepening of tumor shrinkage since previous scan. At the selected dose of 1.2 mg once daily, at week 16 there were nine evaluable patients for tumor volume change with seven patients experiencing tumor volume reduction. At week 28, there were three evaluable patients for volume change in the selected dose of 1.2 mg once daily with all three patients experiencing continuous tumor shrinkage. AL102 was generally well tolerated at all doses. Most adverse events were grade 1 or 2 and the most frequent was diarrhea. No grade 4 or 5 events were observed and only low rates of grade 3 events were observed. At the selected dose of 1.2 mg once daily, three out of the 14 patients (21.4%) experienced grade 3 events. Ovarian dysfunction was observed in about 22% of women with childbearing potential (N=23). At the end of Part A, all patients will be eligible to enroll into an open label extension study at the selected dose where long-term efficacy and safety will be monitored. Ayala is advancing Part B of the RINGSIDE study with a selected dose of 1.2 mg once daily and enrolling patients in the open-label extension study at the same dose. Part B of the study is a double-blind placebo-controlled study enrolling up to 156 patients with progressive disease, randomized between AL102 or placebo.

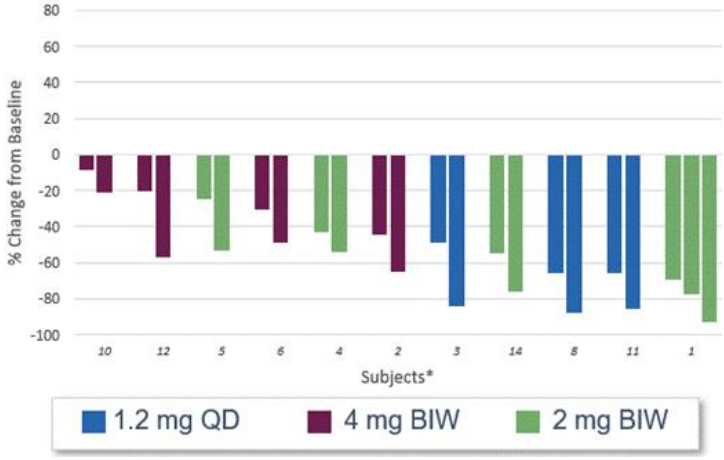
Week 16 VOLUME results available at July 14, 2022:



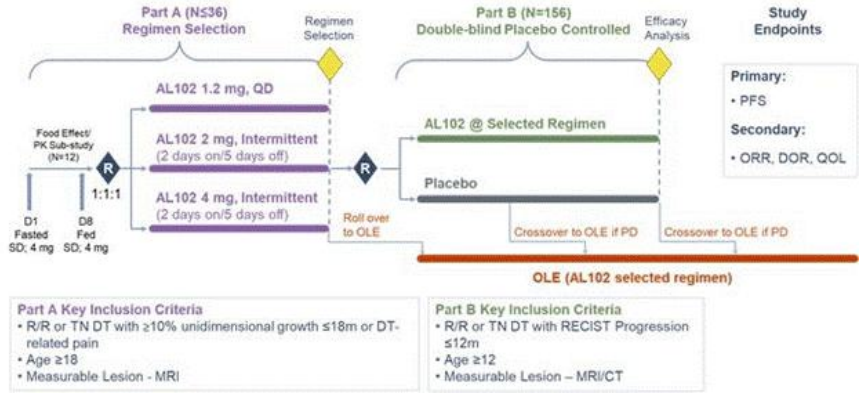
Week 16 Central RECIST results available at data cut (N=29):



Patients with more than 1 scan available at July 14, 2022, showing VOLUME results of consecutive scans results per subject (N=11)



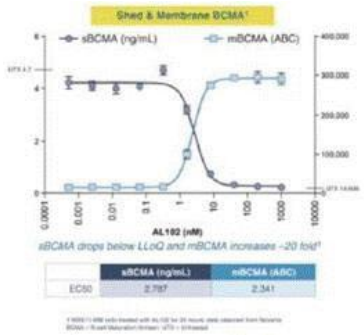
The design of the Phase 2/3 RINGSIDE study is below:



AL102 for the Treatment of Multiple Myeloma

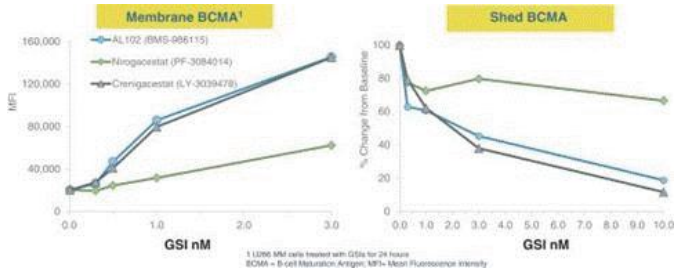
Despite numerous advances in the treatment landscape for MM, the disease remains incurable. BCMA is ubiquitously expressed on myeloma cells and is currently a target of active studies utilizing a number of therapeutic approaches. Increasing the expression of the BCMA on target cells and reducing the shedding in the circulation is believed to potentially enhance therapies and increase responses.

AL102 Reduced Shed BCMA and Increased Membrane BCMA Levels in MM Cell Lines

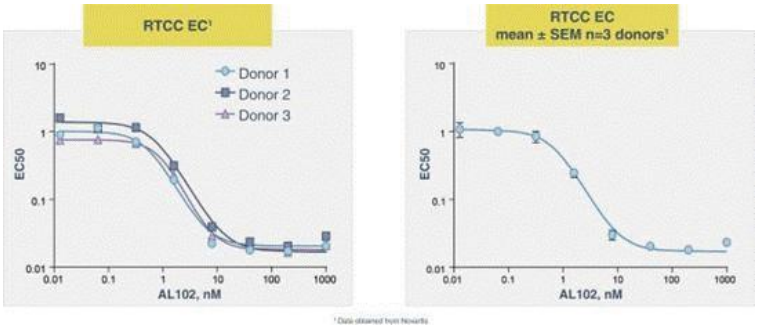


Soluble BCMA levels (ng/mL) from culture supernatants of KMS11 cells treated overnight with a serial dilution of AL102 are shown on the left Y axis. Antibody binding capacity, or ABC, of anti-BCMA on the surface of AL102 treated KMS11 cells is shown on the right Y axis. AL102 inhibited shedding of BCMA from KMS11 cells in a dose-dependent manner, which resulted in increased BCMA expression on the cell surface over the same dose range. Untreated KMS11 cells have a BCMA ABC of approximately 14,000. The average ABC with treatment of 10 nM AL102 was approximately 285,000, representing an approximate 20-fold increase in cell surface BCMA expression with AL102 treatment.

In addition, Ayala tested increasing concentrations of three different GSI molecules, AL102, Nirogacestat and Crenigacestat on shed BCMA and membrane BCMA in UM266 multiple myeloma cell lines. As seen in the figures below, similar dose related activity as measured by mean flurescence intensity, or MFI, for membrane BCMA and by change from baseline for shed BCMA was observed for AL102 and Crenigacestat while relatively weaker activity was observed for Nirogacestat.



As shown below, in an assay designed by Novartis to evaluate the BisAb redirected t-cell cytotoxicity, or RTCC, activity *in vitro*, using human MM cells from donors, AL102 enhanced BisAb RTCC activity in a dose-dependent manner with enhancement of BisAb potency at concentrations of approximately 8nM or higher.



Novartis has initiated a Phase 1 study with its bi-specific anti-BCMA agent, and is responsible for the conduct and expenses of any trials of AL102 in combination with their BCMA-targeting agents. The first patient was dosed with AL102 in combination with Novartis' BCMA targeting agent in April 2021. Ayala believes that the clinical activity of BCMA-targeting agents may also be enhanced in clinical trials when used in combination with a GSI such as AL102.

Ayala collaborated with Novartis to develop AL102 for the treatment of multiple myeloma in combination with Novartis' B-cell maturation antigen targeting therapies. On June 2, 2022, Novartis informed Ayala that it did not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating Ayala's collaboration agreement with them.

AL101 for the Treatment of R/M Adenoid Cystic Carcinoma

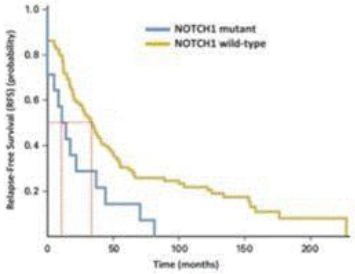
Disease Background

ACC is a rare solid tumor malignancy of secretory glands including the salivary glands. While major salivary glands are located in the mouth, minor salivary glands are scattered throughout the aerodigestive tract and are mostly concentrated in cheeks, lips, tongue, palate and floor of the mouth. ACC can also arise in other sites outside the head and neck. When presenting in the major salivary glands, ACC can cause symptoms of varying severity, including numbness, difficulty swallowing or paralysis of a facial nerve.

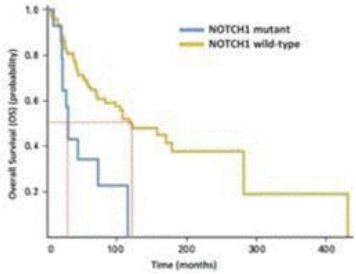
ACC is characterized by its high recurrence rate and, along with its persistent and relentless progressive course, often manifests as local recurrences and late-onset distant metastasis. ACC has an annual incidence of approximately 3,400 patients in the United States, approximately 1,700 of which are R/M ACC patients. Based on primary literature and Ayala's bioinformatics research, Ayala estimates that 18% to 22% of R/M ACC patients have Notch-activating mutations.

Notch Is a Tumorigenic Driver in ACC and
Correlates with a Distinct Pattern of Metastases and Poor Prognosis

Median RFS = 12.5 vs 33.9 months (*p=0.01*)



Median OS = 29.6 vs 121.9 months (*p=0.001*)



Data from MD Anderson Cancer Center

As the understanding of the biology of cancer and ACC specifically evolved, the importance of the Notch pathway and Notch-activating mutations was established. A recent publication from MD Anderson Cancer Center examined the relationship between Notch-activating mutations and ACC patient prognosis in 102 subjects, as illustrated in the figures above. The figure on the left shows that the relapse free survival, or time from diagnosis to relapse, was reduced from 33.9 months for Notch 1 wild-type, or WT, patients to 12.5 months for Notch 1 mutant patients. In addition, patients with Notch-activating mutations were more likely to present with advanced-stage disease and they developed a somewhat different pattern of metastatic disease compared to Notch 1 WT patients. Similarly, the graphic on the right demonstrates that median overall survival was reduced from 121.9 months for Notch 1 WT patients to 29.6 months for Notch 1 mutant patients. Similar results were subsequently observed in an additional retrospective study analyzing data from 84 ACC subjects at Memorial Sloan Kettering Cancer Center, where median overall survival was reduced from 204.5 months for Notch 1 WT patients to 55.1 months for Notch 1 mutant patients.

Current Treatment Landscape

The current standard of care is typically surgery followed by radiation. Radiation or systemic therapy, comprised of chemotherapy and targeted drugs, may be recommended if the tumor cannot be surgically removed or in cases of advanced metastatic disease. There are limited systemic therapy treatment options, and no FDA-approved therapies, available for patients with R/M ACC. According to the Surveillance, Epidemiology, and End Results the relative survival rate for all ACC patients in the United States between 1975 and 2016 was 81% at five years and 66% at ten years. Treatment has been particularly ineffective for ACC patients with metastatic disease, where survival rates are much lower: 33% at five years and 24% at ten years. According to published data from 31 Phase 2 clinical trials in ACC conducted since 2005 using a variety of treatment modalities, these treatments showed limited or no clinical activity in unselected ACC subjects. The ORR in 30 of these trials ranged from 0% to 20%, with a 47% ORR observed in one trial conducted in China. In 15 of the 31 trials, a 0% ORR was observed. Accordingly, there remains a lack of effective treatment options for patients with R/M ACC.

Ayala's Proposed Solution for R/M ACC: AL101

Ayala is developing AL101 as a potent, selective and injectable small molecule GSI for patients with R/M ACC with Notch-activating mutations and believes that AL101 has the potential to be the first FDA-approved therapy for this patient population.

Ayala's Ongoing Phase 2 ACCURACY Trial:

Ayala is currently evaluating subjects in its ongoing Phase 2 ACCURACY trial of AL101 as a monotherapy for the treatment of R/M ACC. Ayala's Phase 2 ACCURACY trial is an open-label, single-arm, multi-center study of AL101 administered intravenously, or IV, in subjects with ACC bearing Notch-activating mutations who have previously been treated for or are newly diagnosed with metastatic disease.

The primary endpoint of Ayala's Phase 2 ACCURACY trial is the ORR as measured by RECIST 1.1 with confirmation by an independent review committee. Secondary endpoints include ORR by investigator review, DOR and PFS by an independent review committee and an investigator review, overall survival, safety and tolerability and PK. The Phase 2 ACCURACY trial is powered to assess statistical significance for these endpoints. However, the Phase 2 ACCURACY trial is ongoing and formal statistical testing will not be performed until the study is complete.

Part 1 of the trial dosed 45 subjects at 4 mg of AL101 IV once weekly. Stage 2 of the trial dosed additional 42 subjects at 6 mg of AL101 IV once weekly.

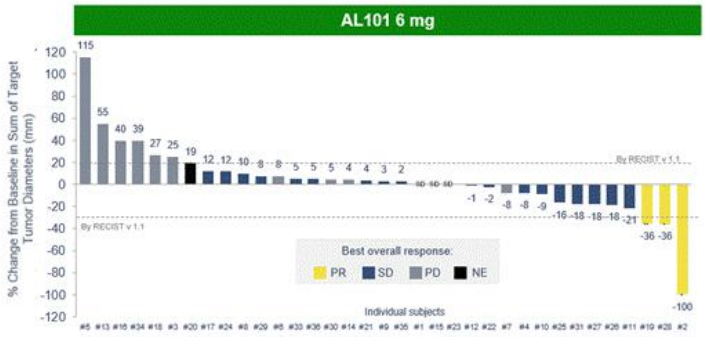
Ongoing Phase 2 ACCURACY Trial Interim Clinical Data (April 14, 2022 data cut-off date):

The study enrolled subjects in two cohorts, the 4mg cohort, followed by the 6mg cohort. Eighty-seven subjects were enrolled in the study and 77 subjects were evaluable for efficacy as of the data cut-off date of April 14, 2022. Ayala's interim data of its Phase 2 ACCURACY trial as of April 14, 2022 included the efficacy results of 41 subjects in the 4mg cohort, and 36 in the 6mg cohort using RECIST. No CRs were observed, and the disease control (PR+SD) rate across both dose cohorts was 69% (53/77). The number and rates of PRs, SDs and disease control as read by investigator are shown in the following table:

Best Tumor Response	**AL101 4 mg (N=41)** n (%)	**AL101 6 mg (N=36)** n (%)
Partial Response (PR)	6 (14.6%)	3 (8.3%)
Stable Disease (SD)	23 (56.1%)	21 (58.3%)
Progressive Disease (PD)	12 (29.3%)	10 (27.8%)
Missing or Not Evaluable (NE)	0 (0.0%)	2 (5.6%)
Disease control (PR+SD) rate	29 (70.7%)	24 (66.7%)

The best objective responses observed in both cohorts of Ayala's Phase 2 ACCURACY trial, as determined by the investigator and measured by RECIST, are shown in the following graph, by individual subject. The dotted lines under the x-axis represent cutoffs for PR, defined as a 30% or greater reduction in the sum of the longest diameters of target lesions for RECIST or, for bone-only disease patients, a 50% or greater reduction in lesion size for the MD Anderson modified bone response criteria. Progressive disease is defined as a 20% or greater increase in the sum of the longest diameters. SD is reflected between the dotted lines at 20% and -30%.

Best Overall Response by Investigator Review

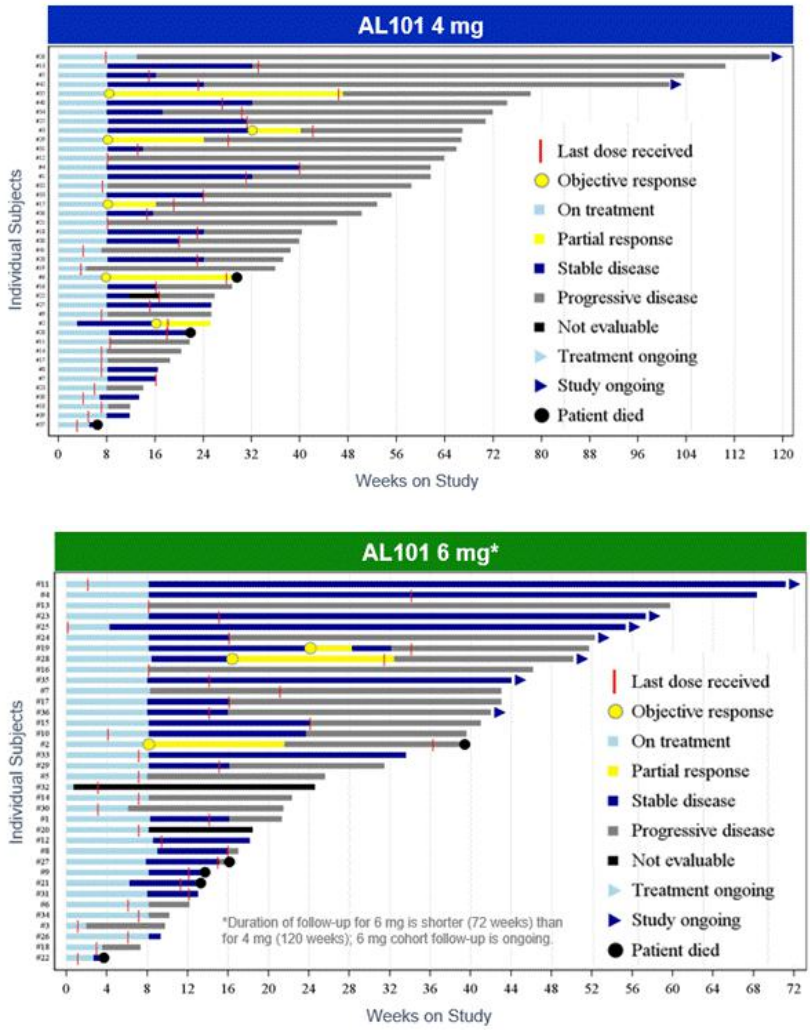


*Confirmed response
**Unconfirmed response
B: indicates bone-only subjects.

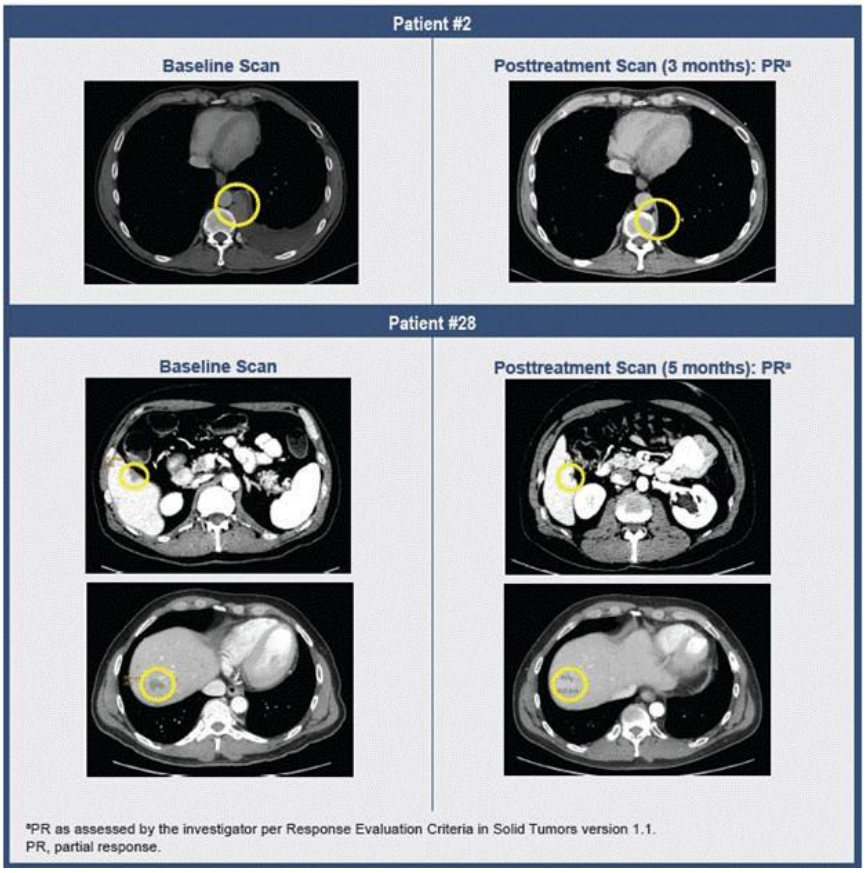
Central Review is ongoing and shows results consistent with the investigator's evaluations.

Time of Response by Investigator's Review

The following graphs depict the treatment duration and clinical response of subjects in Ayala's Phase 2 ACCURACY trial, by cohort, as of April 14, 2022. Time to PR is denoted using yellow circles and the three subjects who remain on therapy as of the data cutoff are denoted using blue arrows. Radiographic evaluations are performed every eight weeks and the first point at which a subject achieved a PR is indicated by the change in line color following the yellow response circles.



The figures below are radiographic scan results from two subjects participating in the 6mg cohort of Ayala's Phase 2 ACCURACY trial who exhibited Partial Responses with AL101 6-mg treatment.



Phase 2 ACCURACY Trial Interim Safety Results

All 87 treated patients in the AL101 experienced treatment-emergent AEs. Grade 3/4 AEs occurred in 54 patients (62.1%) and 49 experienced at least one serious TEAE (56.3%). There were nine deaths (10.3%) resulting from TEAEs in the study. The detailed data per cohort as well as the number and rates of patients for whom drug discontinuation/interruption/dose reduction were required are in the following table:

	AL101 4 mg (N=45) n (%)	Al101 6 mg (N=42) n (%)	Total (N=87) n (%)
Any treatment-emergent adverse event (AE)	45 (100)	42 (100)	87 (100)
Grade 3/4 AEs	22 (48.9)	32 (76.2)	54 (62.1)
Serious AEs (SAE)	23 (51.1)	26 (61.9)	49 (56.3)
Deaths	5 1.1)	4 (9.5)	9 (10.3)
AEs leading to discontinuation of AL101	7 (15.6)	11 (26.2)	18 (20.7)
AEs requiring AL101 dose interruption	26 (57.8)	28 (66.7)	54 (62.1)
AEs requiring AL101 dose reduction	6 (13.3)	15 (35.7)	21 (24.1)

The most frequent treatment related AEs Reported in ≥20% of Subjects are listed in the following table:

	AL101 4 mg (N=45) n (%)	AL101 6 mg (N=42) n (%)	Total (M=87) n (%)
Diarrhoea	28 (62.2%)	33 (78.6%)	61 (70.1%)
Fatigue	23 (51.1%)	21 (50.0%)	44 (50.6%)
Nausea	24 (53.3%)	17 (40.5%)	41 (47.1%)
Hypophosphataemia	20 (44.4%)	13 (31.0%)	33 (37.9%)
Vomiting	13 (28.9%)	11 (26.2%)	24 (27.6%)
Cough	12 (26.7%)	10 (23.8%)	22 (25.3%)
Epistaxis	10 (22.2%)	7 (16.7%)	17 (19.5%)
Decreased appetite	5 (11.1%)	10 (23.8%)	15 (17.2%)
Dry mouth	4 (8.9%)	9 (21.4%)	13 (14.9%)

Listed in order of descending frequency in the total study population

Regulatory Approval Strategy

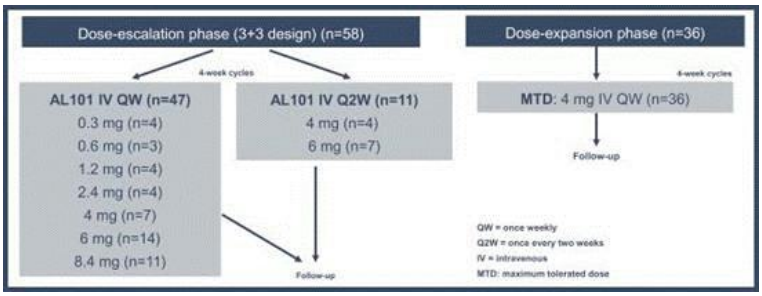
The FDA has granted ODD to AL101 for the treatment of ACC. In addition, the FDA has granted Fast Track designation to AL101 for the treatment of R/M ACC. Given the significant unmet medical need and lack of FDA-approved therapies for patients with R/M ACC, Ayala may seek a potential expedited regulatory review pathway pending additional results from the ongoing Phase 2 ACCURACY trial.

Phase 1 Studies

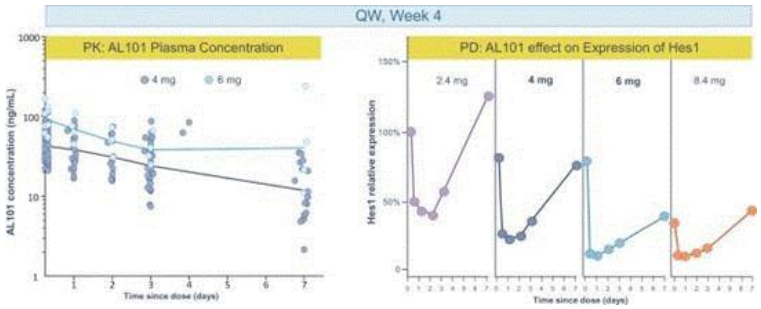
BMS evaluated AL101 in more than 200 unselected subjects with various cancers across three Phase 1 studies. While these Phase 1 studies did not report statistically significant overall results, clinical activity was observed in cancers in which activation of the Notch pathway is a known tumorigenic driver. In these Phase 1 studies, the recommended clinical dose for Ayala's ongoing Phase 2 ACCURACY trial was established. A summary of the three Phase 1 studies is below.

CA216001

In a Phase 1 study of AL101 in heavily pretreated subjects with advanced or metastatic tumors, which Ayala refers to as the CA216001 study, AL101 IV was administered as a monotherapy. A total of 58 subjects were evaluated in the dose-escalation phase and an additional 36 subjects were evaluated in the dose-expansion phase. Of these subjects, 43 were treated with 4 mg of AL101 IV once weekly and 14 subjects were treated with 6 mg of AL101 IV once weekly. An additional 11 subjects were treated in a twice-weekly dosing arm and received either 4 mg or 6 mg of AL101 IV twice weekly. The primary objective of the CA216001 study was to evaluate the safety and tolerability of AL101. Secondary objectives included evaluating the PK, PD, changes in the expression of Notch-induced genes and the anti-tumor activity of AL101. Formal statistical testing for these endpoints was not performed and the results were presented as descriptive statistics. The design of this study, including dose groupings, is depicted below.



Of the 94 subjects evaluated in this study, two subjects had ACC and three subjects had desmoid tumors. PRs were observed in three subjects, including one subject with ACC and two subjects with desmoid tumors. In addition, SD was observed in 10 subjects, including one subject with ACC and one subject with desmoid tumors. As shown in the below graphs, the PK of AL101 was linear, with dose-dependent increases in exposure that correlated with suppression of the PD marker Hes1.



Subjects enrolled in the CA216001 study were heavily pretreated, with over 70% of subjects previously undergoing at least three lines of prior therapy. AL101 was generally observed to be well tolerated at the dose chosen for Ayala's Phase 2 ACCURACY trial. During the course of the study, there were 27 deaths, including one death due to hepatic failure in the highest weekly dose tested (8.4 mg) that was assessed by the investigator to be treatment-related. Treatment was discontinued in nine subjects due to TRAEs. Approximately 89% of subjects experienced at least one TRAE and approximately 51% of subjects experienced at least one Grade 3 or 4 TRAEs. In addition, approximately 16% of subjects dosed with 4 mg and approximately 29% of subjects dosed with 6 mg experienced TRSAEs. The following table represents the most commonly reported TRAEs.

TRAEs reported in ≥15% of all treated subjects	Subjects treated with AL101 4 mg QW (n=43)		Subjects treated with AL101 6 mg QW (n=14)		All AL101 treated subjects (n=94)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Diarrhea, n (%)	29 (67)	8 (19)	10 (71)	6 (43)	59 (63)	18 (19)
Hypophosphatemia, n (%)	26 (60)	18 (42)	11 (79)	7 (50)	50 (53)	33 (35)
Fatigue, n (%)	15 (35)	0	11 (79)	0	42 (45)	1 (1)
Nausea, n (%)	18 (42)	1 (2)	10 (71)	0	41 (44)	1 (1)
Vomiting, n (%)	13 (30)	1 (2)	5 (36)	1 (7)	28 (30)	4 (4)
Decreased appetite, n (%)	11 (26)	0	6 (43)	0	25 (27)	0
Hypokalemia, n (%)	9 (21)	3 (7)	3 (21)	1 (7)	15 (16)	6 (6)

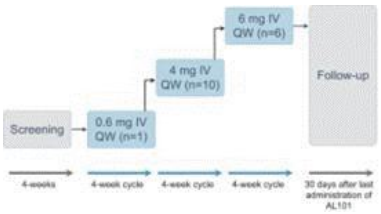
QW = once weekly

The results from this Phase 1 study of AL101 supported advancing the once weekly dosing regimen of 4 mg or 6 mg and showed early signs of clinical activity across solid tumor types. In addition, AL101 was generally observed to be well tolerated at the dose chosen for Ayala's Phase 2 ACCURACY trial.

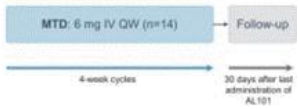
CA216002

In a Phase 1 study of AL101 in 31 heavily pretreated subjects, which included four T-LL subjects and 27 T-ALL subjects, AL101 IV was administered QW, or once weekly, as a monotherapy. Ayala refers to this study as the CA216002 study. A total of 17 subjects were evaluated in the dose-escalation phase and an additional 14 subjects were evaluated in the dose-expansion phase. The primary objective of the CA216002 study was to evaluate the safety and tolerability of AL101. Secondary objectives included evaluating the PK, PD changes in the expression of Notch-induced genes and the anti-tumor activity of AL101. Formal statistical testing for these endpoints was not performed and the results were presented as descriptive statistics. The design of this study, including dose groupings, is depicted below.

Dose-escalation Phase (3+3 design) (n=17)



Dose-expansion Phase (n=14)



A total of 26 T-ALL subjects in this study received either a 4 mg or 6 mg dosage of AL101, 11 of whom had Notch 1 mutations. Objective responses were observed in three subjects with T-ALL, each in the 6 mg dose group, with CRs observed in two subjects and a PR observed in one subject. Of these three subjects, two had Notch 1 mutations. Following the administration of AL101, eight subjects with T-ALL experienced a 50% or greater reduction in leukemic blasts in bone marrow.

Subjects enrolled in the CA216002 study were heavily pretreated, with over 50% of subjects previously undergoing at least three lines of prior therapy. AL101 was generally well tolerated during the study. During the course of the study, there were 20 deaths, including one patient in the 4 mg once weekly dosing group who was heavily pretreated with at least four prior systemic therapies and died due to gastrointestinal hemorrhage. While this patient's death was assessed by the investigator not to be treatment-related, BMS determined that it was possible the death was treatment-related. Treatment was discontinued in one subject due to TRAEs. Approximately 74% of subjects experienced at least one TRAE and approximately 23% of subjects experienced at least one Grade 3 or 4 TRAEs. In addition, approximately 16% of subjects experienced TRSAEs, which included single events of hepatoxicity and hypersensitivity in the 4 mg dose cohort and single events of anemia, diarrhea and infusion-related reaction in the 6 mg dose cohort. The following table represents the most commonly reported TRAEs.

TRAEs reported in ≥ 15% of all treated subjects	Subjects treated with AL101 4 mg QW (n=10)		Subjects treated with AL101 6 mg QW (n=20)		All AL101 treated subjects (n=31)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Diarrhea, n (%)	3 (30)	1 (10)	12 (60)	0	15 (48)	1 (3)
Nausea, n (%)	1 (10)	0	4 (20)	0	5 (16)	0
Vomiting, n (%)	0	0	4 (20)	0	4 (13)	0

The results from this Phase 1 study of AL101 supported advancing the anticipated once weekly dosing regimen of 6 mg, as this dose showed signs of clinical activity and was generally observed to be well tolerated.

CA216003

In a Phase 1 study in heavily pretreated subjects with advanced or metastatic solid tumors, which Ayala refers to as the CA216003 study, AL101 IV was administered in combination with three different chemotherapy regimens. A total of 95 subjects were evaluated in the study, with 90 subjects receiving both chemotherapy and AL101. The primary objective of the CA216003 study was to evaluate the safety and tolerability of AL101 in combination with chemotherapy. Secondary objectives included evaluating the PK of AL101 in combination with chemotherapy, PD changes in the expression of Notch-induced genes after treatment with AL101 in combination with chemotherapy and the anti-tumor activity of AL101 in combination with chemotherapy. Formal statistical testing for these endpoints was not performed and the results were presented as descriptive statistics.

Of the 95 subjects evaluated in this study, 22 subjects had triple negative breast cancer, or TNBC. Of the TNBC subjects, a CR was observed in one subject, PRs were observed in seven subjects and SD was observed in five subjects.

Subjects enrolled in the CA216003 study were heavily pretreated, with 40% of subjects previously undergoing at least three lines of prior therapy. AL101 in combination with chemotherapy was generally observed to be well tolerated during the study. During the course of the study, there were 32 deaths, but none were assessed by the investigator or BMS to be treatment-related. Treatment was discontinued in 15 subjects due to TRAEs. Nearly all subjects experienced at least one TRAE and approximately 82% of subjects experienced at least one Grade 3 or 4 TRAE. In addition, approximately 34% of subjects experienced TRSAEs. The most commonly reported Grade 3 or 4 TRSAEs included febrile neutropenia (10%) and diarrhea (6%). The most commonly reported TRAEs included: fatigue (78%), diarrhea (63%), hypophosphatemia (62%), nausea (52%), decreased appetite (46%), vomiting (39%), alopecia (38%), anemia (31%), neutropenia (26%), rash (26%), dysgeusia, or distortion of the sense of taste, (20%), dehydration (19%), weight decrease (18%), thrombocytopenia, or low blood platelet count, (17%), hypokalemia, or low potassium levels, (17%), stomatitis, or inflammation of the mouth and lips, (16%) and myalgia, or muscle soreness (16%).

License Agreements

Bristol-Myers Squibb Company License Agreement

In November 2017, Ayala entered into a license agreement, or the BMS License Agreement, with BMS, under which BMS granted Ayala a worldwide, non-transferable, exclusive, sublicensable license under certain patent rights and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102, or the BMS Licensed Compounds, and products containing AL101 or AL102, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

Under the BMS License Agreement, Ayala is obligated to use commercially reasonable efforts, either through ourselves or through Ayala's affiliates or sublicensees, to develop at least one BMS Licensed Product. As between BMS and Ayala, Ayala has sole responsibility for, and bears the cost of, conducting research and development and preparing all regulatory filings and related submissions with respect to the BMS Licensed Compounds and/or BMS Licensed Products. BMS has assigned and transferred all INDs for the BMS Licensed Compounds to Ayala. Ayala is also required to use commercially reasonable efforts to obtain regulatory approvals in certain major market countries for at least one BMS Licensed Product, as well as to commercialize and sell each BMS Licensed Product after obtaining such regulatory approval. As between BMS and Ayala, Ayala has sole responsibility for, and bear the cost of, commercializing BMS Licensed Products. For a limited period of time, Ayala may not, either by ourselves or through Ayala's affiliates, sublicensees, or any other third parties, engage directly or indirectly in the clinical development or commercialization of a Notch inhibitor molecule that is not a BMS Licensed Compound.

As consideration of the rights granted by BMS to Ayala under the BMS License Agreement, Ayala paid BMS a payment of $6 million and issued to BMS 1,125,929 shares of Series A preferred stock valued at approximately $7.3 million. Ayala is required to pay BMS payments upon the achievement of certain development or regulatory milestone events of up to $95 million in the aggregate with respect to the first BMS Licensed Compound to achieve each such event and up to $47 million in the aggregate with respect to each additional BMS Licensed Compound to achieve each such event. Ayala is also obligated to pay BMS payments of up to $50 million in the aggregate for each BMS Licensed Product that achieves certain sales-based milestone events and tiered royalties on net sales of each BMS Licensed Product by Ayala or its affiliates or sublicensees at rates ranging from a high single-digit to low teen percentage, depending on the total annual worldwide net sales of each such Licensed Product. If Ayala sublicenses or assigns any rights to the licensed patents, the BMS Licensed Compounds and/or the BMS Licensed Products, Ayala is required to share with BMS a portion of all consideration Ayala receives from such sublicense or assignment, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced BMS Licensed Compound or BMS Licensed Product that is subject to the applicable sublicense or assignment, but such portion may be reduced based on the milestone or royalty payments that are payable by Ayala to BMS under the BMS License Agreement.

The BMS License Agreement remains in effect, on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis, until the expiration of royalty obligations with respect to a given BMS Licensed Product in the applicable country. Royalties are paid on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis from the first commercial sale of a particular BMS Licensed Product in a country until the latest of (a) 10 years after the first commercial sale of such BMS Licensed Product in such country, (b) when such BMS Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such BMS Licensed Product in such country.

Any inventions, and related patent rights, invented solely by either party pursuant to activities conducted under the BMS License Agreement shall be solely owned by such party, and any inventions, and related patent rights, conceived of jointly by Ayala and BMS pursuant to activities conducted under the BMS License Agreement shall be jointly owned by Ayala and BMS, with BMS's rights thereto included in Ayala's exclusive license. Ayala has the first right-with reasonable consultation with, or participation by, BMS-to prepare, prosecute, maintain and enforce the licensed patents, at Ayala's expense.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to Ayala (a) for insolvency-related events involving Ayala, (b) for Ayala's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, (c) for Ayala's failure to fulfill its obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if Ayala or its affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. Ayala has the right to terminate the BMS License Agreement (a) for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Product has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if Ayala reasonably determines that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products. Upon termination of the BMS License Agreement in its entirety by Ayala for convenience or by BMS, Ayala grants an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of its patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay Ayala a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/or BMS Licensed Products.

Manufacturing

Ayala relies on third parties to manufacture AL101 and AL102. Ayala has entered into agreements with leading contract manufacturing organizations, or CMOs, to produce both AL101 and AL102 for its ongoing and planned clinical studies and clinical trials for AL101 and AL102. Ayala is also currently in the process of manufacturing batches to support all of its expected clinical supply needs as well as batches to support a potential NDA submission. Ayala requires all of its contract manufacturing organizations, or CMOs, to conduct manufacturing activities in compliance with cGMP requirements. Ayala currently relies solely on these CMOs for scale-up and process development work and to produce sufficient quantities of its product candidates for use in clinical trials. Ayala anticipates that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but does not have any formal agreements at this time to cover commercial production. Ayala may also elect to enter into agreements with other CMOs to manufacture supplies of drug substance and finished drug product.

Sales and Marketing

Ayala intends to market and commercialize its product candidates, if approved, by building its own specialized sales and marketing organization initially in the United States. Ayala believes its target market can be addressed by a small number of dedicated marketing and medical sales specialists covering specialized oncologists treating the target patient population. Ayala may also selectively pursue strategic collaborations with third parties to maximize the commercial potential of its product candidates, if approved.

Competition

The pharmaceutical industry is characterized by rapid evolution of technologies and intense competition. While Ayala believes that its product candidates, technology, knowledge, experience and scientific resources provide Ayala with competitive advantages, Ayala faces competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that Ayala successfully develops and commercializes will compete with approved treatment options, if any, including off-label therapies, and new therapies that may become available in the future. Key considerations that would impact Ayala's ability to effectively compete with other therapies include the efficacy, safety, method of administration, cost, level of promotional activity and intellectual property protection of Ayala's products. Many of the companies against which Ayala may compete have significantly greater financial resources and expertise than Ayala does in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products.

Ayala considers its most direct competitors with respect to AL101 and AL102 to be companies developing GSIs, including SpringWorks Therapeutics, Inc. and Celgene Corporation, recently acquired by BMS, or companies that are developing Notch inhibitors, including, but not limited to, Cellestia Biotech AG and Ciclomed LLC.

In addition, with respect to AL101 for the treatment of ACC, Ayala is aware that other companies are, or may be, developing products for this indication, including, but not limited to, GlaxoSmithKline plc, Cellestia Biotech AG and Elevar Therapeutics, Inc., which Ayala believes all are at an early development stage.

With respect to AL102, Ayala is aware that other companies are, or may be, developing product candidates for the treatment of desmoid tumors, including, but not limited to, SpringWorks Therapeutics, Inc., Bayer Corporation, Cellestia Biotech AG and Iterion Therapeutics, Inc.

In addition, with respect to AL102 for the treatment of T-ALL, Ayala is aware that other companies are, or may be, developing products for this indication, including, but not limited to, Sanofi S.A., Janssen Pharmaceutica, Jazz Pharmaceuticals plc and Vasgene Therapeutics, Inc.

With respect to MM, Ayala is aware that other companies are, or may be, developing product candidates with GSI as anti-BCMA agents, including, but not limited to, SpringWorks Therapeutics, Inc. in collaboration with GlaxoSmithKline plc, Janssen, Allogene, Pfizer, Precision Biosciences and Celgene Corporation, recently acquired by BMS.

Smaller or early-stage companies, including oncology-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may also compete with Ayala in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, enrolling patients in clinical trials and acquiring technologies complementary to, or necessary for, Ayala's programs.

The availability of reimbursement from government and private payors will also significantly impact the pricing and competitiveness of Ayala's products. Ayala's competitors may obtain FDA or other regulatory approvals for their products more rapidly than Ayala may obtain approvals for its product candidates, if any, which could result in Ayala's competitors establishing a strong market position before Ayala is able to commercialize its product candidates.

Intellectual Property

Ayala's success depends in part on its ability to obtain and maintain intellectual property and proprietary protection for its product candidates, manufacturing and process discoveries and other know-how, to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of others, and to defend and enforce, and prevent others from infringing, misappropriating or otherwise violating, Ayala's intellectual property and proprietary rights. Ayala takes efforts to protect its proprietary position using a variety of methods, which include pursuit of U.S. and foreign patent applications related to its proprietary technology, inventions and improvements, such as compositions of matter and methods of use, that Ayala determines are important to the development and implementation of its business. Ayala also may rely on trade secrets, trademarks, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain its proprietary position. For more information regarding risks relating to intellectual property, please see *"Risk Factors—Risks Related to the Business of Ayala—Risks Related to Ayala's Intellectual Property*."

Patents and Patent Applications

The term of individual patents depends upon the legal term of patents in the countries in which they are obtained. In most countries in which Ayala files patent applications, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application, assuming the patent has not been terminally disclaimed over a commonly-owned patent or a patent naming a common inventor, or over a patent not commonly owned but that was disqualified as prior art as the result of activities undertaken within the scope of a joint research agreement. In the United States, the term of a patent may also be eligible for patent term adjustment for delays within the United States Patent and Trademark Office, or USPTO. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 may permit a patent term extension of up to five years beyond the expiration of the patent. While the length of such patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per approved drug may be extended and only those claims covering the approved drug product, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when Ayala's products receive FDA approval, Ayala expects to apply for patent term extensions on patents covering those products. Ayala plans to seek any available patent term extension to any issued patents Ayala may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA and the USPTO in the United States, will agree with Ayala's assessment of whether such extensions should be granted, and if granted, the length of such extensions.

As of October 31, 2022, Ayala owned or exclusively licensed a total of five issued U.S. patents, 128 granted foreign patents, seven pending U.S. patent applications, 54 pending foreign patent applications, and three pending Patent Cooperation Treaty, or PCT, applications.

In November 2017, Ayala entered into the BMS License Agreement, pursuant to which Ayala acquired exclusive worldwide rights under certain patents and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102. For more information regarding the BMS License Agreement, please see "*Ayala's Business—License Agreements*." As of October 31, 2022, the patent rights exclusively in-licensed under the BMS License Agreement include the following patent families:

- A patent family having claims directed to the composition of matter of AL101 and methods of treating certain types of cancer, which includes two issued U.S. patents, 64 granted patents in 64 foreign jurisdictions (including China, the European Patent Office, or EPO, Japan and the Russian Federation) and four pending patent applications in four foreign jurisdictions. Without taking potential patent term extension or adjustment into account, the issued patents and any patents issued from pending applications in this family are expected to expire in 2032.

- A patent family having claims directed to the composition of matter of AL102 and methods of treating certain types of cancer, which includes two issued U.S. patents, 63 granted patents in 63 foreign jurisdictions (including China, the EPO, Japan and the Russian Federation), and four pending patent applications in four foreign jurisdictions. Without taking potential patent term extension or adjustment into account, the issued patents and any patents issued from pending applications in this family are expected to expire in 2033.

- A patent family consisting of one issued U.S. patent having claims directed to the method of use for the combination of AL101 with gemcitabine for treating cancer that is expected to expire, without taking potential patent term extension or adjustment into account, in 2034.

- A patent family consisting of one PCT patent application having claims directed to polymorphs of AL102 that is expected to expire, without taking potential patent term extension or adjustment into account, in 2041.

As of October 31, 2022, Ayala solely owned five U.S. pending patent applications, two PCT applications, and 35 foreign pending applications. In addition, Ayala co-owned two U.S. pending applications and 12 foreign pending applications with BMS, covering the use of AL101 for treating T-ALL and for the use of AL102 for treating Desmoid tumors.

One of Ayala's solely-owned patent families, consisting of one pending U.S. patent application and 11 foreign pending applications, includes claims directed to methods of using AL101 to treat Notch-altered ACC.

Another solely-owned patent family, consisting of one pending U.S. patent application and 11 foreign pending applications, includes claims directed to an improved method for producing AL102.

Any patents issued from Ayala's owned patent applications or from patent applications claiming the priority of such patent applications are expected to expire, without taking potential patent term extension or adjustment into account, between 2039 and 2042.

Trade Secrets

Ayala also relies upon trade secrets, know-how, confidential information and continuing technological innovation to develop and maintain its competitive position, and seek to protect and maintain the confidentiality of such items to protect aspects of its business that are not amenable to, or that Ayala does not presently consider appropriate for, patent protection. Ayala maintains efforts to protect such proprietary rights through a variety of methods, including confidentiality agreements, invention assignment agreements, and non-solicitation and non-compete agreements with employees, consultants, collaborators, advisors, suppliers and other parties who may have access to Ayala's confidential or proprietary information. These agreements generally provide that all confidential information developed or made known to the other party during the course of its relationship with Ayala is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the other party contributed as an inventor shall be assigned to Ayala, and as such, will become Ayala's property. There can be no assurance, however, that these agreements will be self-executing or otherwise provide meaningful protection or adequate remedies for Ayala's trade secrets or other proprietary information, including in the event of unauthorized use or disclosure of such information. Ayala also seeks to preserve the integrity and confidentiality of its trade secrets and other confidential information by maintaining physical security of its premises and physical and electronic security of its information technology systems. While Ayala has confidence in the measures it takes to protect and preserve its trade secrets, such measures can be breached, and Ayala may not have adequate remedies for any such breach. In addition, Ayala's trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding risks relating to trade secrets, third parties and other factors that could affect Ayala's intellectual property rights, please see "*Risk Factors—Risks Related to the Business of Ayala—Risks Related to Ayala's Intellectual Property*."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those Ayala is developing. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice requirements, or GCPs to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, Ayala must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans exposed to the drug, and any clinically important increased rate of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2:* The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- *Phase 3:* The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach consensus on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Orphan Drug Designation

Under the ODA, the FDA may grant ODD to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. ODD must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has ODD subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product candidate for seven years if a competitor obtains approval of the same drug as defined by the FDA or if such product candidate is determined to be contained within the competitor's product for the same indication or disease. In addition, if an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the FDA has a Fast Track designation program that is intended to expedite or facilitate the process for reviewing drug products that meet certain criteria. Specifically, drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a Fast Track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a Fast Track or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a disease compared to available products. The FDA will attempt to direct additional resources to the evaluation of an application for a product candidate designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product candidate may be eligible for accelerated approval. Product candidates intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will generally require that a sponsor of a drug receiving accelerated approval to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon NDA sponsors and any third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon Ayala and any third-party manufacturers that Ayala may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by Ayala and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an Abbreviated New Drug Application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

FDA Regulation of Companion Diagnostics

Ayala expects that certain of its product candidates may require an in vitro diagnostic to identify appropriate patient populations for its product candidates. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. Ayala expects that any companion diagnostic developed for its product candidates will utilize the PMA pathway.

If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel product candidates, a companion diagnostic device and its corresponding drug candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Foreign Government Regulation

To market any product outside of the United States, Ayala would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of Ayala's products. The foreign regulatory approval process includes all of the risks associated with FDA approval, as well as additional country-specific regulation

Whether or not Ayala obtains FDA approval for a product candidate, Ayala must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, approval process, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU, are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the GLP as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an IEC, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market Ayala's future product candidates in the EU and many other foreign jurisdictions, Ayala must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, Ayala must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MA" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Product for Human Use of the EMA and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as: (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) designated orphan medicines, (iii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases and (iv) advanced therapy medicinal products such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

The aforementioned EU rules are generally applicable in the EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom, or UK, left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the UK during the transition period under the terms of the EU-UK Withdrawal Agreement. The transition period, which ended on December 31, 2020, maintained access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement, or TCA, and became effective on the January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the CTR will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain, or GB. Broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has published a guidance on how various aspects of the UK regulatory regime for medicines will operate in GB and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. The new guidance was given effect via the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019, or the Exit Regulations.

Regulation of Companion Diagnostics in the EU

In the EU, in vitro diagnostic medical devices, or IVD MDs, are regulated by Directive 98/79/EC which regulates the placing on the market, the CE marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufactures and devices as well as the vigilance procedure. In vitro diagnostic medical devices must comply with the requirements provided for in the Directive, and with further requirements implemented at national level (as the case may be).

The regulation of companion diagnostics will be subject to further requirements once the in-vitro diagnostic medical devices Regulation (No 2017/746), or IVDR, will become applicable on May 26, 2022. However on October 14, 2021, the European Commission proposed a "progressive" roll-out of the IVDR to prevent disruption in the supply of IVD MDs. The European Parliament and Council voted to adopt the proposed regulation on December 15, 2021 and the regulation entered into force on January 2022. The IVDR will fully apply on May 26, 2022 but there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The IVDR introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue a CE certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a MAA for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authorities or the EMA.

The aforementioned EU rules are generally applicable in the EEA.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, consumer fraud, pricing reporting, and transparency laws and regulations with respect to payments and other transfers of value made to physicians and other healthcare providers, as well as similar foreign laws in jurisdictions outside the U.S.

For example, the AKS prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA and the civil monetary penalties statute. The federal civil and criminal false claims laws, including the FCA, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians, certain other healthcare professionals, teaching hospitals, and applicable manufacturers and group purchasing organizations as well as ownership and investment interests held by physicians and their immediate family members. Additional reporting and transparency requirements for payments to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives go into effect in 2022 for payments made in 2021.

Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting obligations to resolve allegations of non-compliance, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and individual imprisonment.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to Ayala's operations or the operations of its partners. In the United States, federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are more and more challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and Ayala expects there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, absent additional congressional action. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Ayala expects additional state, federal and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for health products, which could result in reduced demand for Ayala's products, if approved or additional pricing pressure.

For instance, in December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation which entered into force in January 2022 intends to boost cooperation among EU member states in assessing health technologies, including some medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Employees

As of September 30, 2022, Ayala had 29 employees, including eight employees with M.D. or Ph.D. degrees. Of these employees, 23 employees are engaged in research and development activities. None of Ayala's employees is represented by a labor union or covered by a collective bargaining agreement.

Properties

Ayala's principal office is located at Oppenheimer 4, Rehovot 7670104, Israel, where Ayala leases office and laboratory space under a lease agreement that terminates in 2029. Ayala believes that its facilities are sufficient to meet its current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

Ayala is not subject to any material legal proceedings.

Corporate Information

Ayala was incorporated in Delaware in November 2017. Ayala's offices are located at Oppenheimer 4, Rehovot 7670104, Israel. Ayala's Common Stock is listed on The Nasdaq Global Market under the symbol "AYLA."

ADVAXIS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this proxy statement/prospectus contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, product demand, market acceptance and other factors discussed in this proxy statement/prospectus under the heading "Risk Factors". This Management's Discussion and Analysis of Financial Conditions and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this report proxy statement/prospectus.

Overview

Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, or *Lm*, bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable the T cells to attack tumor cells.

Advaxis believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of our product candidates have an expected low cost of goods.

Advaxis is currently winding down or has wound down clinical studies of *Lm* Technology immunotherapies in four program areas:

- Non-small cell lung cancer (ADXS-503)
- Human Papilloma Virus ("HPV")-associated cancers ("AXAL")
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these clinical program areas are anchored in Advaxis' *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these four program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

Recent Developments

Termination of Merger Agreement; Strategic Considerations

On July 4, 2021, Advaxis entered into a merger agreement (the "Biosight Merger Agreement"), subject to shareholder approval, with Biosight Ltd. ("Biosight") and Advaxis Ltd. ("Biosight Merger Sub"), a direct, wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Biosight was to merge with and into Biosight Merger Sub, with Biosight continuing as the surviving company and a wholly-owned subsidiary of Advaxis (the "Biosight Merger"). Immediately after the Biosight Merger, Advaxis stockholders as of immediately prior to the Biosight Merger were expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders were expected to own approximately 75% of the outstanding shares of the combined company.

On December 30, 2021, Advaxis terminated the Biosight Merger Agreement, as Advaxis was unable to obtain shareholder approval to complete the transaction. As announced in December 2021, Advaxis plans to continue to explore additional options to maximize stockholder value.

Financings

On January 31, 2022, Advaxis closed on an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D convertible redeemable preferred stock. The shares to be sold have an aggregate stated value of $5,000,000. Each share of the Series D preferred stock has a purchase price of $4.75, representing an original issue discount of 5% of the stated value. The shares of Series D preferred stock are convertible into shares of Advaxis' common stock, upon the occurrence of certain events, at a conversion price of $20.00 per share. The conversion, at the option of the stockholder, may occur at any time following the receipt of the stockholders' approval for a reverse stock split. Advaxis will be permitted to compel conversion of the Series D preferred stock after the fulfillment of certain conditions and subject to certain limitations. The Series D preferred stock will also have a liquidation preference over the common stock, and may be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. Advaxis and the holders of the Series D preferred stock will also enter into a registration rights agreement to register the resale of the shares of common stock issuable upon conversion of the Series D preferred stock. Total gross proceeds from the offering, before deducting the financial advisor's fees and other estimated offering expenses, are $4.75 million.

Results of Operations for the Nine Months Ended July 31, 2022 and 2021

Revenue

Revenue was $250,000 for the nine months ended July 31, 2022 compared to $3,240,000 for the nine months ended July 31, 2021. In the prior period, we recognized royalty payments from OST.

Research and Development Expenses

We invest in research and development to advance our *Lm* technology through our pre-clinical and clinical development programs. Research and development expenses for the nine months ended July 31, 2022 and July 31, 2021 were categorized as follows (in thousands):

We invest in research and development to advance our *Lm* technology through our pre-clinical and clinical development programs. Research and development expenses for the nine months ended July 31, 2022 and July 31, 2021 were categorized as follows (in thousands):

	Nine Months Ended July 31,		Increase (Decrease)	
	2022	2021	$	%
Hotspot/Off-the-Shelf therapies	$ 3,076	$ 2,531	$ 545	22%
Prostate cancer	85	207	(122)	(59)%
HPV-associated cancers	332	1,865	(1,533)	(82)%
Personalized neoantigen-directed therapies	8	400	(392)	(98)%
Other expenses	1,870	3,613	(1,743)	(48)%
Total research & development expense	$ 5,371	$ 8,616	$ (3,245)	(38)%
Stock-based compensation expense included in research and development expense	$ 36	$ 142	$ (106)	(75)%

Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapy for the nine months ended July 31, 2022 increased approximately 22% to $3,076,000 compared to the same period in 2021. The increase is attributable to patient recruitment costs and manufacturing costs pertaining to the HOT-503 study incurred in the current period.

Prostate Cancer (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the nine months ended July 31, 2022 decreased approximately $122,000, or 59%, compared to the same period in 2021. The study has been completed and we do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

HPV-Associated Cancers (AXAL)

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the nine months ended July 31, 2022 decreased approximately $1,533,000, or 82%, compared to the same period in 2021. The decrease is attributable to wind down costs associated with the closure of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. We do not anticipate that we will continue to incur significant costs associated with the wind down of our Phase 3 AIM2CERV study.

Personalized Neoantigen-Directed Therapies (ADXS-NEO)

Research and development costs associated with personalized neoantigen-directed therapies for the nine months ended July 31, 2022 decreased approximately $392,000, or 98%, compared to the same period in 2021. The study has been completed and we do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the nine months ended July 31, 2022 decreased approximately $1,743,000, or 48%, compared to the same period in 2021. The decrease is attributable to (1) prior period losses on disposal of property and equipment in connection with the termination of our office lease at our former location, (2) decrease in personnel costs due to decreases in headcount, stock compensation and bonus accruals, and (3) decrease in depreciation expense.

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses for the nine months ended July 31, 2022 and July 31, 2021 were as follows (in thousands):

	Nine Months Ended July 31,		Increase (Decrease)	
	2022	2021	$	%
General and administrative expense	$ 6,331	$ 9,038	$ (2,707)	(30)%
Stock-based compensation expense included in general and administrative expense	$ 38	$ 369	$ (331)	(90)%

General and administrative expenses for the nine months ended July 31, 2022 decreased approximately $2,707,000, or 30%, compared to the same period in 2021. This decrease primarily relates to (1) legal and consulting fees related to the Previously Proposed Merger in the prior period, (2) prior period losses on disposal of property and equipment in connection with the termination of our office lease at our former location, (3) prior period sublicense fees paid to the University of Pennsylvania for the OST milestones reached, (4) decrease in personnel costs due to decreases in stock compensation and bonus accruals, and (5) decreases in rent, utilities and depreciation due to the termination of our office lease at our former location. These decreases were partially offset by (1) an increase in proxy solicitation fees related to the Previously Proposed Merger and the reverse stock split and (2) an increase in amounts paid in settlement of shareholder demand letters in the current period.

Intangible Asset Impairment

During the nine months ended July 31, 2022, the Company recorded an impairment charge under ASC 350 for its patents owned and in-licensed intellectual property of approximately $3,005,000.

Changes in Fair Values

For the nine months ended July 31, 2022, we recorded non-cash income from changes in the fair value of derivative liabilities of approximately $4,685,000. The decrease in the derivative liabilities was attributable to a decrease in our share price from $38.80 on October 31, 2021 to $3.73 on July 31, 2022.

For the nine months ended July 31, 2021, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $1,814,000. The decrease in the fair value of liability warrants resulted primarily from the issuance of warrants in the April 2021 Private Placement. The warrants issued in the April 2021 Private Placement had a decrease in fair value of approximately $1,821,000 from date of issuance to July 31, 2021, which resulted from a decrease in our share price from $45.60 on April 14, 2021 to $32.80 on July 31, 2021.

Liquidity and Capital Resources

Management's Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have historically suffered recurring losses and we have required significant cash resources to execute our business plans. These losses are expected to continue for the foreseeable future.

Historically, the Company's major sources of cash have comprised proceeds from various public and private offerings of its securities (including common stock), debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants, and interest income. From October 2013 through July 31, 2022, the Company raised approximately $339.4 million in gross proceeds from various public and private offerings of our common stock. The Company has sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future. As of July 31, 2022 and October 31, 2021, the Company had an accumulated deficit of approximately $438.4 million and $428.6 million, respectively, and stockholders' equity of approximately $28.2 million and $38.9 million, respectively.

The COVID-19 pandemic has created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect the Company's business, financial condition, and access to sources of liquidity. As of July 31, 2022, the Company had approximately $28.2 million in cash and cash equivalents. The actual amount of cash that the Company will need to continue operating is subject to many factors.

The Company recognizes that it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that the Company will be able to obtain financing on terms acceptable to it or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations. The Company believes it has sufficient capital to fund its obligations, as they become due, in the ordinary course of business into the third fiscal quarter of 2024. The Company based this estimate on assumptions that may prove to be incorrect, and we could use available capital resources sooner than currently expected.

Cash Flows

Operating Activities

Net cash used in operating activities includes spending associated with our clinical trial programs and general and administrative activities. Net cash used in operating activities was approximately $12,307,000 for the nine months ended July 31, 2022 compared to $11,703,000 for the nine months ended July 31, 2021. The variance is due to fluctuations in cash collected from revenue generated, as well as timing of disbursements relating to accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities was approximately $201,000 for nine months ended July 31, 2022 compared to $104,000 for the nine months ended July 31, 2021. The decrease is the result of proceeds on a prior period disposal of property and equipment partially offset by reductions in purchases for intangible assets.

Financing Activities

Net cash used in financing activities was approximately $956,000 for the nine months ended July 31, 2022 compared to net cash provided by financing activities of $31,886,000 for the nine months ended July 31, 2021. On January 31, 2022, the Company closed on an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D Preferred Stock. The shares sold had an aggregate stated value of $5,000,000. Each share of the Series D Preferred Stock was sold for a purchase price of $4.75, representing an original issue discount of 5% of the stated value. Total net proceeds from the offering, after deducting the financial advisor's fees and other estimated offering expenses, were approximately $4.3 million. The Series D preferred stock also had a liquidation preference over the shares of common stock, and could be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. On April 6, 2022, the holders of all 1,000,000 outstanding shares of the Series D Preferred Stock exercised their right to cause the Company to redeem all of such shares at a price per share equal to 105% of the stated value per share of $5.00, and such shares were redeemed accordingly.

In November 2020, the Company closed on a public offering of 383,333 shares of its common stock at a public offering price of $24.00 per share. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $8.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 191,674 shares of common stock. The warrants have an exercise price per share of $28.00, are exercisable immediately and will expire five years from the date of issuance.

On April 12, 2021, the Company completed an offering of (i) 219,718 shares of common stock, (ii) 95,899 pre-funded warrants to purchase 95,899 shares of common stock and (iii) registered common share purchase warrants to purchase 140,552 shares of common stock with two healthcare focused, institutional investors. The Company also issued to the investors, in a concurrent private placement, unregistered common share purchase warrants to purchase 175,065 shares of the Company's common stock. We received gross proceeds of approximately $20 million, before deducting the fees and expenses payable by us in connection with the offering.

During the nine months ended July 31, 2021, warrant holders from the Company's November 2020 and April 2021 offerings exercised 230,343 warrants in exchange for 230,343 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of approximately $3.8 million.

Off-Balance Sheet Arrangements

As of July 31, 2022, we had no off-balance sheet arrangements.

Critical Accounting Estimates

The preparation of condensed financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and income and expenses during the periods reported. Actual results could materially differ from those estimates. We have identified the following critical accounting estimates:

Warrant Liabilities

We account for our warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for liability classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Some of our warrants meet the criteria as liability classified derivative instruments and are recorded at fair value on the grant date and re-valued at each reporting date, with changes in the fair value reported in the statements of operations. Warrant liabilities are classified on the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date. Volatility in our common stock may result in significant changes in the value of the warrant liabilities and resulting gains and losses on our condensed consolidated statement of operations.

Intangible Assets

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning on July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Management reviews its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents related to ADXS-HPV (AXAL), ADXS-HOT, ADXS-PSA, ADXS-HER2 and other products that are in development, and the Lm technology licensed from the University of Pennsylvania. There are various scenarios under which an impairment charge may be recorded, which include if a competitor were to gain FDA approval for a similar treatment before the Company, if future clinical trials fail to meet the targeted endpoints, or if a drug application is rejected or fails to be issued. Lastly, if the Company is unable to raise enough capital to continue funding its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

Recently Issued Accounting Standards Not Yet Effective or Adopted

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying condensed consolidated financial statements.

Quantitative and Qualitative Disclosures About Market Risk

On July 31, 2022, we had approximately $28.2 million in cash and cash equivalents, which consisted primarily of bank deposits and money market funds. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements. We use a combination of internal and external management to execute our investment strategy and achieve our investment objectives. We typically invest in highly-rated securities (such as money market funds), and our investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Results of Operations for the Fiscal Year Ended October 31, 2021 Compared to the Fiscal Year Ended October 2020

Revenue

Revenue increased approximately $3.0 million for the year ended October 31, 2021 compared to $0.3 million for the year ended October 31, 2020. In the current period, we recognized royalty payments from OST.

Research and Development Expenses

We invest in research and development to advance our *Lm* technology through our preclinical and clinical development programs. Research and development expenses for the years ended October 31, 2021 and 2020 were categorized as follows (in thousands):

	Fiscal Years Ended October 31,		Increase (Decrease)	
	2021	2020	$	%
Hotspot/Off-the-shelf therapies	$ 4,261	$ 3,515	$ 746	21%
Prostate cancer	30	948	(918)	(97)%
HPV-associated cancers	2069	3,667	(1,598)	(44)%
Personalized neoantigen-directed therapies	495	1,266	(771)	(61)%
Other expenses	3707	6,216	$ (2,509)	(40)%
Total research & development expense	$ 10562	$ 15,612	$ (5,050)	(32)%
Stock-based compensation expense included in research and development expense	$ 164	$ 308	$ (144)	(47)%

Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapy for the fiscal year ended October 31, 2021 increased approximately 21% to $4.3 million compared to the same period in 2020. The increase is attributable to the costs associated with the increase in patient enrollment in the ADXS-503 study and the commencement of our investigator-sponsored ADXS-504 study.

Prostate Cancer (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the fiscal year ended October 31, 2021 decreased approximately $0.9 million, or 97%, compared to the same period in 2020. The decrease is attributable to the winding down of the Phase 1/2 study of our ADXS-PSA compound in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody. We do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

	Fiscal Years Ended October 31,		Increase (Decrease)	
	2021	2020	$	%
General and administrative expense	$ 11,464	$ 11,090	$ 374	3%
Stock-based compensation expense included in general and administrative expense	$ 402	$ 583	$ (181)	(31)%

HPV-Associated Cancers (AXAL)

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the fiscal year ended October 31, 2021 decreased approximately $1.6 million, or 44%, compared to the same period in 2020. The decrease is attributable to wind down costs associated with the closure of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. We do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

Personalized Neoantigen-Directed Therapies (ADXS-NEO)

Research and development costs associated with personalized neoantigen-directed therapies for the fiscal year ended October 31, 2021 decreased approximately $0.8 million, or 61%, compared to the same period in 2020. The decrease is attributable to wind down costs associated with the termination of our ADXS-NEO study. We do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the fiscal year ended October 31, 2021 decreased approximately $2.5 million, or 40%, compared to the same period in 2020. The decrease was primarily attributable to a decrease in salary related expenses, temporary worker expenses and consulting expenses due to a change in focus on the clinical development of our ADXS-503 and HOT-504 programs and substantially less on our early research programs.

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses for the years ended October 31, 2021 and 2020 were as follows (in thousands):

General and administrative expenses for the year ended October 31, 2021 increased approximately $0.4 million, or 3%, compared to the same period in 2020. This increase primarily relates to increases in (1) legal and consulting fees, including $1.4 million in legal and consulting fees related to the Merger with Biosight (2) sublicense fees (3) proxy solicitation fees related to both the annual shareholder meeting and the Merger with Biosight, (4) amounts paid in settlement of a shareholder demand letter and (5) losses on disposal of property and equipment in connection with the termination of our office lease at our former location. These increases were partially offset by decreases in (1) rent and utilities due to the termination of our office lease at our former location, (2) personnel costs and (3) charges related to the abandonment of non-strategic intellectual property.

Changes in Fair Values

For the year ended October 31, 2021, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $1.0 million. The decrease in the fair value of liability warrants resulted primarily from the issuance of warrants in the April 2021 Private Placement. The warrants issued in the April 2021 Private Placement decreased in fair value from date of issuance to October 31, 2021 due to a decrease in our share price from $45.60 on April 14, 2021 to $38.80 on October 31, 2021.

For the fiscal year ended October 31, 2020, we recorded non-cash expense from changes in the fair value of the warrant liability of $0.

Loss on shares issued in settlement of warrants

On October 16, 2020, Advaxis entered into private exchange agreements with certain holders of warrants issued in connection with Advaxis' January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 62,500 shares of our common stock at an exercise price of $100.00 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, Advaxis agreed to issue 37,500 shares of common stock to the investors in exchange for the warrants. In connection with the exchange of warrants for common stock, Advaxis recorded a loss of approximately $77,000 as the fair value of the shares issued exceeded the fair value of warrants exchanged.

Liquidity and Capital Resources

Management's Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have historically suffered recurring losses and we have required significant cash resources to execute our business plans. These losses are expected to continue for the foreseeable future.

Historically, Advaxis' major sources of cash have comprised proceeds from various public and private offerings of its securities (including common stock), debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants, and interest income. From October 2013 through October 31, 2021, Advaxis raised approximately $339.4 million in gross proceeds ($30.0 million during the year ended October 31, 2021) from various public and private offerings of our common stock. Advaxis has sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future. As of October 31, 2021 and October 31, 2020, Advaxis had an accumulated deficit of approximately $428.6 million and $410.7 million, respectively, and stockholders' equity of approximately $38.9 million and $30.2 million, respectively.

The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect Advaxis' business, financial condition, and access to sources of liquidity. As of October 31, 2021, Advaxis had approximately $41.6 million in cash and cash equivalents. The actual amount of cash that Advaxis will need to continue operating is subject to many factors.

Advaxis recognizes that it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that Advaxis will be able to obtain financing on terms acceptable to it or whether Advaxis will become profitable and generate positive operating cash flow. If Advaxis is unable to raise sufficient additional funds, it will have to further scale back its operations. Advaxis believes it has sufficient capital to fund its obligations, as they become due, in the ordinary course of business into the 3rd fiscal quarter of 2023. Advaxis based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $15.4 million for the fiscal year ended October 31, 2021 compared to $21.9 million for the fiscal year ended October 31, 2020. Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. The decrease was due to measures to control costs for non-essential items in areas that did not support our strategic direction, and as a result, we have continued to reduce non-strategic operating expenditures over the past several quarters.

Investing Activities

Net cash used in investing activities was approximately $11,000 for the fiscal year ended October 31, 2021 compared to $0.7 million for the fiscal year ended October 31, 2020. The decrease is a result of proceeds on disposal of property and equipment and the abandonment of certain non-strategic intellectual property in the prior period that led to less patent costs in the current period.

Financing Activities

Net cash provided by financing activities was approximately $31.9 million for the fiscal year ended October 31, 2021 as compared to $15.5 million for the fiscal year ended October 31, 2020. In April 2021, Advaxis completed an offering of (i) 219,718 shares of common stock, (ii) 95,899 pre-funded warrants to purchase 95,899 shares of common stock and (iii) registered common share purchase warrants to purchase 140,552 shares of common stock (the "Registered Direct Offering") with two healthcare focused, institutional investors. Advaxis also issued to the investors, in a concurrent private placement, unregistered common share purchase warrants to purchase 175,065 shares of Advaxis' common stock (the "Private Placement" and together with the Registered Direct Offering, the "April 2021 Offering"). We received gross proceeds of approximately $20 million, before deducting the fees and expenses payable by us in connection with the April 2021 Offering.

On November 27, 2020, Advaxis completed an underwritten public offering of 333,333 shares of common stock and common stock warrants to purchase up to 166,674 shares of common stock (the "November 2020 Offering"). On November 24, 2020, the underwriters notified us that they had exercised their option to purchase an additional 50,000 shares of common stock and 25,000 warrants in full. After giving effect to the full exercise of the underwriters' option, we issued and sold an aggregate 383,333 shares of common stock and warrants to purchase up to 191,674 shares of common stock. We received gross proceeds of approximately $9.2 million, before deducting the underwriting discounts and commissions and fees and expenses payable by us in connection with the November 2020 Offering.

During the year ended October 31, 2021, warrant holders from Advaxis' November 2020 offering exercised 134,437 warrants in exchange for 134,437 shares of Advaxis' common stock and warrant holders from Advaxis' April 2021 Offering exercised 95,399 pre-funded warrants in exchange for 95,399 shares of Advaxis' common stock. Pursuant to these warrant exercises, Advaxis received aggregate proceeds of approximately $3.8 million which were payable upon exercise.

In January 2020, we completed a public offering of 125,000 shares of our common stock, which resulted in net proceeds of approximately $9.7 million. Additionally, during the year end October 31, 2020, we sold 31,113 shares under the ATM program for net proceeds of $1.531 million, and we sold 140,525 shares of common stock under the Lincoln Park Purchase Agreement for net proceeds of approximately $5.1 million.

Off-Balance Sheet Arrangements

As of October 31, 2021, we had no off-balance sheet arrangements.

Critical Accounting Policies

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Advaxis only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, Advaxis assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. Advaxis then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Advaxis enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to Advaxis of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, Advaxis performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) Advaxis satisfies each performance obligation. As part of the accounting for these arrangements, Advaxis must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. Advaxis uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which Advaxis recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to Advaxis' intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, Advaxis recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, Advaxis considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, Advaxis considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, Advaxis utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Advaxis evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue Advaxis records in future periods.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, Advaxis evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of Advaxis or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. Advaxis evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, Advaxis re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Stock Based Compensation

Advaxis has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. Advaxis measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the consolidated statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. Advaxis estimates the fair value of stock option awards on the date of grant using the Black Scholes Model ("BSM") for the remaining awards, which requires that Advaxis makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if Advaxis revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

Advaxis accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, Advaxis recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

Derivative Financial Instruments

Advaxis does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. Advaxis evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, Advaxis used the Monte Carlo simulation model and the Black-Scholes model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

Intangible Assets

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning on July 1, 2002. These legal and filing costs are invoiced to Advaxis through Penn and its patent attorneys.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable and its carrying amount exceeds its fair value, which is based upon estimated undiscounted future cash flows. Net assets are recorded on the consolidated balance sheet for patents and licenses related to AXAL, ADXS-HOT and ADXS-PSA and other products that are in development. However, if a competitor were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, Advaxis would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, Advaxis would record an impairment of its estimated book value.

Leases

Effective November 1, 2019, Advaxis adopted ASC Topic 842, *Leases* ("ASC 842") using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, *Leases*.

At the inception of an arrangement, Advaxis determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the consolidated balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. Advaxis has elected not to recognize on the consolidated balance sheet leases with terms of 12 months or less. Advaxis typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in Advaxis' assessment unless there is reasonable certainty that Advaxis will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in Advaxis' leases is typically not readily determinable. As a result, Advaxis utilizes its incremental borrowing rate, which reflects the fixed rate at which Advaxis could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, Advaxis utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

New Accounting Standards

See Note 2 to our financial statements that discusses new accounting standards.

AYALA MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of Ayala's financial condition and results of operations together with Ayala's audited consolidated financial statements and unaudited condensed consolidated financial statements, or together, Ayala's consolidated financial statements, and the related notes included elsewhere in this proxy statement/prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this proxy statement/prospectus includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this proxy statement/prospectus, Ayala's actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Ayala is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. Ayala's differentiated development approach is predicated on identifying and addressing tumorigenic drivers of cancer, through a combination of Ayala's bioinformatics platform and next-generation sequencing, or NGS, to deliver targeted therapies to underserved patient populations. Ayala's current portfolio of product candidates, AL101 and AL102, targets the aberrant activation of the Notch pathway using gamma secretase inhibitors, or GSIs. Gamma secretase is the enzyme responsible for Notch activation and, when inhibited, turns off the Notch pathway activation. Aberrant activation of the Notch pathway has long been implicated in multiple solid tumor and hematological cancers and has often been associated with more aggressive cancers. In cancers, Notch is known to serve as a critical facilitator in processes such as cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, all of which contribute to a poorer patient prognosis. AL101 and AL102 are designed to address the underlying key drivers of tumor growth, and Ayala's initial Phase 2 clinical data of AL101 suggest that Ayala's approach may address shortcomings of existing treatment options. Ayala believes that its novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from rare and aggressive cancers.

Ayala's product candidates, AL101 and AL102, are being developed as potent, selective, small molecule GSIs. Ayala obtained an exclusive, worldwide license to develop and commercialize AL101 and AL102 from BMS in November 2017. BMS evaluated AL101 in three Phase 1 studies involving more than 200 total subjects and AL102 in a single Phase 1 study involving 36 subjects with various cancers who had not been prospectively characterized for Notch activation, and to whom Ayala refers as unselected subjects. While these Phase 1 studies did not report statistically significant overall results, clinical activity was observed across these studies in cancers in which Notch has been implicated as a tumorigenic driver.

Ayala is currently evaluating AL102, its oral GSI for the treatment of desmoid tumors, in its RINGSIDE Phase 2/3 pivotal study. In February 2022, Part A completed enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102. Ayala reported initial interim data from Part A in July 2022 with additional data released at a medical conference in September 2022, showing efficacy across all cohorts, with early tumor responses that deepened over time. AL102 was well tolerated. Ayala has initiated Part B of RINGSIDE (Phase 3), and is enrolling patients in an open label extension study. Part B of the study is a double-blind placebo-controlled study enrolling up to 156 patients with progressive disease, randomized between AL102 or placebo. The study's primary endpoint will be progression free survival, or PFS, with secondary endpoints including objective response rates, or ORR, duration of response, or DOR and patient reported Quality of Life, or QOL, measures. On September 27, 2022, Ayala announced that the FDA has granted Fast Track designation for AL102 for the treatment of progressing desmoid tumors. The FDA grants Fast Track designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track designation can benefit from early and frequent communication with the agency, in addition to a rolling submission of the marketing application, with potential pathways for expedited approval that have the objective of getting important new therapies to patients more quickly.

In addition, Ayala collaborated with Novartis to develop AL102 for the treatment of multiple myeloma in combination with Novartis' B-cell maturation antigen targeting therapies. On June 2, 2022, Novartis informed Ayala that it does not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the agreement with them.

Ayala is currently concluding a Phase 2 ACCURACY trial of AL101 for the treatment of R/M ACC, in subjects with progressive disease and Notch-activating mutations. Ayala refers to this trial as the ACCURACY trial. Ayala uses NGS to identify patients with Notch-activating mutations, an approach that Ayala believes will enable it to target the patient population with cancers that it believes are most likely to respond to and benefit from AL101 treatment. Ayala chose to initially target R/M ACC based on Ayala's differentiated approach, which is comprised of: data generated in a Phase 1 study of AL101 in unselected, heavily pretreated subjects conducted by BMS, Ayala's own data generated in patient-derived xenograft models, Ayala's bioinformatics platform and Ayala's expertise in the Notch pathway.

If approved, Ayala believes that AL101 has the potential to be the first therapy approved by the FDA for patients with R/M ACC and to address the unmet medical need of these patients. AL101 was granted ODD in May 2019 for the treatment of ACC and Fast Track designation in February 2020 for the treatment of R/M ACC. Ayala reported interim data regarding the most recent safety efficacy, pharmacokinetics, and pharmacodynamics data from Phase 2 of the ACCURACY trial in June 2022.

As part of Ayala's efforts to focus its resources on the more advanced programs and studies including the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC, Ayala elected to discontinue the TENACITY trial, which was evaluating AL101 as a monotherapy in an open-label Phase 2 clinical trial for the treatment of patients with Notch-activated recurrent/metastatic triple-negative breast cancer, or R/M TNBC.

Ayala was incorporated as a Delaware corporation on November 14, 2017, and its headquarters is located in Rehovot, Israel. Ayala's operations to date have been limited to organizing and staffing its company, business planning, raising capital and conducting research and development activities for its product candidates. To date, Ayala has funded its operations primarily through the sales of Ayala Common Stock and convertible preferred stock.

Ayala has incurred significant net operating losses in every year since its inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Ayala's net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. Ayala's net losses were approximately $10.2 million and $28.4 million for the three and nine months ended September 30, 2022, respectively, and approximately $40.3 million and $30.1 million for the years ended December 31, 2021 and 2020, respectively. As of the nine months ended September 30, 2022, Ayala had an accumulated deficit of $139.6 million. Ayala anticipates that its expenses will increase significantly as Ayala:

- pays for transaction costs and expenses related to the Merger;
- advances its development of AL101 for the treatment of R/M ACC;
- advances its Phase 2/3 RINGSIDE pivotal trial of AL102 for the treatment of desmoid tumors, or obtain and conduct clinical trials for any other product candidates;

- assuming successful completion of its Phase 2 ACCURACY trial of AL101 for the treatment of R/M ACC, may be required by the FDA to complete Phase 3 clinical trials to support submission of an NDA for AL101 for the treatment of R/M ACC;
- establishes a sales, marketing and distribution infrastructure to commercialize AL101 and/or AL102, if approved, and for any other product candidates for which it may obtain marketing approval;
- maintains, expands, protects and enforces its intellectual property portfolio;
- hires additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial and other personnel, to execute its business plan; and
- adds clinical, scientific, operational, financial and management information systems and personnel to support its product development and potential future commercialization efforts, and to enable it to operate as a public company.

Ayala does not expect to generate revenue from product sales unless and until it successfully completes clinical development and obtains regulatory approval for a product candidate. Additionally, Ayala currently uses contract research organizations, or CROs, to carry out its clinical development activities. Furthermore, Ayala incurs additional costs associated with operating as a public company. As a result, Ayala will need substantial additional funding to support its continuing operations, pursue its growth strategy and continue as a going concern. Until such time as Ayala can generate significant revenue from product sales, if ever, Ayala expects to fund its operations through public or private equity offerings or debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources. Ayala may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Ayala's failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on its financial condition and its ability to develop its current or any future product candidates.

Because of the numerous risks and uncertainties associated with therapeutics product development, Ayala is unable to predict accurately the timing or amount of increased expenses or when or if it will be able to achieve or maintain profitability. Even if Ayala can generate revenue from product sales, Ayala may not become profitable. If Ayala fails to become profitable or is unable to sustain profitability on a continuing basis, then Ayala may be unable to continue its operations at planned levels and be forced to reduce or terminate its operations.

As of September 30, 2022, Ayala had cash and cash equivalents and restricted bank deposits of approximately $11.5 million. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources, Ayala has concluded that substantial doubt exists with respect to its ability to continue as a going concern within one year after the date of the issuance of the September 30, 2022 unaudited condensed consolidated financial statements. See "*—Liquidity and Capital Resources*." Substantial doubt about Ayala's ability to continue as a going concern may materially and adversely affect the price per share of its Common Stock, and it may be more difficult for Ayala to obtain financing. If potential collaborators decline to do business with Ayala or potential investors decline to participate in any future financings due to such concerns, Ayala's ability to increase its cash position may be limited. Ayala will need to generate significant revenues to achieve profitability, and it may never do so. Because of the numerous risks and uncertainties associated with the development of Ayala's current and any future product candidates, the development of its platform and technology and because the extent to which it may enter into collaborations with third parties for development of any of its product candidates is unknown, Ayala is unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of its product candidates.

If Ayala raises additional funds through marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements with third parties, it may be required to relinquish valuable rights to its technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to it. If Ayala is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate product candidate development programs or future commercialization efforts, grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself or discontinue operations.

Agreement and Plan of Merger

On October 18, 2022, Ayala entered into the Merger Agreement with Advaxis and Merger Sub. As a result of the Merger, Advaxis will be renamed "Ayala Pharmaceuticals, Inc." closing of the Merger is expected to occur during the first quarter of 2023. The representations, warranties, agreements and covenants of the parties set forth in the Merger Agreement will terminate at the closing.

Voting and Support Agreements

On October 18, 2022, concurrently with the execution of the Merger Agreement, Advaxis entered into voting and support agreements, each a Voting Agreement, and together the Voting Agreements, with each of IBF I and aMoon (each in its capacity as Ayala's stockholder), pursuant to which, among other things and subject to the terms and conditions therein, each such stockholder agreed to vote all shares of Ayala's capital stock that it beneficially owns, representing approximately 22.4% and 20.3%, respectively, of Ayala's total current outstanding voting power, in favor of, among other things, the approval and adoption of the Merger Agreement and the Transactions, including the Merger. The Voting Agreements provide that, in the event of a Company Change in Recommendation (as defined in the Merger Agreement), the number of shares of Ayala's capital stock subject to the Voting Agreements shall only be 30% of Ayala's total current outstanding voting power, and the number of shares of Ayala's capital stock of each of IBF I and aMoon subject to the Voting Agreements shall be reduced proportionately based on the number of shares of Ayala's capital stock of subject thereto.

Bristol-Myers Squibb License Agreement

In November 2017, Ayala entered into an exclusive worldwide license agreement with BMS for AL101 and AL102, each a small molecule gamma secretase inhibitor in development for the treatment of cancers. Under the terms of the license agreement, Ayala has licensed the exclusive worldwide development and commercialization rights for AL101 (previously known as BMS-906024) and AL102 (previously known as BMS-986115).

Ayala is responsible for all future development and commercialization of AL101 and AL102. In consideration for the rights granted under the agreement, Ayala paid BMS a payment of $6 million and issued to BMS 1,125,929 shares of Series A preferred stock valued at approximately $7.3 million, which converted to 562,964 shares of Ayala Common Stock in connection with Ayala's initial public offering, or IPO. Ayala is obligated to pay BMS up to approximately $142 million in the aggregate upon the achievement of certain clinical development or regulatory milestones and up to $50 million in the aggregate upon the achievement of certain commercial milestones by each product containing the licensed BMS compounds. In addition, Ayala is obligated to pay BMS tiered royalties ranging from a high single-digit to a low teen percentage on worldwide net sales of all products containing the licensed BMS compounds.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to Ayala (a) for insolvency-related events involving Ayala, (b) for Ayala's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, (c) for Ayala's failure to fulfill Ayala's obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if Ayala or Ayala's affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. Ayala has the right to terminate the BMS License Agreement (a) for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Product has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if Ayala reasonably determines that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products. Upon termination of the BMS License Agreement in its entirety by Ayala for convenience or by BMS, Ayala grants an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of Ayala's patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay Ayala a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/or BMS Licensed Products.

Novartis License Agreement

In December 2018, Ayala entered into an evaluation, option and license agreement, or the Novartis Agreement, with Novartis, pursuant to which Ayala granted Novartis an exclusive option to obtain an exclusive license to research, develop, commercialize and manufacture AL102 for the treatment of multiple myeloma.

Ayala supplied Novartis quantities of AL102, products containing AL102 and certain other materials for purposes of conducting evaluation studies not comprising human clinical trials during the option period, together with Ayala's know-how as may have been reasonably be necessary in order for Novartis to conduct such evaluation studies. Novartis agreed to reimburse Ayala for all such expenses.

At any time during the option term, Novartis may have exercised its option by payment of a low eight figure option exercise fee. If Novartis exercised its option, it would have been obligated to pay Ayala up to an additional $245 million upon the achievement of certain clinical development and commercial milestones. In addition, Novartis was obligated to pay Ayala tiered royalties at percentages ranging from a mid-single digit to a low double-digit percentage on worldwide net sales of products licensed under the agreement.

On June 2, 2022, Novartis informed Ayala that Novartis does not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the agreement.

Components of Results of Operations

Revenue Recognition

Ayala recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, which applies to all contracts with customers. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606, Ayala assesses the goods or services promised within the contract and determines those that are performance obligations and assess whether each promised good or service is distinct.

Customer option to acquire additional goods or services gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract.

In a contract with multiple performance obligations, Ayala must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations.

Ayala evaluates each performance obligation to determine if it can be satisfied at a point in time or over time.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration Ayala expects to be entitled to receive in exchange for those goods or services.

In December 2018, Ayala entered into the Novartis Agreement for which Ayala paid for its research and development costs. For additional details regarding the Novartis Agreement, refer to Note 5 of Ayala's audited consolidated financial statements and Note 2 to Ayala's unaudited condensed consolidated financial statements included elsewhere in this proxy statement/prospectus. In June 2022, Novartis terminated the agreement.

Ayala concluded that there was one distinct performance obligation under the Novartis Agreement: Research and development services, an obligation which was satisfied over time.

Ayala concluded that progress towards completion of the research and development performance obligation related to the Novartis Agreement was best measured in an amount proportional to the expenses incurred from the total estimated expenses. Ayala periodically reviewed and updated Ayala's estimates, when appropriate. The transaction price to recognized as revenue under the Novartis Agreement consisted of the reimbursable research and development costs.

Operating Expenses

Ayala's operating expenses since inception have consisted solely of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for Ayala's research activities, including the development of and pursuit of regulatory approval of Ayala's lead product candidates, AL101 and AL102, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for personnel engaged in research and development functions;

- expenses incurred in connection with the preclinical and clinical development of Ayala's product candidates, including under agreements with CROs, investigative sites and consultants;
- costs of manufacturing Ayala's product candidates for use in its preclinical studies and clinical trials, as well as manufacturers that provide components of its product candidates for use in its preclinical and current and potential future clinical trials;
- costs associated with Ayala's bioinformatics platform;
- consulting and professional fees related to research and development activities;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of Ayala's facility, utilities, depreciation and other supplies.

Ayala expenses research and development costs as incurred. Ayala's external research and development expenses consist primarily of costs such as fees paid to consultants, contractors and CROs in connection with its preclinical and clinical development activities. Ayala typically uses its employee and infrastructure resources across its development programs and does not allocate personnel costs and other internal costs to specific product candidates or development programs with the exception of the costs to manufacture its product candidates.

Research and development activities are central to Ayala's business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Ayala expects that its research and development expenses will continue to be significant for the foreseeable future as it continues to advance its pivotal Phase 2/3 RINGSIDE study of AL102 for the treatment of desmoid tumors and initiate additional clinical trials, including AL102 for the treatment of R/R T-ALL, scale its manufacturing processes, continue to develop additional product candidates and hire additional clinical and scientific personnel.

The successful development of AL101, AL102 and any future product candidate is highly uncertain. Accordingly, at this time, Ayala cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of these product candidates. Ayala is also unable to predict when, if ever, it will generate revenue and material net cash inflows from the commercialization and sale of any of its product candidates for which it may obtain marketing approval. Ayala may never succeed in achieving regulatory approval for any of its product candidates. The duration, costs and timing of preclinical studies, clinical trials and development of Ayala's product candidates will depend on a variety of factors, including:

- successful completion of clinical trials with adequate safety, tolerability and efficacy profiles for AL101, AL102 and any potential future product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority;
- approval of INDs for AL101 and AL102 and any potential future product candidate to commence planned or future clinical trials in the United States or foreign countries;
- significant and changing government regulation and regulatory guidance;
- timing and receipt of marketing approvals from applicable regulatory authorities;
- establishing arrangements with contract manufacturing organizations, or CMOs, for third-party clinical and commercial manufacturing to obtain sufficient supply of Ayala's product candidates;

- obtaining, maintaining, protecting and enforcing patent and other intellectual property rights and regulatory exclusivity for Ayala's product candidates;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with other organizations;
- acceptance of the product, if and when approved, by patients, the medical community and third-party payors;
- competition with other therapies; and
- maintenance of a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization enabling activities of any of Ayala's product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require Ayala to conduct clinical trials beyond those that Ayala anticipates will be required for the completion of clinical development of a product candidate, or if Ayala experiences significant delays in its clinical trials due to patient enrollment or other reasons, Ayala would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting, auditing, tax services and insurance costs.

Ayala expects that its general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of its product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, Ayala expects to incur increased expenses associated with being a public company, including the costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Financial Income, Net

Financial income, net primarily consists of interest income earned on Ayala's cash and cash equivalents and restricted bank deposits.

Results of Operations

Comparison of the three and nine months ended September 30, 2022, and 2021

The following table summarizes Ayala's results of operations for the three and nine months ended September 30, 2022 and 2021:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
	($ in thousands) (Unaudited)			
Revenues from licensing agreement	$ 91	$ 625	$ 587	$ 2,360
Cost of services	(91)	625	(497)	(2,360)
Gross profit	—	—	90	—
Operating expenses:				
Research and development	7,196	7,368	20,279	22,414
General and administrative	2,885	2,198	7,586	7,037
Operating loss	(10,081)	(9,566)	(27,775)	(29,451)
Financial Income (Loss), net	(1)	(63)	(141)	(177)
Loss before income tax	(10,082)	(9,629)	(27,916)	(29,628)
Taxes on income	(106)	(167)	(509)	(577)
Net loss	(10,188)	(9,796)	(28,425)	(30,205)

Revenue

To date, Ayala has not generated any revenue from product sales, and does not expect to generate any revenue from the sale of products in the foreseeable future. If Ayala's development efforts for its product candidates are successful and result in regulatory approval and successful commercialization efforts, Ayala may generate revenue from product sales in the future. Ayala cannot predict if, when, or to what extent it will generate revenue from the commercialization and sale of its product candidates. Ayala may never succeed in obtaining regulatory approval for any of its product candidates.

For the three months ended September 30, 2022 and 2021, Ayala recognized approximately $91 thousand and $0.6 million in revenue, respectively, mainly as a result of the termination of the Novartis Agreement.

For the nine months ended of September 30, 2022 and 2021, Ayala recognized approximately $0.6 million and $2.4 million in revenue, respectively, mainly as a result of the termination of the Novartis Agreement.

Refer to Note 2 to Ayala's unaudited condensed consolidated financial statements for information regarding its recognition of revenue under the Novartis Agreement.

Research and Development

Research and development expenses were $7.2 million for the three months ended September 30, 2022 compared to $7.4 million for the three months ended September 30, 2021, a decrease of $0.2 million. Research and development expenses were $20.3 million for the nine months ended September 30, 2022 compared to $22.4 million for the nine months ended September 30, 2021, a decrease of $2.1 million. The decrease was due to the termination of the TENACITY trial and winding down of the ACCURACY trial.

The following table summarizes Ayala's research and development expenses by product candidate or development program for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
	($ in thousands) (Unaudited)			
Program-Specific Costs:				
AL 101				
ACC	940	3,415	2,703	11,351
TNBC[(1)]	926	1,966	3,460	5,926
General Expenses	728	693	1,904	1,496
AL 102				
General Expenses	71	8	251	32
Desmoid	4,531	1,286	11,961	3,609
Total Research and Development Expenses	$ 7,196	$ 7,368	$ 20,279	$ 22,414

(1) As part of Ayala's efforts to focus its resources on the more advanced programs and studies including the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC, Ayala elected to discontinue the TENACITY trial, which was evaluating AL101 as a monotherapy in an open-label Phase 2 clinical trial for the treatment of patients with Notch-activated R/M TNBC.

Ayala expects its research and development expenses to increase for the foreseeable future as it continues to invest in research and development activities related to developing its product candidates, including investments in manufacturing, as its programs advance into later stages of development and as it conducts additional clinical trials.

General and Administrative

General and administrative expenses were $2.9 million for the three months ended September 30, 2022 compared to $2.2 million for the three months ended September 30, 2021, an increase of $0.7 million. General and administrative expenses were $7.6 million for the nine months ended September 30, 2022 compared to $7.0 million for the nine months ended September 30, 2021, an increase of $0.5 million.

Financial Loss, net

Financial loss, net was $1 thousand for the three months ended September 30, 2022 compared to the financial loss, net of $63 thousand for the three months ended September 30, 2021. Financial loss, net was $141 thousand for the nine months ended September 30, 2022 compared to the financial loss, net of $177 thousand for the same period in 2021.

Comparison of the years ended December 31, 2021 and 2020

The following table summarizes Ayala's results of operations for the year ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
	($ in thousands)	
Revenue from license agreement	$ 3,506	$ 3,708
Cost of revenue	(3,506)	(3,708)
Gross profit	-	-
Operating expenses:		
Research and development	29,941	22,406
General and administrative	9,277	7,371
Operating loss	(39,218)	(29,777)
Financial income (expenses), net	(260)	56
Loss before income tax	(39,478)	(29,721)
Taxes on income	(776)	(425)
Net loss	$ (40,254)	$ (30,146)

Revenue

Revenue associated with the research and development services under the Novartis Agreement in the amount of $3.5 million was recognized in the year ended December 31, 2021, compared to $3.7 million recognized in fiscal year 2020.

Research and Development Expenses

Research and development expenses were $29.9 million for the year ended December 31, 2021 compared to $22.4 million for the year ended December 31, 2020, an increase of $7.5 million. This increase was primarily driven by additional costs in connection with the initiation and advancement of the Phase 2/3 RINGSIDE pivotal study for desmoids tumors.

The following table summarizes Ayala's research and development expenses by product candidate or development program for the years ended December 31, 2021 and 2020:

	Years Ended December 31,	
	2021	**2020**
Program-specific costs:		
AL101		
ACC	$ 15,363	$ 13,684
TNBC	8,051	6,828
General Expenses	1,484	1,563
AL102		
General Expenses	42	39
Desmoid	5,001	292
Total research and development expenses	$ 29,941	$ 22,406

General and Administrative Expenses

General and administrative expenses were $9.3 million for the year ended December 31, 2021 compared to $7.4 million for the year ended December 31, 2020, an increase of $1.9 million. This increase was primarily due to higher expenses in connection with Ayala's operations as a public company, including officer and director insurance, increased headcount and stock-based compensation.

Financial Income (expenses), net

Financial expense, net was $260 thousand for the year ended December 31, 2021 compared to financial income, net of $56 thousand for the year ended December 31, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Since Ayala's inception, it has not generated any revenue from product sales and has incurred significant operating losses and negative cash flows from its operations. Ayala's net losses were approximately $10.2 million and $28.4 million for the three and nine months ended September 30, 2022, respectively, and approximately $40.3 million and $30.1 million for the years ended December 31, 2021 and 2020, respectively. As of September 30, 2022, Ayala had an accumulated deficit of $139.6 million.

On May 12, 2020, Ayala completed the sale of shares of its Common Stock in its IPO. In connection with the IPO, Ayala issued and sold 3,940,689 shares of Ayala Common Stock, including 274,022 shares associated with the partial exercise on June 4, 2020 of the underwriters' option to purchase additional shares, at a price to the public of $15.00 per share, resulting in net proceeds to Ayala of approximately $52.2 million after deducting underwriting discounts and commissions and estimated offering expenses payable by Ayala. All shares issued and sold were registered pursuant to a registration statement on Form S-1 (File No. 333-236942), as amended, declared effective by the SEC, on May 7, 2020, or the IPO Registration Statement.

On February 19, 2021, Ayala entered into a Securities Purchase Agreement, or the 2021 Purchase Agreement, with the purchasers named therein, or the Investors. Pursuant to the 2021 Purchase Agreement, Ayala agreed to sell (i) an aggregate of 333,333 shares of its Common Stock, or the Private Placement Shares, par value $0.01 per share, together with warrants to purchase an aggregate of 116,666 shares of its Common Stock with an exercise price of $18.10 per share, or the Common Warrants, for an aggregate purchase price of $4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of its Common Stock with an exercise price of $0.01 per share, or the Pre-Funded Warrants and collectively with the Common Warrants, the Private Placement Warrants, together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of $19,986,661.67, collectively, the Private Placement. The Private Placement closed on February 23, 2021.

In June 2021, Ayala entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which Ayala may, from time to time, issue and sell Ayala Common Stock with an aggregate value of up to $200.0 million in "at-the-market" offerings, or the ATM, under its registration statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021, or the ATM Registration Statement. Sales of Ayala Common Stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act of 1933, as amended, including sales made directly through The Nasdaq Global Market or on any other existing trading market for Ayala's Common Stock. Pursuant to the Sales Agreement, during the year ended December 31, 2021, Ayala sold a total of 827,094 shares of Ayala Common Stock for total net proceeds of approximately $10.0 million. During the three and nine months ended September 30, 2022, Ayala sold a total of 305,517 and 310,417 shares of Common Stock for total net proceeds of approximately $468 thousand and $517 thousand, respectively.

The exercise price and the number of shares of Ayala Common Stock issuable upon exercise of each Private Placement Warrant are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Ayala Common Stock. In addition, in certain circumstances, upon a fundamental transaction, a holder of Common Warrants will be entitled to receive, upon exercise of the Common Warrants, the kind and amount of securities, cash or other property that such holder would have received had they exercised the Private Placement Warrants immediately prior to the fundamental transaction. The Pre-Funded Warrants will be automatically exercised on cashless basis upon the occurrence of a fundamental transaction. Each Common Warrant is exercisable from the date of issuance and has a term of three years and each Pre-Funded Warrant is exercisable from the date of issuance and has a term of ten years. Pursuant to the 2021 Purchase Agreement, Ayala registered the Private Placement Shares and Private Placement Warrants for resale by the Investors on a registration statement on Form S-3, or the Private Placement Registration Statement.

As of September 30, 2022, Ayala had cash and cash equivalents and restricted bank deposits of approximately $11.5 million.

Cash Flows

Cash Flows for the nine months ended September 30, 2022 and September 30, 2021

The following table summarizes Ayala's cash flow for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	**2021**
	($ in thousands) (Unaudited)	
Net cash used in operating activities	$ (26,342)	$ (30,564)
Net cash used in investing activities	-	(5)
Net cash provided by financing activities	512	29,383
Net increase (decrease) in cash and cash equivalents and short-term restricted bank deposits	$ (25,830)	$ (1,186)

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2022 of approximately $26.3 million was primarily attributable to Ayala's net loss of $29.7 million, the decrease in Ayala's prepaid expenses of $1.5 million, and the decrease in Ayala's other accounts payable of $0.4 million, partially offset by stock- based compensation of $1.9 million.

Net cash used in operating activities during the nine months ended September 30, 2021 of $30.6 million was primarily attributable to Ayala's net loss of $30.2 million, adjusted for non-cash expenses of $0.8 million.

Investing Activities

Ayala did not have any cash provided by investing activities during the nine months ended September 30, 2022. Net cash used by investing activities of $5 thousand as of September 30, 2021 was primarily to purchase property and equipment.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2022 of $512 thousand was attributable to the Private Placement, net of issuance costs, and sales pursuant to the ATM.

Net cash provided by financing activities during the nine months ended September 30, 2021 of $29.4 million was primarily attributable to the Private Placement, net of issuance costs.

Cash Flows for the years ended December 31, 2021 and 2020

The following table provides information regarding Ayala's cash flows for the years ended December 31, 2021 and 2020:

	Years Ended December 31,	
	2021	**2020**
	($ in thousands)	
Net cash used in operating activities	$ (38,356)	$ (27,541)
Net cash (used in) provided by investing activities	(5)	181
Net cash provided by financing activities	33,330	52,922
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (5,031)	$ 25,562

Operating Activities

The cash used in operating activities resulted primarily from expenses associated with Ayala's clinical development programs and early-stage research and general and administrative expenses.

Net cash used in operating activities during the year ended December 31, 2021 of $38.4 million was primarily attributable to Ayala's net loss of $40.3 million, adjusted for stock-based compensation of $2.7 million.

Net cash used in operating activities during the year ended December 31, 2020 of $27.5 million was primarily attributable to Ayala's net loss of $30.1 million, adjusted for non-cash expenses of $2.6 million, which includes stock-based compensation of $1.6 million and a net decrease in working capital of $1.0 million.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2021, of $5 thousand was attributable to purchases of property and equipment.

Net cash provided by investing activities during the year ended December 31, 2020, of $181 thousand was primarily attributable to maturing of bank deposits.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2021 of 33.3 million was primarily attributable to Ayala's issuance of shares and warrants, net of issuance costs.

Net cash provided by financing activities during the year ended December 31, 2020 of $52.9 million was primarily attributable to Ayala's IPO, net of issuance costs.

Funding Requirements

Ayala's future capital requirements are difficult to forecast and will depend on many factors, including its ability to consummate the Merger; if the Merger is not completed, the timing and nature of any other strategic transactions that it undertakes. Ayala expects its expenses to increase in connection with its ongoing activities, particularly as it continues the research and development for, initiates later-stage clinical trials for, and seeks marketing approval for, its product candidates. In addition, if Ayala obtains marketing approval for any of its product candidates, Ayala expects to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, Ayala incurs additional costs associated with operating as a public company. Accordingly, Ayala will need to obtain substantial additional funding in connection with its continuing operations. If Ayala is unable to raise capital when needed or on attractive terms, Ayala would be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts.

As of September 30, 2022, Ayala had cash and cash equivalents and restricted bank deposits of $11.5 million. Ayala evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date of the issuance of the September 30, 2022 unaudited condensed consolidated financial statements. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources at September 30, 2022, Ayala has concluded that substantial doubt exists with respect to its ability to continue as a going concern within one year after the date of the issuance of the September 30, 2022 unaudited condensed consolidated financial statements. Ayala's future capital requirements will depend on many factors, including:

- the costs of consummating the Merger and Ayala's ability to consummate the Merger;
- the costs of conducting future clinical trials of AL101 and AL102;
- the cost of manufacturing additional material for future clinical trials of AL101 and AL102;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates Ayala may develop or acquire, if any;
- the costs, timing and outcome of regulatory review of Ayala's product candidates;
- the achievement of milestones or occurrence of other developments that trigger payments under any current or future license, collaboration or other agreements;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of Ayala's product candidates for which it receives marketing approval;
- the amount of revenue, if any, received from commercial sales of Ayala's product candidates, should any of its product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting and enforcing Ayala's intellectual property rights and defending intellectual property-related claims;
- the severity, duration and impact of the COVID-19 pandemic, which may adversely impact Ayala's business and clinical trials;
- Ayala's headcount growth and associated costs as it expands its business operations and its research and development activities; and
- the costs of operating as a public company.
- Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and Ayala may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, Ayala's product candidates, if approved, may not achieve commercial success. Ayala's commercial revenues, if any, will be derived from sales of products that it does not expect to be commercially available for many years, if at all. Accordingly, Ayala will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to Ayala on acceptable terms, or at all.

Until such time, if ever, as Ayala can generate substantial product revenues, Ayala expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Ayala does not have any committed external source of funds. To the extent that Ayala raises additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Any debt financing, if available, may involve agreements that include restrictive covenants that limit Ayala's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact Ayala's ability to conduct its business.

If Ayala raises funds through collaborations, strategic alliances or licensing arrangements with third parties, such as its former agreement with Novartis, Ayala may have to relinquish valuable rights to its technologies, intellectual property, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favourable to Ayala. If Ayala is unable to raise additional funds through equity or debt financings when needed, Ayala may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that Ayala would otherwise prefer to develop and market itself.

On June 2, 2022, Novartis informed Ayala that it did not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the Novartis Agreement.

Critical Accounting Policies and Use of Estimates

Ayala's management's discussion and analysis of financial condition and results of operations is based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires Ayala to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in its consolidated financial statements during the reporting periods. These items are monitored and analyzed by Ayala for changes in facts and circumstances, and material changes in these estimates could occur in the future. Ayala based its estimates on historical experience, known trends and events, and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While Ayala's significant accounting policies are described in more detail in the notes to Ayala's consolidated financial statements appearing elsewhere in this proxy statement/prospectus, Ayala believes the following accounting policies used in the preparation of its consolidated financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

As part of the process of preparing Ayala's consolidated financial statements, Ayala is required to estimate its accrued research and development expenses. This process involves reviewing purchase orders and open contracts, communicating with Ayala's personnel to identify services that have been performed on Ayala's behalf and calculating the level of service performed and the associated cost incurred for the services when Ayala has not yet been invoiced or otherwise notified of the actual cost. The majority of Ayala's service providers invoice Ayala monthly in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. Ayala makes calculations of its accrued expenses as of each balance sheet date in Ayala's consolidated financial statements based on facts and circumstances known to Ayala at that time. Ayala periodically confirms the accuracy of its calculations with the service providers and makes adjustments if necessary. The significant calculation in Ayala's accrued research and development expenses include the following costs incurred for services in connection with research and development activities for which Ayala has not yet been invoiced:

- vendors in connection with clinical development activities;
- vendors in connection with the testing of clinical trial materials;
- CROs in connection with clinical trials; and
- investigative sites in connection with clinical trials.

Ayala contracts with CROs to conduct clinical and other research and development services on Ayala's behalf. Ayala bases its expenses related to CROs on its calculations of the services received and efforts expended pursuant to quotes and contracts with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to Ayala's CROs will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, Ayala estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from Ayala's estimate, Ayala adjusts the accrual or amount of prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although Ayala does not expect its calculations to be materially different from amounts actually incurred, Ayala's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to Ayala's prior calculations of accrued research and development expenses.

Stock-Based Compensation

Ayala measures stock options and other stock-based awards granted to employees, directors, consultants or advisors of the company or its affiliates based on their fair value on the date of the grant and recognizes compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. Ayala applies the accelerated method of expense recognition to all awards with only service-based vesting conditions.

For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed.

Ayala estimates the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of Ayala's Common Stock and assumptions Ayala makes for the volatility of its Common Stock, the expected term of its stock options, the risk-free interest rate for a period that approximates the expected term of its stock options and its expected dividend yield.

Previously, as a private company with no active public market for Ayala's Common Stock, Ayala's board of directors historically determined the fair value of Ayala's Common Stock on each date of grant, with input from management. Ayala's board of directors periodically determined the estimated per share fair value of Ayala's Common Stock at various dates using valuations performed by third parties. All options to purchase shares of Ayala's Common Stock were intended to be granted with an exercise price per share no less than the fair value per share of its Common Stock underlying those options on the date of grant, based on the information known to Ayala on the date of grant. Ayala's determinations of the fair value of its Common Stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Guide.

Ayala's board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of Ayala's Common Stock, including:

- the lack of an active public market for Ayala's Common Stock and convertible preferred stock;
- the prices at which Ayala sold shares of its convertible preferred stock in arm's-length transactions and the superior rights, preferences and privileges of the convertible preferred stock relative to its Common Stock, including the liquidation preferences of its preferred stock;
- Ayala's results of operations and financial condition, including cash on hand;
- the material risks related to Ayala's business;
- Ayala's stage of development and business strategy;
- the composition of, and changes to, Ayala's management team and board of directors;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed initial public offerings, or IPOs, of companies in the life sciences and biotechnology sectors; and
- the likelihood of achieving a liquidity event such as an IPO given prevailing market conditions.

Ayala's valuations were prepared in accordance with the guidelines in the Practice Guide, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its Common Stock. Through September 2019, Ayala utilized the option pricing method, or OPM, and a guideline transaction method, which Ayala believed was the most appropriate for each of the valuations of its Common Stock performed by its independent third-party valuation specialist. The OPM treats Ayala's security classes as call options on total equity value, and allocates Ayala's equity value across its security classes based on the rights and preferences of the securities within the capital structure under an assumed liquidation event. The OPM method is used when the range of possible future outcomes is difficult to predict and forecasts would be highly speculative. Ayala believed this method was the most appropriate given the expectation of various potential liquidity outcomes and the difficulty of selecting appropriate enterprise values given Ayala's early stage of development, while allowing Ayala to accurately capture the potential downside risk of its clinical-stage assets. Beginning in November 2019, for options granted after September 30, 2019, Ayala utilized a hybrid of the OPM and Probability-Weighted Expected Return Method, or PWERM. The PWERM is a scenario based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to Ayala, as well as the economic and control rights of each share class. Under this hybrid method, Ayala considered both the initial public offering liquidity scenario and an alternative scenario in the event an initial public offering does not occur. In October 2019, Ayala engaged a new third-party valuation firm to retrospectively estimate the value of its Common Stock as of certain prior dates. Stock-based compensation was awarded as a result of such retrospective valuations.

There are significant judgments and estimates inherent in the determination of the fair value of Ayala's Common Stock. These judgments and estimates are management's best estimates and include assumptions regarding Ayala's future operating performance, the time to completing an initial public offering or other liquidity event, the related company valuations associated with such events and the determinations of the appropriate valuation methods. If Ayala had made different assumptions, Ayala's stock-based compensation expense, net loss and net loss per common share could have been different.

Emerging Growth Company Status

The Jumpstart Our Business Start-ups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as Ayala to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. Ayala has elected to use this extended transition period under the JOBS Act. As a result, Ayala's financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of Ayala's financials to those of other public companies more difficult.

Ayala will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of Ayala's IPO, or December 31, 2025, (b) in which Ayala has total annual gross revenues of $1.235 billion or more, or (c) in which Ayala is deemed to be a large accelerated filer under the rules of the SEC, which means the market value of Ayala's outstanding Common Stock held by non-affiliates exceeds $700 million as of last business day of Ayala's most recently completed second fiscal quarter, and (2) the date on which Ayala has issued more than $1.0 billion in nonconvertible debt during the previous three years.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Ayala and Advaxis are each smaller reporting companies as defined by Rule 12b-2 of the Exchange Act, as amended, and are not required to provide the information under this item.

MANAGEMENT FOLLOWING THE MERGER

Executive Officers and Directors

Executive Officers and Directors of the Combined Company Following the Merger

Advaxis' President and Chief Executive Officer, Kenneth A. Berlin, will lead the combined company, with Andres Gutierrez, M.D., Ph.D. (of Advaxis) serving as Chief Medical Officer and Igor Gitelman (of Advaxis) serving as Interim Chief Financial Officer. The board of directors will consist of seven directors: four designated by Ayala and three by Advaxis, with David Sidransky to be nominated as Chairman of the board of directors.

The following table lists the names, ages and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon completion of the Merger:

Name	Age	Position
Executive Officers:		
Kenneth A. Berlin		President and Chief Executive Officer and Director
Igor Gitelman		Interim Chief Financial Officer
Andres Gutierrez, M.D., Ph.D.		Chief Medical Officer
Non-Employee Directors:		
David Sidransky, M.D.		Chairman of the Board of Directors Independent Director
Roni A. Appel		Independent Director
Vered Bisker-Leib, Ph.D.		Independent Director
Murray A. Goldberg		Independent Director
Robert Spiegel, M.D.		Independent Director
Samir N. Khleif, M.D.		Independent Director

Executive Officers

Kenneth Berlin. Mr. Berlin has served as Advaxis' President and Chief Executive Officer and a member of its Board of Directors since April 2018. Mr. Berlin previously served as Advaxis' Interim Chief Financial Officer from September 2020 to May 2022. Prior to joining Advaxis, Mr. Berlin served as President and Chief Executive Officer of Rosetta Genomics from November 2009 until April 2018. Prior to Rosetta Genomics, Mr. Berlin was Worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. At Veridex he grew the organization to over 100 employees, launched three cancer diagnostic products, led the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from an R&D entity to a commercial provider of oncology diagnostic products and services. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. From 2001 until 2004 he served as Vice President, Licensing and New Business Development in the pharmaceuticals group, and from 2004 until 2007 served as Worldwide Vice President, Franchise Development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California Los Angeles School of Law. Mr. Berlin's experience in life science companies, as well as his business experience in general qualify him to service as our director.

Igor Gitelman. Mr. Gitelman was elected by the Board of Directors of Advaxis, Inc. to serve on an interim basis as its Interim Chief Financial Officer, until his successor is chosen and qualified. In this role, Mr. Gitelman will be the combined company's Principal Financial Officer. Kenneth A. Berlin, who had formerly served as Advaxis' Interim Chief Financial Officer, will be the combined company's President and Chief Executive Officer. Mr. Gitelman has served as the Advaxis' VP of Finance since November 2020 and Chief Accounting Officer since February 2021. Before joining the Company, Mr. Gitelman served as CFO Executive Financial Consultant for Accu Reference Medical Labs, a clinical diagnostic laboratory. Before that, from February 2017 through November 2018, Mr. Gitelman served as a chief accounting officer of Cancer Genetics, Inc., a drug discovery, preclinical oncology, and immuno-oncology services company. Prior to that, Mr. Gitelman served as an Assistant to Vice President (AVP) of Finance and Tax at clinical diagnostic laboratory, BioReference Laboratories, Inc., from October 2005 to October 2016. During this time at BioReference Laboratories, Inc., Mr. Gitelman held various positions of increasing responsibility managing the company's internal audit function, SEC financial reporting, tax and corporate finance functions.

Andres Gutierrez. Dr. Gutierrez has served as Advaxis' Executive Vice President and Chief Medical Officer since April 2018. Prior to joining Advaxis, Dr. Gutierrez served as Chief Medical Officer for Oncolytics Biotech, Inc. from November 2016 to April 2018. Prior to Oncolytics, Dr. Gutierrez was Chief Medical Officer at SELLAS Life Sciences Group from November 2015 to September 2016 and was Medical Director, Early Development Immuno-Oncology at BMS from October 2012 to November 2015, where he oversaw the development of translational and clinical development of immuno-oncology programs in solid tumors and hematological malignancies. Earlier, Dr. Gutierrez was Medical Director for several biotechnology companies, including Sunesis Pharmaceuticals, BioMarin Pharmaceutical, Proteolix and Oculus Innovative Sciences, leading key programs with talazoparib and carfilzomib, among others. Prior to Oculus, he served as Director of the Gene & Cell Therapy Unit at the National Institutes of Health in Mexico City and as a consultant physician at the Hospital Angeles del Pedregal.

Non-Employee Directors

David Sidransky, M.D. Dr. Sidransky will become Chairman of the Board of Directors of the combined company upon completion of the Merger. Dr Sidransky currently serves as the Chairman of Advaxis and Ayala Boards of Directors and has served as a member of our Board of Directors since July 2013 and November 2017, respectively. He is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division and Professor of Oncology, Otolaryngology, Genetics, and Pathology at Johns Hopkins University School of Medicine. He has served as Chairman or Lead of the Board of Directors of Champions Oncology since October 2007 and was a director and Vice-Chairman of ImClone Systems until its merger with Eli Lilly Inc.. He is the Chairman of Tamir Biotechnology and Ayala and serves on the Board of Directors of Galmed and Orgenesis. He has served on scientific advisory boards of MedImmune, Roche, Amgen, and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. Dr. Sidransky served as Director (2005-2008) of the American Association for Cancer Research (AACR). He earned his B.S. from Brandeis University and his Medical Doctorate from Baylor College of Medicine. Dr. Sidransky's experience in life science companies, as well as his scientific knowledge, qualify him to service as our director and non-executive chairman.

Roni A. Appel, LL.B., M.B.A. Mr. Appel has served as a member of Advaxis Board since November 2004. He was Advaxis' President and Chief Executive Officer from January 1, 2006 until December 2006 and Secretary and Chief Financial Officer from November 2004 to September 2006. From December 15, 2006 to December 2007, Mr. Appel served as a consultant to us. Mr. Appel currently is a self-employed consultant and the Co-Founder and President of Spirify Pharma Inc. Previously, he served as Chief Executive Officer of Anima Biotech Inc., from 2008 through January 31, 2013. From 1999 to 2004, he was a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1996, he worked as an attorney. Mr. Appel holds an M.B.A from Columbia University (1998) and an LL.B. from Haifa University (1994). Mr. Appel's longstanding service with us and his entrepreneurial investment career in early stage biotech businesses qualify him to serve as our director.

Vered Bisker-Leib, Ph.D., M.B.A. Dr. Bisker-Leib will become a director of the combined company upon completion of the Merger. Dr. Bisker-Leib has served as a member of the Ayala Board since August 2020. Dr. Bisker-Leib is the President and Chief Operating Officer of Compass Therapeutics, Inc. where she has been a member of the executive leadership team since November 2017. Prior to Compass, Dr. Bisker-Leib advised Atlas Ventures portfolio companies as an entrepreneur-in-residence from November 2016 to November 2017. Previously, as the Chief Business Officer of Cydan Development, Inc. from October 2014 to October 2016, Dr. Bisker-Leib founded biotech companies focused on therapies addressing rare diseases, including Imara Inc. Dr. Bisker-Leib was a member of BMS' strategic transactions group where she assumed roles of increasing responsibility across five therapeutic areas, most recently as an Executive Director and Global Head of business development for the cardiovascular and metabolic franchises. Dr. Bisker-Leib received a Ph.D. in Chemical Engineering and an M.B.A. from the University of Massachusetts, Amherst. Dr. Bisker-Leib has a B.Sc. in Chemical Engineering from the Israel Institute of Technology, Haifa. We believe that Dr. Bisker-Leib's extensive experience in the life-science industry qualifies her to serve on our board of directors.

Murray A. Goldberg, M.B.A. Mr. Goldberg will become a director of the combined company upon completion of the Merger. Mr. Goldberg has served as a member of the Ayala Board since December 2017. Mr. Goldberg held various management positions at Regeneron Pharmaceuticals, Inc., a biopharmaceutical company, from March 1995 to March 2015, including as Senior Vice President of Administration and Assistant Secretary from October 2013 to March 2015, as Chief Financial Officer and Senior Vice President, Finance and Administration and Assistant Secretary from March 1995 to October 2013 and as Treasurer from March 1995 to October 2012. Mr. Goldberg previously served on the boards of directors of Aerie Pharmaceuticals Inc., a biopharmaceutical company, from August 2013 to June 2020, where he also served as the chairman of its audit committee, and Teva Pharmaceuticals Industries Ltd. from July 2017 to June 2020. Mr. Goldberg received a B.S. in Engineering from New York University, a Master's degree in International Economics from the London School of Economics and an M.B.A. from the University of Chicago. We believe that Mr. Goldberg is qualified to serve on our board of directors because of his broad financial, operational and transactional experience in the industry.

Robert Spiegel, M.D., F.A.C.P. Dr. Spiegel will become a director of the combined company upon completion of the Merger. Dr. Spiegel has served as a member of the Ayala Board since December 2017. Since 2012, Dr. Spiegel has served as an Associate Professor at the Weill Cornell Medical School. In addition, Dr. Spiegel has served as a Senior Advisor to Warburg Pincus, a private equity firm, and an Advisor to the Israel Biotech Fund, a venture investment fund since 2010 and 2016, respectively. Prior to these positions, Dr. Spiegel served as Chief Medical Officer of PTC Therapeutics, Inc., a biopharmaceutical company, from March 2011 to April 2016. Prior to his time at PTC Therapeutics, Dr. Spiegel held various management positions at Schering-Plough Corporation, a global healthcare company, including as Chief Medical Officer and Senior Vice President of the Schering-Plough Research Institute, the pharmaceutical research arm of the Schering-Plough Corporation from 1998 to 2009. Dr. Spiegel is currently a member of the board of directors of Geron Corporation and Cyclacel Pharmaceuticals, Inc., biopharmaceutical company, since 2010 and 2018, respectively. Dr. Spiegel has previously served as a member of the board of directors for Sucampo Pharmaceuticals, Inc., a biopharmaceutical company, Edge Therapeutics, Inc., a biotechnology company, Avior Computing Corporation, a privately-held governance risk and compliance process technology company, Talon Therapeutics, Inc., a biopharmaceutical company, Capstone Therapeutics Corp., a biotechnology company, the Cancer Institute of New Jersey and Cancer Care New Jersey. Dr. Spiegel received a B.A. in 1971 from Yale University and an M.D. from the University of Pennsylvania in 1975. Following his residency in internal medicine, Dr. Spiegel completed a fellowship in medical oncology at the National Cancer Institute. We believe that Dr. Spiegel's extensive medical and scientific knowledge as well as his experience in the life science industry qualifies him to serve on our board of directors.

Samir Khleif, M.D. Dr. Khleif has served as a member of Advaxis' Board of Directors since October 2014. He currently serves as the Director of the State of Georgia Cancer Center, Georgia Regents University Cancer Center and the Cancer Service Line. Dr. Khleif was formerly Chief of the Cancer Vaccine Section at the NCI, and also served as a Special Assistant to the Commissioner of the FDA leading the Critical Path Initiative for oncology. Dr. Khleif is a Georgia Research Alliance Distinguished Cancer Scientist and Clinician and holds a professorship in Medicine, Biochemistry and Molecular Biology, and Graduate Studies at Georgia Regents University. Dr. Khleif's research program at Georgia Regents University Cancer Center focuses on understanding the mechanisms of cancer-induced immune suppression, and utilizing this knowledge for the development of novel immune therapeutics and vaccines against cancer. His research group designed and performed some of the first cancer vaccine clinical trials targeting specific genetic changes in cancer cells. He led many national efforts and committees on the development of biomarkers and integration of biomarkers in clinical trials, including the AACR-NCI-FDA Cancer Biomarker Collaborative and the ASCO Alternative Clinical Trial Design. Dr. Khleif is the author of many book chapters and scientific articles on tumor immunology and biomarkers process development, and he is the editor for two textbooks on cancer therapeutics, tumor immunology, and cancer vaccines. Dr. Khleif was inducted into the American Society for Clinical Investigation, received the National Cancer Institute's Director Golden Star Award, the National Institutes of Health Award for Merit, the Commendation Medal of the US Public Health Service, and he was recently appointed to the Institute of Medicine National Cancer Policy Forum. Dr. Khleif's distinguished career as well as his extensive expertise in vaccines and immunotherapies qualify him to serve as our director.

Election of Officers

The combined company's executive officers will be appointed by, and serve at the discretion of, the combined company's board of directors. There are no family relationships among any of the combined company's proposed directors or executive officers.

Board of Directors of the Combined Company Following the Merger

Advaxis' board of directors currently consists of six directors, each elected at each annual meeting to serve until their successor is duly elected and qualified, subject to their earlier resignation or removal. Its By-Laws provide that the number of directors is to be no less than one and no more than nine and shall be fixed by action of the directors. It is anticipated that the incoming directors will be appointed to vacant director seats of the combined company board of directors as expanded by board resolution.

There are no family relationships among any of the proposed combined company directors and officers.

Director Independence

In order to have the common stock of the combined company listed on The Nasdaq Capital Market, the Advaxis intends to file an initial listing application with Nasdaq with Nasdaq prior to the closing of the Merger, and to undertake the actions necessary to allow the stock of the combined company to be listed on The Nasdaq Capital Market as of the closing of the Merger or promptly thereafter. Because Advaxis is not currently listed on Nasdaq, the combined company will be required to meet the initial listing standards of The Nasdaq Capital Market applicable to companies seeking to uplist one or more securities from another U.S. market. Accordingly, Advaxis must meet all the requirements set forth in Rule 5505(a) and at least one of the Standards in Rule 5505(b).

Nasdaq's listing standards require that the combined company's board of directors consist of a majority of independent directors, as determined under the applicable rules and regulations of Nasdaq. The boards of Ayala and Advaxis have determined that each of David Sidransky, M.D.; Roni A. Appel; Vered Bisker-Leib, Ph.D.; Murray A. Goldberg; Samir N. Khleif, M.D.; and Robert Spiegel, M.D. are expected to qualify as independent directors following the completion of the Merger.

Committees of the Board of Directors

Presently, Advaxis' board of directors has the following standing committees: Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and the Research and Development Committee. Each of the standing committees is composed solely of independent directors. Following the completion of the Merger the combined company will continue to have the following standing committees: Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and Research and Development Committee.

Audit Committee

Advaxis' audit committee oversees its corporate accounting and financial reporting process. Among other matters, the audit committee is responsible for recommending the engagement of auditors to the full board of directors; reviewing the results of the audit engagement with the independent registered public accounting firm; reviewing the quality and integrity of our financial statements in consultation with our independent accountants and suggesting an appropriate course of action for any irregularities; reviewing the adequacy, scope, and results of the internal accounting controls and procedures; reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm; and reviewing the auditors' fees.

The audit committee of the combined company is expected to retain these duties and responsibilities following the completion of the Merger.

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the audit committee. To qualify as independent to serve on the combined company's audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from the combined company, other than for service as a director, or be an affiliated person of the combined company. Advaxis and Ayala believe that, following the completion of the Merger, the composition of the audit committee will comply with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

Advaxis' compensation committee determines the salaries, bonuses, and incentive and equity compensation of our officers subject to applicable employment agreements, provides recommendations for the salaries and incentive compensation of our other employees and consultants, and reviews and oversees our compensation programs and policies generally. For executives other than the Chief Executive Officer, the compensation committee receives and considers performance evaluations and compensation recommendations submitted to the compensation committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the compensation committee, which determines any adjustments to his compensation as well as awards to be granted.

The compensation committee of the combined company is expected to retain these duties and responsibilities following completion of the Merger.

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the compensation committee. Each member of the combined company's compensation committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. Advaxis and Ayala believe that, following the completion of the Merger, the composition of the compensation committee will comply with the applicable requirements of the rules and regulations of Nasdaq.

Nominating and Corporate Governance Committee

The functions of Advaxis' nominating and corporate governance committee include identifying and recommending to the board of directors individuals qualified to serve as members of the board of directors and on the committees of the board of directors; advising the board of directors with respect to matters of board composition, procedures and committees; developing and recommending to the board of directors a set of corporate governance principles applicable to us and overseeing corporate governance matters generally including review of possible conflicts and transactions with persons affiliated with directors or members of management; and overseeing the annual evaluation of the board of directors and our management.

The nominating and corporate governance committee of the combined company is expected to retain these duties and responsibilities following completion of the Merger.

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the nominating and corporate governance committee. Advaxis and Ayala believe that, after the completion of the Merger, the composition of the nominating and corporate governance committee will meet the requirements for independence under, and the functioning of such nominating and corporate governance committee will comply with, any applicable requirements of the rules and regulations of Nasdaq.

Research and Development Committee

Advaxis' research and development committee was established in August 2013 with the purpose of providing advice and guidance to the board of directors on scientific and medical matters and development. The functions of the research and development committee include providing advice and guidance to the board of directors on scientific matters and providing advice and guidance to the board of directors on medical matters. The combined company will also have a research and development committee.

Compensation Committee Interlocks and Insider Participation

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the compensation committee. Each member of the compensation committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of the proposed combined company's executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who is proposed to serve on the combined company's board of directors or compensation committee following the completion of the Merger.

Non-Employee Director Compensation

Please refer to "Advaxis Director Compensation" above for a discussion of Advaxis' current policies with regard to the compensation of its non-employee directors. In connection with closing of the Merger, it is expected that the combined company will provide compensation to non-employee directors that is consistent with Advaxis' current practices; however, these director compensation policies may be re-evaluated by the combined company and the compensation committee following the completion of the Merger and may be subject to change. Non-employee directors are expected to receive an annual retainer fee and equity compensation in the form of a stock option grant.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS OF THE COMBINED COMPANY

In addition to the compensation arrangements, including employment, termination-of-employment and change-in-control arrangements, with Ayala's and Advaxis' directors and executive officers, including those discussed in the sections titled "Management Following the Merger," "Ayala Executive Compensation" and "Advaxis Executive Compensation," the following is a description of each transaction involving Advaxis since November 1, 2019, each transaction involving Ayala since January 1, 2019 and each currently proposed transaction in which:

- either Ayala or Advaxis has been or is a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of the average of Ayala's or Advaxis' total assets at year-end for the last two completed fiscal years, as applicable; and
- any of Advaxis' directors, executive officers or holders of more than 5% of Advaxis' capital stock, or any of the Ayala directors who will be directors of the combined company, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Related-Party Transactions for Both Parties

Dr. Sidransky's Interests in the Merger

Dr. David Sidransky, a member of the Advaxis Board and the Ayala Board, is a co-founder and owner of IBF I. IBF I is an owner of Common Stock of Ayala. IBF I owns an aggregate of 3,315,119 of Ayala's Common Stock, which represent, in the aggregate, ownership of approximately 22.37% of Ayala's outstanding shares. Additionally, Dr. Sidransky introduced the parties of the Merger.

Ayala Transactions

Investors' Rights Agreement

Ayala entered into an Investors' Rights Agreement in December 2017, which was amended in March 2018 and December 2018, with the holders of its preferred stock, including entities with which certain of Ayala's directors are related. The agreement provides for certain rights relating to the registration of such holders' Ayala Common Stock, including shares issuable upon conversion of preferred stock, and a right of first refusal to purchase future securities sold by us. See "*Comparison of Rights of Holders of Advaxis Capital Stock and Ayala Capital Stock—Registration Rights*" for additional information.

Stockholders Agreement

Ayala entered into an Amended and Restated Stockholders Agreement in December 2017, which was amended in December 2018, by and among Ayala and certain of its stockholders, pursuant to which the following directors were elected to serve as members on Ayala's board of directors and, as of the date of this proxy statement/prospectus, continue to so serve: Robert Spiegel, M.D., F.A.C.P., Murray A. Goldberg, David Sidransky, M.D., and Roni Mamluk, Ph.D. Dr. Mamluk was selected to serve on Ayala's board of directors in her capacity as Ayala's president and chief executive officer. Dr. Sidransky was initially selected to serve on Ayala's board of directors as representative of holders of Ayala's preferred stock, as designated by Israel Biotech Fund I, L.P. Mr. Goldberg and Dr. Spiegel were initially selected to serve on Ayala's board of directors as industry expert directors, as designated by Israel Biotech Fund I, L.P. The stockholders agreement terminated immediately prior to the consummation of Ayala's initial public offering.

Indemnification Agreements

Ayala has entered into indemnification agreements with each of its directors. These agreements, among other things, require Ayala to indemnify each director (and in certain cases their related venture capital funds) to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director.

Stock Option Grants to Directors

Ayala has granted stock options to certain of its directors as more fully described in the section entitled "*Ayala Director Compensation*."

Policies and Procedures for Related Person Transactions

Ayala's board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which Ayala was or will be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest *provided that*, if Ayala qualifies as a "smaller reporting company" pursuant to the rules of the Securities and Exchange Commission, the policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which Ayala was or will be a participant, where the amount involved exceeds the lesser of (1) $120,000 or (2) one percent of the average of Ayala's total assets at fiscal year-end for the last two completed fiscal years, and in which any related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by Ayala of a related person. In reviewing and approving any such transactions, Ayala's audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's-length transaction and the extent of the related person's interest in the transaction.

Advaxis Transactions

Advaxis' policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on Advaxis' experience in the business sectors in which Advaxis operate and the terms of its transactions with unaffiliated third parties, it believes that all transactions that Advaxis enters will meet this policy standard at the time they occur.

Voting and Support Agreements

In connection with the execution of the Merger Agreement, certain Ayala stockholders, who collectively beneficially own or control approximately 42.5% of Ayala's Common Stock as of October 31, 2022, entered into Voting Agreements with Advaxis under which such stockholders have agreed to, among other things, vote in favor of the Merger and the Merger Agreement and against any competing transaction. For a more complete description, see the section titled "*Agreements Related to the Merger—Voting and Support Agreements*" beginning on page 201 of this proxy statement/prospectus.

Indemnification Agreements

Advaxis has offered to enter into indemnification agreements with all directors and has entered into an indemnification agreement with all directors except Samir Khleif. Advaxis has also entered into an indemnification agreement with three of its executive officers, Igor Gitelman, Ken Berlin and Andres Gutierrez. The indemnification agreements and its amended and restated certificate of incorporation and amended and restated bylaws require Advaxis to indemnify its directors and executive officers to the fullest extent permitted by Delaware law.

ANTICIPATED ACCOUNTING TREATMENT

Under GAAP, the Merger will be accounted for as a "reverse acquisition" pursuant to which Ayala will be considered the acquiring entity for accounting purposes. Ayala's historical results of operations will replace Advaxis' historical results of operations for all periods prior to the Merger; after completion of the Merger, the results of operations of both companies will be included in the combined company's financial statements.

The combined company will account for the Merger using the business combination method of accounting under GAAP. Accounting Standards Codification ("ASC") 805 "Business Combinations" ("ASC 805") provides guidance for determining the accounting acquirer in a business combination when equity interests are exchanged between two entities. ASC 805 provides that in a business combination effected through an exchange of equity interests, such as the Merger, the entity that issues the equity interests is generally the acquiring entity. Commonly, the acquiring entity is the larger entity. However, the facts and circumstances surrounding a business combination sometimes indicate that a smaller entity acquires a larger one. ASC 805 further provides that in identifying the acquiring entity in a combination effected through an exchange of equity interests, all pertinent facts and circumstances must be considered, including the relative voting rights of the stockholders of the constituent companies in the combined company, the composition of the board of directors and senior management of the combined company and the terms of the exchange of equity securities in the business combination, including payment of any premium.

Based on the relative voting interests of Ayala and Advaxis in the combined company whereby the Ayala stockholders will have majority voting interest, the Combined Board will be composed of three current Ayala Board members, two current Advaxis Board members, one board member currently serving on both boards, and the chief executive officer of Advaxis, Ayala is considered to be the acquirer of Advaxis for accounting purposes. This means that the total purchase price will be allocated to Advaxis' tangible and identifiable intangible assets and liabilities based on their estimated relative fair market values at the date of the completion of the Merger. Final valuations of property, plant and equipment, and intangible and other assets have not yet been completed as management is still reviewing the existence, characteristics and useful lives of Advaxis' intangible assets. The completion of the valuation work could result in significantly different amortization expenses and balance sheet classifications. After completion of the Merger, the results of operations of both companies will be included in the financial statements of the combined company.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial information is presented to illustrate the effect of the merger of Advaxis and Ayala. The information under the "Unaudited Pro Forma Condensed Combined Balance Sheet" in the table below gives effect to the Merger as if it had taken place on July 31, 2022, the closing date of Advaxis' latest period presented. The information under "Unaudited Pro Forma Condensed Combined Statement of Operations" in the table below gives effect to the Merger as if it had taken place on November 1, 2020, the first day of Advaxis' 2021 fiscal year. This unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting where Ayala is considered the acquirer of Advaxis for accounting purposes.

Advaxis and Ayala have different fiscal years. Advaxis' fiscal year ends on October 31, whereas Ayala's fiscal year ends on December 31. The unaudited pro forma condensed combined balance sheet and statements of operations have been prepared utilizing period ends that differ by less than 93 days, as permitted by Rule 11-02 of Regulation S-X of the Exchange Act. All dollar amounts, except per share, are in thousands.

The unaudited pro forma condensed combined financial information is presented to illustrate the estimated effects of the pending merger between Advaxis and Ayala based on the historical financial position and results of operations of Advaxis and Ayala. It is presented as follows:

- The unaudited pro forma condensed combined balance sheet as of September 30, 2022 was prepared based on (i) the historical unaudited condensed consolidated balance sheet of Advaxis as of July 31, 2022 and (ii) the historical unaudited condensed consolidated balance sheet of Ayala as of September 30, 2022.

- The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2021 was prepared based on (i) the historical audited consolidated statement of operations of Advaxis for the year ended October 31, 2021 and (ii) the historical audited consolidated statement of operations of Ayala for the year ended December 31, 2021.

- The unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2022 was prepared based on (i) the historical unaudited condensed consolidated statement of operations of Advaxis for the nine months ended July 31, 2022 and (ii) the historical unaudited condensed consolidated statement of operations of Ayala for the nine months ended September 30, 2022.

The unaudited pro forma condensed combined financial information set forth below primarily gives effect to the following:

- the consummation of the merger;
- the application of the acquisition method of accounting in connection with the reverse merger in accordance with U.S. GAAP;
- the cashless exercise of Ayala's pre-funded warrants;
- transaction costs incurred in connection with the merger.

Assumptions underlying the pro forma adjustments are described in the accompanying notes, which should be read in conjunction with the unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information has been presented for informational purposes only and is not necessarily indicative of what the combined company's financial position or results of operations actually would have been had the Merger been completed as of the dates indicated. In addition, the unaudited pro forma condensed combined financial information does not purport to project the future financial position or operating results of the combined company. The historical consolidated financial information has been adjusted in the accompanying unaudited pro forma condensed combined financial information to give effect to the Merger. The accompanying unaudited pro forma condensed combined statements of operations do not include any pro forma adjustments to reflect certain expected financial benefits of the merger, such as tax savings, cost synergies or revenue synergies, or the anticipated costs to achieve those benefits, including the cost of integration activities, or restructuring actions which may be achievable. Future results may vary significantly from the results reflected due to various factors, including those discussed in the section entitled "Risk Factors" beginning on page 25. The information presented below should be read in conjunction with the historical consolidated financial statements of Advaxis and Ayala, including the related notes, included in the proxy statement/prospectus filed with the SEC.

The unaudited pro forma condensed combined financial information has been prepared using the acquisition method of accounting under existing GAAP, which is subject to change. Ayala is deemed the accounting acquirer in the Merger for accounting purposes and Advaxis is treated as the accounting acquiree, based on a number of factors considered at the time of preparation of this Registration Statement, including control over the post-merger company as evidenced by the composition of the board of directors as well as the relative equity ownership after the closing of the Merger. The application of acquisition accounting to Advaxis is dependent upon the working capital positions at the closing of the Merger and on other factors such as the share price of Advaxis as well as certain valuations that have yet to progress to a stage where there is sufficient information for a definitive measurement. The combined company will complete the valuations upon completion of the Merger and will finalize the purchase price allocation as soon as practicable within the measurement period, but in no event later than one year following the closing date of the Merger. The assets and liabilities of Advaxis and other pro forma adjustments have been measured based on various preliminary estimates using assumptions that Advaxis and Ayala believe are reasonable, based on information that is currently available. Accordingly, the pro forma adjustments are preliminary. Differences between these preliminary estimates and the final acquisition accounting could be significant, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operation and financial position.

The unaudited pro forma condensed combined financial information has been compiled in a manner consistent with the accounting policies adopted by Ayala. Upon completion of the Merger, the combined company will perform a detailed review of Advaxis' accounting policies and will conform the combined company policies. The combined company may identify differences between the accounting policies of the two companies that, when conformed, could have a material impact on the consolidated financial statements of the combined company. Transactions between Ayala and Advaxis during the periods presented in the unaudited pro forma condensed combined financial information were not significant.

This unaudited pro forma condensed combined financial information was derived from and should be read in conjunction with the accompanying notes, as well as the following historical financial statements and the related notes of Advaxis and Ayala:

- Separate historical audited consolidated financial statements of Ayala as of and for the year ended December 31, 2021 and unaudited condensed consolidated financial statements of Ayala as of September 30, 2022 and for the nine months ended September 30, 2022 and the related notes included in this proxy statement/prospectus; and

- Separate historical audited consolidated financial statements of Advaxis as of and for the year ended October 31, 2021 and unaudited condensed consolidated financial statements of Advaxis as of and for the nine months ended July 31, 2022 and the related notes included elsewhere in this proxy statement/prospectus.

Unaudited Pro Forma Condensed Combined Balance Sheet
As of September 30, 2022
(in thousands, except for per share amounts)

	Ayala Pharmaceuticals, Inc. September 30, 2022	Advaxis, Inc. July 31, 2022	Transaction Accounting Adjustments		Pro Forma Combined
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 11,195	$ 28,150	$ -		$ 39,345
Short-term restricted bank deposits	110	-	-		110
Trade receivables	129	-	-		129
Prepaid expenses and other current assets	1,598	1,667	-		3,265
Total Current Assets	13,032	29,817			42,849
Property and equipment (net of accumulated depreciation)	999	73	-		1,072
Intangible assets (net of accumulated amortization)	-	181	(71)	**5A**	110
Operating right-of-use asset	-	19	-		19
Other assets	229	11	-		240
TOTAL ASSETS	$ 14,260	$ 30,101	$ (71)		$ 44,290
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities:					
Trade payables	$ 2,326	$ 90	$ -		$ 2,416
Other accounts payables	3,379	-	-		3,379
Accrued expenses	-	1,510	9,743	**5B**	12,276
			1,023	**5C**	
Current portion of operating lease liability	-	19	-		19
Common stock warrant liability	-	287	(52)	**5F**	235
Total Current Liabilities	5,705	1,906	10,714		18,325
Long term rent liability	396	-	-		396
Total Liabilities	6,101	1,906	10,714		18,721
Commitments and Contingencies					
Shareholders' Equity:					
Preferred stock	-	-	-		-
Common stock	139	2	(136)	**5D**	5
Additional paid-in capital	147,586	466,561	(459,675)	**5D**	155,821
			1,349	**5G**	
Accumulated deficit	(139,566)	(438,368)	438,368	**5D**	(130,257)
			(9,743)	**5B**	
			(1,023)	**5C**	
			21,424	**5E**	
			(1,349)	**5G**	
Total stockholders' equity	8,159	28,195	(10,785)		25,569
Total liabilities and stockholders' equity	$ 14,260	$ 30,101	$ (71)		$ 44,290

Unaudited Pro Forma Condensed Combined Statement of Operations
Year ended December 31, 2021
(in thousands)

	Ayala Pharmaceuticals, Inc. For the year ended December 31, 2021	Advaxis, Inc. For the year ended October 31, 2021	Transaction Accounting Adjustments		Pro Forma Combined
Revenue	$ 3,506	$ 3,240	$ -		$ 6,746
Cost of revenue	(3,506)	-	-		(3,506)
Gross profit	-	3,240	-		3,240
Operating expenses					
Research and development expenses	29,941	10,562	-		40,503
General and administrative expenses	9,277	11,464	(339)	6A	32,517
			9,743	6C	
			1,023	6D	
			1,349	6E	
Total Operating Expenses	39,218	22,026	11,776		73,020
Loss from operations	(39,218)	(18,786)	(11,776)		(69,780)
Other income (expense):	-	-	-		
Interest income (expense)	(260)	5	-		(255)
Net changes in fair value of derivative liabilities	-	970	-		970
Loss on shares issued in settlement of warrants	-	-	-		-
Other expense	-	(1)	-		(1)
Net Loss Before Benefit for Income Taxes	(39,478)	(17,812)	(11,776)		(69,066)
Income Tax Expense	776	50	-		826
Net loss	$ (40,254)	$ (17,862)	$ (11,776)		$ (69,892)
Net income (loss) per share Basic & Diluted	$ (2.80)	$ (9.84)	$ -		$ (15.48)
Weighted average number of common shares outstanding Basic & Diluted	14,398,905	1,815,951			4,514,306

Unaudited Pro Forma Condensed Combined Statement of Operations
For the nine months ended September 30, 2022
(in thousands)

	Ayala Pharmaceuticals, Inc. For the nine months ended: September 30, 2022	Advaxis, Inc. For the nine months ended: July 31, 2022	Transaction Accounting Adjustments		Pro Forma Combined
Revenue	$ 587	$ 250	$ -		$ 837
Cost of revenue	(497)	-			(497)
Gross profit	90	250	-		340
Operating expenses					
Research and development expenses	20,279	5,371	-		25,650
General and administrative expenses	7,586	6,331	(348)	**6A**	13,569
Intangible asset impairment	-	3,005	(3,005)	**6B**	-
Total Operating Expenses	27,865	14,707	(3,353)		39,219
Loss from operations	(27,775)	(14,457)	3,353		(38,879)
Other income (expense):					
Interest income (expense)	(141)	57	-		(84)
Net changes in fair value of derivative liabilities	-	4,685	-		4,685
Other expense	-	(3)	-		(3)
Net Loss Before Benefit for Income Taxes	(27,916)	(9,718)	3,353		(34,281)
Income Tax Expense	509	50	-		559
Net loss	$ (28,425)	$ (9,768)	$ 3,353		$ (34,840)
Accretion of discount and redemption feature of convertible preferred stock	-	(1,025)	-		(1,025)
Income available to common stockholders	$ (28,425)	$ (10,793)	$ 3,353		$ (35,865)
Net income (loss) per share Basic & Diluted	$ (1.85)	$ (5.93)	$ -		$ (7.64)
Weighted average number of common shares outstanding Basic & Diluted	15,365,342	1,819,545			4,695,416

Notes to the Unaudited Pro Forma Financial Statements:
(dollars in thousands, except per share amounts)

1. Description of the Merger

On October 18, 2022, Advaxis, Inc., a Delaware corporation ("Advaxis"), Doe Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Ayala Pharmaceuticals, Inc., a Delaware corporation ("Ayala") entered into an Agreement and Plan of Merger (the "Merger Agreement").

The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) Merger Sub will merge with and into Ayala, with Ayala being the surviving entity as a wholly-owned subsidiary of Advaxis (the "Merger" and, collectively with the other transactions contemplated by the Merger Agreement, the "Transactions"), (ii) each share of the common stock, par value $0.01 per share, of Ayala (the "Ayala Common Stock") issued and outstanding immediately prior to the Merger shall be automatically converted into the right to receive 0.1874 shares (as such amount may be adjusted as provided in the Merger Agreement, the "Exchange Ratio") of the common stock, par value $0.001 per share, of the Advaxis (the "Common Stock"), (iii) each outstanding option to purchase shares of the Ayala Common Stock (each, an "Ayala Option") will be substituted and converted automatically into an option (each, a "Advaxis Replacement Option") to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the effective time of the Merger, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala's Common Stock subject to the corresponding Ayala Option immediately prior to the effective time of the Merger, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iv) each restricted stock unit of Ayala (each, an "Ayala RSU") outstanding immediately prior to the effective time of the Merger, whether or not vested or issuable, will be substituted and converted automatically into a restricted stock unit award of Advaxis with respect to a number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the effective time of the Merger by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

2. Basis of Presentation

The preceding unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses." Release No. 33-10786 replaces the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction ("Transaction Accounting Adjustments") and the option to present the reasonably estimable synergies and other transaction effects that have occurred or are reasonably expected to occur ("Management's Adjustments"). Only Transaction Accounting Adjustments are presented in the following unaudited pro forma condensed combined financial information.

The merger is treated as a business combination for accounting purposes, with Ayala as the deemed accounting acquirer and Advaxis as the deemed accounting acquiree. Therefore, the historical basis of Ayala's assets and liabilities will not be remeasured as a result of the merger. In identifying Ayala as the acquiring entity, the companies considered the structure of the merger, relative outstanding share ownership at closing and the composition of the combined company's board of directors and senior management.

The unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting in accordance with ASC 805, which requires, among other things, that assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. The acquisition method of accounting uses the fair value concepts defined in ASC Topic 820, "Fair Value Measurement" ("ASC 820"). Fair value is defined in ASC 820 as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Market participants are assumed to be buyers or sellers in the most advantageous market for the asset or liability. Fair value measurement for an asset assumes the highest and best use by these market participants.

Fair value measurements can be highly subjective, and it is possible the application of reasonable judgment could develop different assumptions resulting in a range of alternative estimates using the same facts and circumstances.

Fair value estimates were determined based on preliminary discussions between Ayala and Advaxis management, and a preliminary valuation of Advaxis' assets and liabilities using July 31, 2022, as the measurement date. The allocation of the aggregate merger consideration used in the preliminary unaudited pro forma condensed combined financial information is based on preliminary estimates. The estimates and assumptions are subject to change as of the effective time of the merger. The final determination of the allocation of the aggregate merger consideration will be based on the actual tangible and intangible assets and the liabilities of Advaxis at the effective time of the merger. Refer to Note 4 for additional information.

For pro forma purposes, the valuation of consideration transferred is based on, among other things, the number of shares of Advaxis Common Stock outstanding and the price per share and number of shares of Ayala Common Stock as of the close of business on November 7, 2022. Refer to Note 4 for additional information. This is used for pro forma purposes only. The consideration transferred will ultimately be based on the number of shares of Advaxis Common Stock outstanding and the number shares of Ayala's Common Stock as of immediately prior to the effective time of the Merger, which could materially change from the assumptions included in this pro forma financial information. Additionally, for the purposes of this pro forma financial information, the consideration transferred ascribes value to outstanding Advaxis warrants and Advaxis options based on the fair value of the instruments.

The unaudited pro forma combined balance sheet data gives effect to the Merger as if it had occurred on July 31, 2022. The unaudited pro forma combined statement of operations data gives effect to the Merger as if it had occurred on November 1, 2020.

The unaudited pro forma condensed combined financial information is presented solely for informational purposes and is not necessarily indicative of the combined results of operations or financial position that might have been achieved for the period or date indicated, nor is it necessarily indicative of the future results of the combined company. The unaudited pro forma condensed combined financial information has not been adjusted to give effect to certain expected financial benefits of the Merger, such as cost synergies or the anticipated costs to achieve these benefits, including the cost of integration activities.

Effective June 6, 2022, Advaxis underwent a 1 for 80 reverse stock split.

3. Accounting Policies

The unaudited pro forma condensed combined financial information has been compiled in a manner consistent with the accounting policies of Ayala. Following the Merger, the combined company will conduct a review of accounting policies of Advaxis in an effort to determine if differences in accounting policies require further reclassification of results of operations or reclassification of assets or liabilities to conform to Ayala's accounting policies and classifications. As a result of that review, the combined company may identify differences among the accounting policies of the companies that, when conformed, could have a material impact on the unaudited pro forma condensed combined financial information.

4. Reverse acquisition and purchase price allocation

Fair Value of Total Consideration Transferred

The fair value of preliminary purchase consideration expected to be transferred on the closing date includes the value of the number of shares of the combined company to be owned by Advaxis stockholders at closing of the Merger and the fair value of common share stock options and warrants outstanding of the combined company ("Share-based Instruments") to be owned by the Advaxis stockholders at such date using a Black-Scholes model. The fair value per share of Advaxis' Common Stock used for the preliminary purchase price allocation was $3.63 per share using the closing price of Ayala's Common Stock on November 7, 2022, divided by the Exchange Ratio. The closing price of Ayala's common stock was determined to be the most accurate measurement of the purchase consideration as the stock is traded on the Nasdaq stock exchange. The estimated value of the purchase consideration reflected in this pro forma condensed combined financial information does not purport to represent the actual value of the purchase consideration that will be deemed to be received by Advaxis shareholders when the Merger is consummated. The final fair value of equity securities issued as part of the purchase consideration will be measured on the Closing Date at the then-current market price of Ayala's common stock. This requirement will likely result in a per share equity component different from the $3.63 assumed in this pro forma condensed combined financial information and that difference may be material.

Purchase consideration	**Amounts**
Number of Advaxis common shares issued and outstanding as of November 7, 2022	1,815,951
Exchange Ratio - Ayala shares to Advaxis shares	0.1874
Equivalent Ayala shares	9,690,240
Ayala price per share as of November 7, 2022	$ 0.6800
Fair value of Advaxis Common Stock	$ 6,589
Fair value of share-based instruments	163
Fair value of total purchase consideration	$ 6,752

Purchase Price Allocation

The following is a preliminary estimate of the allocation of the purchase price to acquired identifiable assets and assumed liabilities of Advaxis, which includes preliminary purchase accounting adjustments to reflect the fair value of intangible assets acquired:

	Amounts
Cash and cash equivalents	$ 28,150
Prepaid expenses and other current assets	1,667
Property and equipment, net	73
Intangible assets	110
Operating right-of-use asset	19
Other assets	11
Total assets	30,030
Common stock warrant liability	(235)
Other current liabilities	(1,619)
Total liabilities	(1,854)
Estimated enterprise value of Advaxis	$ 28,176
Value of consideration exchanged	$ 6,752
Gain from acquisition on Advaxis	$ 21,424

The fair value estimate for all identifiable intangible assets is preliminary and is based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the asset (i.e., its highest and best use). This preliminary fair value estimate could include assets that are not intended to be used, may be sold, or are intended to be used in a manner other than their best use. The final determination of fair value of intangible assets, as well as estimated useful lives, remains subject to change.

	Advaxis Historical Carrying Value	July 31, 2022 Estimated Fair Value	Incremental Amortization, Abandonment and Impairment of Intangible Expense for the Nine Months Ended July 31, 2022	Incremental Amortization, Abandonment and Impairment of Intangible Expense for the Year Ended October 31, 2021
Patents	$ 181	$ -	$ (3,374)	$ (367)
License agreements	-	110	21	28
Total	$ 181	$ 110	$ (3,353)	$ (339)

The finalization may have a material impact on the valuation of intangible assets and the purchase price allocation, which is expected to be finalized subsequent to the Merger. A 10% change in the valuation of intangible assets would cause a corresponding increase or decrease to the gain from acquisition of Advaxis by approximately $11 at the merger date but would not significantly affect amortization expense as amortization of license agreements will be recorded based on revenue from the underlying contracts.

5. Unaudited Pro Forma Combined Balance Sheet Adjustments

The following provides explanations of the various adjustments to the unaudited pro forma combined balance sheet:

A. Represents an adjustment to decrease historical Advaxis intangible assets by $71 as of July 31, 2022 as determined by the net acquired identifiable assets and assumed liabilities. Refer to Note 4 for a discussion of this reverse merger and purchase price allocation.
B. Represents $9,911 of transaction costs expected to be incurred in connection with the Merger, of which approximately $168 was incurred or accrued for on the pro forma balance sheet as of September 30, 2022. The remaining transaction costs of $9,743 were not yet accrued or incurred and reflected in the pro forma balance sheet as of September 30, 2022 and are recorded as an increase in accrued expenses and an increase to accumulated deficit. See also note 6C.

C. Represents severance to be paid to three executives of Ayala of $1,023 as a result of the Merger recorded as an increase in accrued expenses and an increase to accumulated deficit.

D. Represents the elimination of Advaxis common stock, paid-in capital and accumulated deficits as well as the adjustments to reflect the capital structure of the combined company and the cashless exercise of warrants to purchase 1,333,333 shares of common stock of Ayala for $0.01 per share (246,192 net shares of Advaxis Common Stock). See the following explanation of the adjustments:

i. Adjustments to common stock: a decrease in common stock of $136 represents the adjustment to the aggregate historical par value of Ayala and Advaxis of $136, to reflect 4,839,547 shares outstanding at a total par value of $5 ($0.001 par value per share) calculated as follows:

	Amounts
Shares of Advaxis common stock outstanding on July 31, 2022	1,815,951
Advaxis common stock to be issued to Ayala shareholders as of closing of Merger	2,777,404
Advaxis common stock to be issued to Ayala prefunded warrant holders as of closing of Merger	246,192
Total shares of Advaxis common stock outstanding as of merger close	4,839,547
Par value per common share	$ 0.001
Common stock total par value at merger	5
Common stock total par value of Advaxis prior to closing of Merger	(2)
Common stock total par value of Ayala prior to closing of Merger	(139)
Total pro forma merger adjustments	$ (136)

ii. Adjustments to paid-in capital are as follows:

	Amounts
Fair value of consideration paid for Advaxis	$ 6,752
Elimination of Advaxis historical additional paid-in capital	(466,561)
Par value of Advaxis common stock on July 31, 2022	(2)
Par value adjustment of common stock	136
Total pro forma merger adjustments	$ (459,675)

iii. Adjustments to accumulated deficit are as follows:

	Amounts
Pro forma merger adjustments:	
Elimination of historical Advaxis accumulated deficit	$ 438,368
Total pro forma merger adjustments	$ 438,368

E. Represents an adjustment to reduce accumulated deficit by $21,424 for the estimated gain Ayala will recognize with the merger. See Note 4.

F. Represents a reduction in the common stock warrant liability of $52 of Advaxis to update the fair value of the warrant liability as determined by the net acquired identifiable assets and assumed liabilities. See Note 4.
G. Represents stock-based compensation to be recognized for the acceleration of vesting of options of three executives of Ayala of $1,349 as an increase to additional paid in capital and accumulated deficit.

6. Unaudited Pro Forma Statement of Operations Adjustments

The following provides explanations of the various adjustments to the unaudited pro forma combined statement of operations:

A. Represents a decrease to amortization expense of $339 and $348 for the year ended October 31, 2021 and the nine months ended July 31, 2022, respectively, related to the fair value adjustments to intangible assets discussed above in Note 4.
B. Represents a decrease in intangible asset impairment expense of $3,005 for the nine months ended July 31, 2022, respectively, related to the fair value adjustments to intangible assets discussed above in Note 4. If the intangible assets had been revalued as of the beginning of the period presented, no impairment expense would have been required.
C. Represents $9,743 of additional transaction costs for the year ended October 31, 2021 expected to be incurred by the combined companies in conjunction with this reverse merger for transaction related fees and expenses. Total transaction costs of $9,911 are expected, of which, $168 was expensed during the nine months ended September 30, 2022.
D. Represents severance to be paid to three executives of Ayala of $1,023 to be expensed as a result of the merger.
E. Represents stock-based compensation to be recognized for the acceleration of vesting of options of three executives of Ayala of $1,349.

7. Loss per Share

The unaudited pro forma weighted average number of basic and diluted shares outstanding is calculated as follows:

	For the nine months ended September 30, 2022	For the year ended December 31, 2021
Weighted average Ayala shares outstanding - basic	15,365,342	14,398,905
Merger exchange ratio	0.1874	0.1874
	2,879,465	2,698,355
Adjusted for:		
Advaxis shares outstanding as if the merger occurred on November 1, 2020	1,815,951	1,815,951
Advaxis shares to be issued to Ayala warrant holders as if the Merger occurred on November 1, 2020	246,192	246,192
Pro forma adjusted weighted average shares outstanding – basic and dilutive	4,695,416	4,514,306
Pro forma net loss attributable to common shareholders – basic and dilutive	$ (35,865)	$ (69,892)
Pro forma net loss per common share – basic and dilutive	$ (7.64)	$ (15.48)

MARKET PRICE AND DIVIDEND INFORMATION

Advaxis Common Stock

Advaxis' Common Stock is quoted on the OTCQX under the symbol "ADXS".

The closing price of shares of Advaxis Common Stock on October 18, 2022, the trading day immediately prior to the public announcement of the Merger on October 19, 2022, as reported on the OTCQX, was $2.18 per share. Any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

As of November 16, 2022 there were approximately 95 holders of record of Advaxis' Common Stock. The actual number of holders of Advaxis' Common Stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Advaxis Dividends

Advaxis has not declared or paid any cash dividends on Advaxis Common Stock and does not anticipate declaring or paying cash dividends for the foreseeable future.

Ayala Common Stock

Ayala's Common Stock is listed on The Nasdaq Global Market under the symbol "AYLA."

The closing price of shares of Ayala Common Stock on October 18, 2022, the trading day immediately prior to the public announcement of the Merger on October 19, 2022, as reported on The Nasdaq Global Market, was $0.91 per share.

As of November 15, 2022, there were 18 holders of record of Ayala's Common Stock. The actual number of stockholders of Ayala's Common Stock is greater than the number of record holders and includes stockholders whose Ayala Common Stock are held in street name by brokers and other nominees.

Ayala Dividends

Ayala has never declared or paid any cash dividends on its capital stock. Ayala currently intends to retain all available funds and future earnings, if any, for the operation and expansion of its business and does not anticipate declaring or paying any dividends in the foreseeable future.

The payment of dividends, if any, will be at the discretion of the combined company's board of directors and will depend on its results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in its future debt agreements, and other factors that the board of directors of the combined company may deem relevant.

DESCRIPTION OF ADVAXIS CAPITAL STOCK

The following description of Advaxis capital stock and provisions of Advaxis' amended and restated certificate of incorporation, exclusive of the potential amendments described herein in Proposals No. 2 and 3, and second amended and restated bylaws are summaries and are qualified by reference to such restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware corporate law. Advaxis has filed copies of these documents with the SEC as exhibits to its periodic filings.

General

Under Advaxis' amended and restated certificate of incorporation, Advaxis is authorized to issue 170 million shares of common stock, par value $0.001 per share (for purposes of this description, the "Common Stock"), and 5 million shares of "blank check" preferred stock, par value $0.001 per share.

Common Stock

Dividends

Holders of Advaxis Common Stock are entitled to receive ratably any dividends declared by its Board of Directors (the "Board") out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding Preferred Stock ("Preferred Stock"). All outstanding shares are fully-paid and non-assessable.

Conversion Rights

The shares of Common Stock are not convertible into other securities.

Sinking Fund Provisions

Advaxis' Common Stock has no sinking fund provisions.

Redemption Provisions

Advaxis' Common Stock has no right to redemption.

Voting Rights

The holders of Advaxis Common Stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Holders of Advaxis Common Stock do not have a cumulative voting right, which means that the holders of more than one-half of the outstanding shares of Common Stock, subject to the rights of the holders of the Preferred Stock, if any, can elect all of Advaxis' directors, if they choose to do so. In this event, the holders of the remaining shares of Common Stock would not be able to elect any directors. Advaxis' Board is not classified.

Except as otherwise required by Delaware law, and subject to the rights of the holders of Preferred Stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of Common Stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-third of the outstanding shares of Common Stock is present in person or proxy.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of Advaxis' affairs, holders of Common Stock would be entitled to share ratably in its assets that are legally available for distribution to stockholders after payment of liabilities and applicable distribution to the holders of its Preferred Stock (if any outstanding).

Preemption Rights

Advaxis' Common Stock has no right to preemption.

Series E Preferred Stock, par value $0.001 per share

The Board is authorized to issue up to 5,000,000 shares of Preferred Stock in one or more series, and to determine the number of shares of any series of Preferred Stock, the voting power of shares of each such series and the designations, preferences and relative, participating, optional or other special rights, qualifications, limitations or restrictions thereof. In the event that any series of Preferred Stock has been issued, a certificate of designation containing the rights, privileges, and limitations of such series of capital stock shall have been filed with the Secretary of the State of Delaware.

On December 1, 2022, Advaxis filed a certificate of designation (the "Certificate of Designation") with the Secretary of State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the shares of Advaxis' Series E Preferred Stock (the "Series E Preferred Stock"). The Certificate of Designation provides that ten (10) shares of Series E Preferred Stock will have 200,000,000 votes each and will vote together with the outstanding shares of the Advaxis Common Stock as a single class exclusively with respect to any proposal to amend the Advaxis Charter to change the name of Advaxis and to effect a reverse stock split of the Advaxis Common Stock. Also on December 1, 2022, the Company issued all ten (10) authorized shares of Series E Preferred Stock. The holder of these shares has agreed to vote all of such shares on any proposal to amend the Advaxis Charter to change the name of Advaxis and to effect a reverse stock split of the Advaxis Common Stock in the same proportion as shares of Advaxis Common Stock are voted on such proposal. The Series E Preferred Stock otherwise has no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series E Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of Advaxis. The Series E Preferred Stock has no rights with respect to any distribution of assets of Advaxis, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of Advaxis, whether voluntarily or involuntarily. The holder of the Series E Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding shares of Series E Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by the Advaxis Board in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Advaxis Charter implementing a reverse stock split. Upon such redemption, the holder of the Series E Preferred Stock will receive consideration of $1,000 per share in cash.

Anti-Takeover Provisions

Delaware Law

We are subject to Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a Delaware corporation from engaging in any "business combination" with any "interested stockholder" for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) those shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.
- Section 203 defines a "business combination" to include:
- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of Advaxis' company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

Certificate of Incorporation and Bylaws Provisions

Advaxis' amended and restated certificate of incorporation and second amended and restated bylaws contain provisions that could have the effect of discouraging potential Acquisition Proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the amended and restated certificate of incorporation and second amended and restated bylaws, as applicable, among other things:

- provide Advaxis' board of directors with the ability to alter its bylaws without stockholder approval; and
- provide that vacancies on Advaxis' board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third party from acquiring us, even if doing so would be beneficial to Advaxis' stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of Advaxis' board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of Advaxis. These provisions are designed to reduce Advaxis' vulnerability to an unsolicited Acquisition Proposal and to discourage some tactics that may be used in proxy fights. Advaxis believes that the benefits of increased protection of its potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure Advaxis outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for Advaxis' shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in Advaxis' management.

Trading of Advaxis Common Stock

Advaxis' Common Stock is quoted on the OTCQX under the symbol "ADXS".

Transfer Agent and Registrar

The transfer agent and registrar for Advaxis' Common Stock is Continental Stock Transfer and Trust Company, 17 Battery Place, 8th Floor, New York, NY 10004.

COMPARISON OF RIGHTS OF HOLDERS OF ADVAXIS CAPITAL STOCK AND AYALA CAPITAL STOCK

If the Merger is completed, Ayala stockholders will receive shares of Advaxis Common Stock, pursuant to the terms of the Merger Agreement. The following is a summary of certain differences between (i) the current rights of Ayala stockholders under its current articles of association, (ii) the rights of Advaxis stockholders under its amended and restated certificate of incorporation, and its second amended and restated bylaws, and (iii) the DGCL. The summary set forth below is not intended to provide a comprehensive discussion of each company's governing documents or relevant corporate law. This summary is qualified in its entirety by reference to the full text of each company's governing documents and the DGCL. See "*Where You Can Find More Information*" beginning on page 343 of this proxy statement/prospectus for information on how to obtain a copy of these documents.

General

Advaxis is incorporated under the laws of the State of Delaware and Ayala is incorporated under the laws of the State of Delaware. Accordingly, the rights of Advaxis stockholders and Ayala stockholders are governed by the DGCL. As a result of the Merger, Ayala stockholders who receive shares of Advaxis Common Stock will become Advaxis stockholders, and their rights as stockholders will be governed by the DGCL and the Advaxis organizational documents.

Following is a comparison of the rights of Advaxis stockholders and Ayala Stockholders:

Advaxis	Ayala
Organizational Documents The rights of Advaxis stockholders are governed by Advaxis' amended and restated certificate of incorporation, Advaxis' second amended and restated bylaws and the DGCL.	The rights of Ayala stockholders are governed by Ayala's restated certificate of incorporation, Ayala's amended and restated bylaws and the DGCL.
Authorized Capital Stock Advaxis is authorized to issue two classes of capital stock, which are designated, respectively, "common stock" and "preferred stock." The total number of shares that Advaxis is authorized to issue is 175,000,000, of which 170,000,000 shares are common stock, par value $0.001 per share, and 5,000,000 shares are preferred stock, par value $0.001 per share. The number of authorized shares of Advaxis preferred stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the DGCL. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of Common Stock entitled to vote, subject to the provisions of Section 242(b)(2) of the DGCL.	Ayala is authorized to issue two classes of capital stock, which are designated, respectively, "common stock" and "preferred stock." The total number of shares that Ayala is authorized to issue is 210,000,000, of which 200,000,000 shares are common stock, par value $0.01 per share, and 10,000,000 shares are preferred stock, par value $0.01 per share. The number of authorized shares of Ayala preferred stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the corporation entitled to vote thereon, irrespective of the provisions of Section 242(b)(2) of the DGCL. The number of authorized shares of Ayala Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the corporation entitled to vote thereon, irrespective of the provisions of Section 242(b)(2) of the DGCL.

Common Stock	
Advaxis' authorized Common Stock consists of 170,000,000 shares of Common Stock.	Ayala's authorized Common Stock consists of 200,000,000 shares of Common Stock.
Each holder of a share of Advaxis Common Stock is entitled to one vote for each such share held of record on the applicable record date on each matter voted on at a meeting of stockholders.	Each holder of a share of Ayala Common Stock is entitled to one vote for each such share held of record on the applicable record date on each matter voted on at a meeting of stockholders.
Preferred Stock	
Advaxis' authorized preferred stock consists of 5,000,000 shares of preferred stock. No shares of Advaxis preferred stock are currently outstanding.	Ayala's authorized preferred stock consists of 10,000,000 shares of preferred stock. No shares of Ayala preferred stock are currently outstanding.
Number and Qualification of Directors	
The Advaxis Board consists of no less than one and no more than nine members, and the number of directors is fixed from time to time by resolution of the Advaxis Board. The Advaxis Board currently consists of six members.	The Ayala Board consists of no less than one member, and the number of directors is fixed from time to time by resolution of the Ayala Board. The Ayala board currently consists of five members.
Structure of Board of Directors; Term of Directors; Election of Directors	
Each director will hold office until the next annual meeting of stockholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal.	Directors are elected by a plurality of the votes cast by the stockholders entitled to vote thereon. The Ayala charter provides for a classified board of directors with three classes of directors. Approximately one-third of the Ayala Board is elected each year, and board members stand for re-election in the third year after the year of their election and hold office until their successors are duly elected and qualified, or until their earlier death, resignation or removal. Ayala stockholders do not have cumulative voting rights.
Removal of Directors	
Any director may be removed at any time for cause or without cause by the vote of the holders of a majority of the Common Stock then entitled to vote at an election of directors. The vacancy on the board of directors caused by any such removal may be filled by the stockholders at such meeting or as provided below.	Any director may be removed at any time for cause by the vote of the holders of at least two-thirds of the voting power of the capital stock of Ayala entitled to vote at an election of directors. The vacancy on the board of directors caused by any such removal may be filled by the directors as provided below.
Vacancies on the Board of Directors	
Vacancies, and newly created directorships resulting from any increase in the authorized number of directors, may be filled by vote of a majority of the directors then in office (even if such remaining directors constitute less than a quorum) or of the sole remaining director, and the directors so chosen shall hold office until the next annual election and until their successors are duly elected and qualified, or until their earlier resignation or removal.	Vacancies, and newly created directorships resulting from any increase in the authorized number of directors, may be filled by vote of a majority of the directors then in office (even if such remaining directors constitute less than a quorum) or of the sole remaining director, and the directors so chosen shall hold office until the next election of the class for which such director shall have been chosen and until their successors are duly elected and qualified, or until their earlier death, resignation or removal.

Stockholder Action by Written Consent	
Unless otherwise provided in the amended and restated certificate of incorporation, any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, in a consent in writing, setting forth the action so taken, signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.	Any action required or permitted to be taken by stockholders of the corporation must be effected at a duly called annual or special meeting of stockholders of the corporation and may not be effected by a consent in writing.
Quorum for a Board Meeting	
Except as otherwise provided by law or by amended and restated certificate of incorporation, the holders of one-third of the capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business. If, however, such quorum shall not be present or represented at any meeting of the stockholders, the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder entitled to vote at the meeting.	Except as otherwise provided by law, the restated certificate of incorporation or the amended and restated bylaws, the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote thereat, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business. If, however, such quorum shall not be present or represented at any meeting of the stockholders, (i) the chairperson of such meeting, or (ii) the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote thereat, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder entitled to vote at the adjourned meeting.
Special Meetings of Stockholders	
Unless otherwise prescribed by law or by the amended and restated certificate of incorporation, special meetings of stockholders for any purpose or purposes may be called at any time by the board of directors. Written notice of a special meeting stating the place, date and hour of the meeting and the purpose or purposes for which the meeting is called shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting.	Special meetings of stockholders for the purpose or purposes specified in the notice to stockholders of such meeting as provided below may be called at any time by the board of directors, the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) of the corporation. Written notice of a special meeting shall be given as provided below.

Notice of Stockholder Meetings

Notice of all meetings of stockholders is to be given in writing in the manner provided by law and Advaxis' second amended and restated bylaws, stating the place, if any, date and hour, of the meeting and, in the case of a special meeting, the purpose or purposes of the meeting. Unless otherwise required by applicable law, such notice is to be given not less than 10 or more than 60 days before the date of the meeting to each stockholder of record entitled to vote at such meeting.	Notice of all meetings of stockholders is to be given in writing in the manner provided by law and Ayala's amended and restated bylaws, stating the place, if any, date and hour, of the meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting), the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting and, in the case of a special meeting, the purpose or purposes of the meeting. Unless otherwise required by law, the restated certificate of incorporation or the amended and restated bylaws, such notice is to be given not less than 10 or more than 60 days before the date of the meeting to each stockholder of record entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

Advance Notice Requirements for Stockholder Proposals

To be properly brought before an annual meeting of stockholders, business must be of a nature that is appropriate for consideration at an annual meeting and must be (i) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the board of directors, (ii) otherwise properly brought before the meeting by or at the direction of the board of directors, or (iii) otherwise properly brought before the meeting by a stockholder or qualified representative of such stockholder at the meeting who (A) is a record owner of shares of Advaxis' capital stock at the time of giving the notice provided for in this paragraph, (B) is a record owner of shares of Advaxis' capital stock as of the record date for the determination of stockholders entitled to notice of and to vote at the meeting in question, (C) is a record owner of shares of Advaxis' capital stock at the time of the meeting, (D) is entitled to vote at the meeting, and (E) complies with the requirements set forth in this paragraph in all applicable respects.	To be properly brought before an annual meeting of stockholders, business must be of a nature that is appropriate for consideration at an annual meeting and must be (i) brought before the meeting by the corporation and specified in the notice of meeting given by or at the direction of the board of directors, (ii) brought before the meeting by or at the direction of the board of directors (or a committee thereof), or (iii) otherwise properly brought before the meeting by a stockholder who (A) is a record owner of shares of Ayala's capital stock both at the time of giving the notice provided for in the amended and restated bylaws and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) complies with the requirements set forth in the amended and restated bylaws as to such business.

Amendment of Certificate of Incorporation

The affirmative vote of holders of at least a majority of shares present in person or represented by proxy at the meeting and entitled to vote will be required to amend certain provisions of Advaxis' amended and restated certificate of incorporation, including provisions relating to the size of the board, removal of directors, actions by written consent, forum selection and indemnification of directors, officers and agents of Advaxis.

Notwithstanding any other provisions of Advaxis' amended and restated certificate of incorporation, Advaxis' second amended and restated bylaws, or any provision of law which might otherwise permit a lesser vote or no vote, stockholders may vote to amend Advaxis' amended and restated certificate of incorporation pursuant to Section 242 of the DGCL.

The affirmative vote of holders of at least two-thirds of shares present in person or represented by proxy at the meeting and entitled to vote will be required to amend certain provisions of Ayala's restated certificate of incorporation, including provisions relating to the size of the board, removal of directors, actions by written consent, forum selection and indemnification of directors, officers and agents of Ayala.

Notwithstanding any other provisions of law, Ayala's restated certificate of incorporation, Ayala's amended and restated bylaws, or any provision of law which might otherwise permit a lesser vote, stockholders of at least two-thirds of the voting power of the capital stock of the corporation entitled to vote thereon may vote to amend Ayala's restated certificate of incorporation.

Amendment of Bylaws

The second amended and restated bylaws may be altered, amended or repealed, in whole or in part, or new bylaws may be adopted by the stockholders or by the board of directors; provided, however, that notice of such alteration, amendment, repeal or adoption of new bylaws be contained in the notice of such meeting of stockholders or board of directors, as the case may be. All such amendments must be approved by either of the holders of a majority of the outstanding capital stock entitled to vote thereon or by a majority of the entire board of directors then in office.

The amended and restated bylaws may be altered, amended or repealed, or new bylaws may be adopted, by the stockholders or by the board of directors. All such amendments must be approved by either of the holders of at least two-thirds in voting power of the outstanding capital stock of the corporation entitled to vote thereon or by a majority of the entire board of directors then in office.

Limitation on Director Liability

The liability of the Advaxis directors for monetary damages is and will be eliminated to the fullest extent under applicable law. If applicable law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to Advaxis will be eliminated or limited to the fullest extent permitted by applicable law as so amended.

The liability of the Ayala directors for monetary damages is and will be eliminated to the fullest extent under applicable law. If applicable law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to Advaxis will be eliminated or limited to the fullest extent permitted by applicable law as so amended.

Indemnification

To the fullest extent permitted by applicable law, Advaxis is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of Advaxis (and any other persons to which applicable law permits Advaxis to provide indemnification) (i) by a majority vote of the directors who were not parties to such action, suit or proceeding even though less than a quorum, or (ii) if there are no such directors, or, if such directors so direct, by independent legal counsel in a written opinion, or (iii) by the stockholders. If applicable law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to Advaxis will be eliminated or limited to the fullest extent permitted by applicable law as so amended.

To the fullest extent permitted by applicable law, Ayala is authorized to provide indemnification of (and advancement of expenses to) directors and officers of Ayala (i) by a majority vote of the directors who were not parties to such action, suit or proceeding even if less than a quorum, (ii) by a committee of such directors designated by majority vote of such directors even if less than a quorum, (iii) if there are no such directors, or, if such directors so direct, by independent legal counsel in a written opinion, or (iv) by the stockholders.

Conversion Rights

The shares of Advaxis' Common Stock are not convertible into other securities.

The shares of Ayala's Common Stock are not convertible into other securities.

Right of First Refusal

Advaxis does not have a right of first refusal in place.

Ayala does not have a right of first refusal in place.

Right of Co-Sale

Advaxis does not have a right of co-sale in place.

Ayala does not have a right of co-sale in place.

Preemptive Rights

Advaxis stockholders do not have preemptive rights. Thus, if additional shares of Advaxis Common Stock are issued, the current holders of Advaxis Common Stock will own a proportionately smaller interest in a larger number of outstanding shares of Common Stock to the extent that they do not participate in the additional issuance.

Ayala stockholders do not have preemptive rights. Thus, if additional shares of Ayala Common Stock are issued, the current holders of Ayala Common Stock will own a proportionately smaller interest in a larger number of outstanding shares of Common Stock to the extent that they do not participate in the additional issuance.

Distributions to Stockholders

Dividends upon Advaxis capital stock, subject to the provisions of Advaxis' amended and restated certificate of incorporation and applicable law, if any, may be declared by the Advaxis Board pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of Advaxis' amended and restated certificate of incorporation and applicable law. Before payment of any dividend, there may be set aside out of any funds of Advaxis available for dividends such sum or sums as the board of directors from time to time, in its absolute discretion, deems proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of Advaxis, or for any proper purpose, and the board of directors may modify or abolish any such reserve. The Advaxis Board may fix a record date for the determination of holders of Advaxis Common Stock entitled to receive payment of a dividend or distribution declared thereon, which record date is to be not to precede the date upon which the resolution fixing the record date is adopted, and which record date may not be more than 60 days prior to the date fixed for the payment thereof.

Dividends upon Ayala capital stock, subject to the provisions of Ayala's restated certificate of incorporation and applicable law, if any, may be declared by the Ayala Board. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of Ayala's restated certificate of incorporation and applicable law. Before payment of any dividend, there may be set aside out of any funds of Ayala available for dividends such sum or sums by the board of directors for any proper purpose, including but not limited to for the purposes of meeting contingences, equalizing dividends, or repairing or maintaining any property of Ayala, and the board of directors may abolish any such reserve. The Ayala Board may fix a record date for the determination of holders of Ayala capital stock entitled to receive payment of a dividend or distribution declared thereon, which record date may not be more than 60 days prior to the date fixed for the payment thereof. If no such record date is fixed, the record date shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

Registration Rights

Advaxis does not have registration rights in place.

The Amended and Restated Investors' Rights Agreement of Ayala includes registration rights as set forth therein held by holders of Ayala's preferred stock, including entities with which certain of Ayala's directors are related. The agreement provides for certain rights relating to the registration of such holders' common stock, including shares issuable upon conversion of preferred stock, and a right of first refusal to purchase future securities sold by Ayala.

Stock Transfer Restrictions Applicable to Stockholders

Shares of Advaxis are transferable in the manner prescribed by the law and in the second amended and restated bylaws.

Shares of Ayala are transferable in the manner prescribed by the law and in the amended and restated bylaws.

PRINCIPAL STOCKHOLDERS OF ADVAXIS

Advaxis has determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that Advaxis includes shares of Common Stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of October 31, 2022. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as described above, beneficial ownership prior to the completion of the Merger is based on 1,815,951 shares of Advaxis Common Stock outstanding as of October 31, 2022. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852.

Name of Beneficial Owner	Total # of Shares Beneficially Owned	Percentage of Ownership
Directors and Named Executive Officers		
Kenneth Berlin[(1)]	2,205	*%
Igor Gitelman[(2)]	417	*
David Sidransky[(3)]	461	*
Roni Appel[(4)]	508	*
Richard Berman[(5)]	399	*
Samir Khleif[(6)]	448	*
James Patton[(7)]	598	*
Andres Gutierrez[(8)]	1,089	*
All current Directors and Executive Officers as a group (8 individuals)[(9)]	6,125	*%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 271 shares of common stock and (ii) 1,934 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(2) Consists of 417 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(3) Consists of (i) 93 shares of common stock and (ii) 368 shares of common stock underlying options exercisable within 60 days of October 31, 2022.
(4) Consists of (i) 133 shares of common stock, (ii) 351 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022, and (iii) warrants to purchase 24 shares of common stock exercisable within 60 days of October 31, 2022.
(5) Consists of (i) 47 shares of common stock and (ii) 352 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(6) Consists of (i) 59 shares of common stock and (ii) 389 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(7) Consists of (i) 241 shares of common stock and (ii) 357 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(8) Consists of (i) 47 shares of common stock and (ii) 1,042 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.
(9) Consists of (i) 891 shares of common stock, (ii) 5,210 shares of common stock underling stock options exercisable within 60 days of October 31, 2022, and (iii) warrants to purchase 24 shares of common stock exercisable within 60 days of October 31, 2022.

PRINCIPAL STOCKHOLDERS OF AYALA

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of Ayala Common Stock as of October 31, 2022 for:

- each person, or group of affiliated persons, who is known by Ayala to beneficially own more than 5% of Ayala's Common Stock;
- each of Ayala's named executive officers and directors; and
- all of Ayala's executive officers and directors as a group.

Beneficial ownership is reported below in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that the table below include shares of Ayala Common Stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of October 31, 2022. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as described above, beneficial ownership prior to the completion of the Merger is based on 14,820,727 shares of Ayala Common Stock outstanding as of October 31, 2022. Unless otherwise indicated, the address of each beneficial owner listed below is Oppenheimer 4, Rehovot 7670104, Israel.

Name of Beneficial Owner	Total # of Shares Beneficially Owned	**Percentage of Ownership**
Roni Mamluk, Ph.D.(1)	352,415	2.36%
Yossi Maimon(2)	157,436	1.06%
Gary Gordon, M.D., Ph.D.(3)	144,083	*
Vered Bisker-Leib, Ph.D.(4)	13,055	*
Murray A. Goldberg(5)	36,250	*
David Sidransky, M.D.(6)	12,750	*
Robert Spiegel, M.D.(7)	36,250	*
All Directors and Officers as a Group (7 People)(8)	752,239	4.96%
Israel Biotech Fund I, L.P.(9)	3,315,119	22.37%
aMoon Growth Fund Limited Partnership(10)	2,991,473	20.18%
Harel Insurance Company Ltd.(11)	2,153,272	14.53%
Entities affiliated with Redmile Group, LLC(12)	1,480,591	9.99%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 265,345 shares of Ayala Common Stock and (ii) 87,070 shares of Ayala Common Stock underlying stock options that will vest and become exercisable within 60 days of October 31, 2022.
(2) Consists of (i) 69,872 shares of Ayala Common Stock and (ii) 87,564 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(3) Consists of (i) 58,520 shares of Ayala Common Stock and (ii) 85,563 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(4) Consists of 13,055 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(5) Consists of 36,250 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(6) Consists of (i) 250 shares of Ayala Common Stock held by a family member of Dr. Sidransky and (ii) 12,500 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(7) Consists of 36,250 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(8) Consists of (i) 393,987 shares of Ayala Common Stock and (ii) 358,252 shares of Ayala Common Stock underlying stock options exercisable within 60 days of October 31, 2022.
(9) Based solely on a Schedule 13G filed with the SEC on February 8, 2021. Consists of 3,315,119 shares of Ayala Common Stock held by Israel Biotech Fund I, L.P. ("IBF I"). Israel Biotech Fund GP Partners, L.P. ("IBF") is the sole general partner of IBF I. I.B.F. Management, Ltd. ("IBF Management") is the sole general partner of IBF. IBF and IBF Management may be deemed to have sole voting and dispositive power with respect to the Ayala Common Stock held by IBF I. Dr. Robert Spiegel, a member of Ayala's board of directors and an advisor to IBF, Mr. Murray Goldberg, a member of Ayala's board of directors and an advisor to IBF, and Dr. David Sidransky, the chairman of Ayala's board of directors managing partner of IBF and director of IBF Management, disclaim beneficial ownership over such shares, except to the extent of their pecuniary interest therein (as limited partners of IBF I and IBF). The address of IBF I, IBF and IBF Management is Ruhrberg Science Center, Bell Entrance, 4th Floor, 3 Pekeris Street, Rabin Science Park, Rehovot 7670212, Israel.
(10) Based solely on a Schedule 13G/A filed with the SEC on January 24, 2022. Consists of 2,991,473 shares of Ayala Common Stock held by aMoon 2 Fund Limited Partnership ("aMoon"). aMoon 2 Fund G.P. Limited Partnership ("aMoon G.P.") is the sole general partner of aMoon. aMoon General Partner Ltd. ("aMoon Ltd.") is the sole general partner of aMoon G.P. Dr. Yair C. Schindel is the sole shareholder of aMoon Ltd. Thus, aMoon G.P., aMoon Ltd. and Dr. Yair C. Schindel may be deemed to have sole voting and dispositive power with respect to the Ayala Common Stock held by aMoon. The address of aMoon is 34 Yerushalaim Rd, Beit Gamla, 6th Floor, Ra'anana, 4350110, Israel.
(11) Based on a Schedule 13G/A filed with the SEC on January 31, 2022. Consists of 2,153,272 shares of Ayala Common Stock held by Harel Insurance Company Ltd. ("Harel"), a subsidiary of Harel Insurance Investments & Financial Services Ltd. Of the 2,153,272 shares of Ayala Common Stock, (i) 489,438 shares are held for members of the public through, among others, provident funds and/or mutual funds and/or pension funds and/or insurance policies and/or exchange traded funds, which are managed by subsidiaries of the Harel Holdings and Harel Insurance, each of which subsidiaries operates under independent management and makes independent voting and investment decisions, and (ii) 1,663,834 shares are beneficially held for Harel Insurance's own account. Harel Insurance Investments & Financial Services Ltd. is a widely held public company listed on the Tel Aviv Stock Exchange. The address of Harel is 3 Abba Hillel Rd. Ramat Gan, Israel.
(12) Based solely on a Schedule 13G/A filed with the SEC on February 14, 2022 and information known to Ayala. Consists of (i) 667,816 shares owned by certain private investment vehicles managed by Redmile Group, LLC, (ii) 279,933 shares of Ayala Common Stock owned by Redmile Capital Offshore II Master Fund, Ltd and (iii) 387,883 shares of Ayala Common Stock held by Redmile Strategic Master Fund LP, which shares may be deemed beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles. The reported securities may also be deemed beneficially owned by Jeremy C. Green as the principal of Redmile Group, LLC. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. Redmile Group, LLC and Jeremy C. Green may also be deemed to beneficially own 1,799,999 shares issuable upon exercise of certain Warrants to purchase Ayala's Common Stock (the "Warrants"). Pursuant to the terms of the Warrants, a holder of a Warrant does not have the right to exercise any portion of the Warrant held by such holder, and the Company shall not effect any exercise of any Warrant, to the extent (but only to the extent) that after giving effect to such issuance after exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 9.99% (the "Beneficial Ownership Limitation") of the number of shares of Ayala's Common Stock outstanding immediately after giving effect to the issuance of shares of Ayala Common Stock issued upon exercise of the Warrant (the "Beneficial Ownership Blocker"). The Beneficial Ownership Limitation may be changed at a holder's election upon 61 days' notice to the Issuer. Redmile Capital Offshore II Master Fund, Ltd. holds 654,588 shares of Ayala Common Stock issuable upon the exercise of Warrants, subject to the Beneficial Ownership Limitation. Redmile Strategic Master Fund, LP holds 1,145,411 shares of Ayala Common Stock issuable upon the exercise of Warrants, subject to the Beneficial Ownership Limitation. The address for each entity is One Letterman Drive, Building D, Suite D3-300, The Presidio of San Francisco, San Francisco, California 94129.

PRINCIPAL STOCKHOLDERS OF PROPOSED COMBINED COMPANY

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of the common stock of the combined company, assuming the closing of the Merger will occur on October 31, 2022 for:

- each person, or group of affiliated persons, who is known by Advaxis or Ayala to become the beneficial owner of more than 5% of the combined company's common stock upon the consummation of the Merger;
- each of the combined company's named executive officers and directors; and
- all of the combined company's executive officers and directors as a group.

Beneficial ownership is estimated based on 4,593,355 shares of combined company common stock anticipated to be outstanding as of October 31, 2022. The following table (i) gives effect to the net exercise of pre-funded warrants to purchase 1,333,333 shares of Ayala Common Stock as of immediately prior to the closing of the Merger based on the volume weighted average price of Ayala Common Stock on The Nasdaq Global Market on October 31, 2022 and (ii) does not give effect to the reverse stock split for which Advaxis intends to seek stockholder approval in connection with an application to uplist the common stock of the combined company on Nasdaq.

Beneficial ownership is reported below in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that the table below include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of October 31, 2022. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise indicated by footnote, the address for each of the beneficial owners set forth in the table below is c/o Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852.

Name of Beneficial Owner	Total # of Shares Beneficially Owned	Percentage of Ownership
Kenneth A. Berlin(1)	2,205	*%
Igor Gitelman(2)	417	*
Andres A. Gutierrez, M.D., Ph.D.(3)	1,089	*
Roni A. Appel(4)	508	*
Vered Bisker-Leib, Ph.D.(5)	2,446	*
Murray A. Goldberg(6)	6,792	*
Samir N. Khleif, M.D.(7)	448	*
David Sidransky, M.D.(8)	2,849	*
Robert Spiegel, M.D.(9)	6,792	*
All Directors and Officers as a Group (9 People)(10)	23,546	*
Israel Biotech Fund I, L.P.(11)	621,253	13.53%
aMoon Growth Fund Limited Partnership(12)	560,602	12.20%
Harel Insurance Company Ltd.(13)	403,522	8.78%
Entities affiliated with Redmile Group, LLC(14)	458,876	9.99%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 271 shares of common stock and (ii) 1,934 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(2) Consists of 417 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(3) Consists of (i) 47 shares of our common stock and (ii) 1,042 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(4) Consists of (i) 133 shares of common stock, (ii) 351 shares of common stock underlying stock options exercisable within 60 days and (iii) 24 shares of common stock underlying warrants exercisable within 60 days of October 31, 2022.

(5) Consists of 2,446 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(6) Consists of 6,792 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(7) Consists of (i) 59 shares of common stock and (ii) 389 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(8) Consists of (i) 46 shares of common stock held by a family member of Dr. Sidransky, (ii) 93 shares of common stock, and (iii) 2,710 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(9) Consists of 6,792 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022.

(10) Consists of (i) 649 shares of common stock, (ii) 22,873 shares of common stock underlying stock options exercisable within 60 days of October 31, 2022, and (iii) 24 shares of common stock underlying warrants exercisable within 60 days of October 31, 2022.

(11) Based solely on a Schedule 13G filed with the SEC on February 8, 2021 and information known to Advaxis. Consists of 621,253 shares of common stock held by Israel Biotech Fund I, L.P. (“IBF I”). Israel Biotech Fund GP Partners, L.P. (“IBF”) is the sole general partner of IBF I. I.B.F. Management, Ltd. (“IBF Management”) is the sole general partner of IBF. IBF and IBF Management may be deemed to have sole voting and dispositive power with respect to the common stock held by IBF I. Dr. Robert Spiegel, a member of Advaxis’ board of directors and an advisor to IBF, Mr. Murray Goldberg, a member of Advaxis’ board of directors and an advisor to IBF, and Dr. David Sidransky, the chairman of Advaxis’ Board managing partner of IBF and director of IBF Management, disclaim beneficial ownership over such shares, except to the extent of their pecuniary interest therein (as limited partners of IBF I and IBF). The address of IBF I, IBF and IBF Management is Ruhrberg Science Center, Bell Entrance, 4th Floor, 3 Pekeris Street, Rabin Science Park, Rehovot 7670212, Israel.

(12) Based solely on a Schedule 13G/A filed with the SEC on January 24, 2022 and information known to Advaxis. Consists of 560,602 shares of common stock held by aMoon 2 Fund Limited Partnership ("aMoon"). aMoon 2 Fund G.P. Limited Partnership ("aMoon G.P.") is the sole general partner of aMoon. aMoon General Partner Ltd. ("aMoon Ltd.") is the sole general partner of aMoon G.P. Dr. Yair C. Schindel is the sole shareholder of aMoon Ltd. Thus, aMoon G.P., aMoon Ltd. and Dr. Yair C. Schindel may be deemed to have sole voting and dispositive power with respect to the common stock held by aMoon. The address of aMoon is 34 Yerushalaim Rd, Beit Gamla, 6th Floor, Ra'anana, 4350110, Israel.

(13) Based on a Schedule 13G/A filed with the SEC on January 31, 2022 and information known to Advaxis. Consists of 403,522 shares of common stock held by Harel Insurance Company Ltd. ("Harel"), a subsidiary of Harel Insurance Investments & Financial Services Ltd. Of the 403,522 shares of common stock, (i) 91,720 shares are held for members of the public through, among others, provident funds and/or mutual funds and/or pension funds and/or insurance policies and/or exchange traded funds, which are managed by subsidiaries of the Harel Holdings and Harel Insurance, each of which subsidiaries operates under independent management and makes independent voting and investment decisions, and (ii) 311,802 shares are beneficially held for Harel Insurance's own account. Harel Insurance Investments & Financial Services Ltd. is a widely held public company listed on the Tel Aviv Stock Exchange. The address of Harel is 3 Abba Hillel Rd. Ramat Gan, Israel.

(14) Based solely on a Schedule 13G/A filed with the SEC on February 14, 2022 and information known to Advaxis. Consists of (i) 125,148 shares owned by certain private investment vehicles managed by Redmile Group, LLC, (ii) 142,094 shares of common stock held by Redmile Offshore II Master Fund, Ltd, and (iii) 229,535 shares of common stock held by Redmile Strategic Master Fund, LP, which shares may be deemed beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles. The reported securities may also be deemed beneficially owned by Jeremy C. Green as the principal of Redmile Group, LLC. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. Redmile Group, LLC and Jeremy C. Green may also be deemed to beneficially own 87,452 shares issuable upon exercise of certain Warrants to purchase Ayala's Common Stock (the "Warrants"). Pursuant to the terms of the Warrants, a holder of a Warrant does not have the right to exercise any portion of the Warrant held by such holder, and the Company shall not effect any exercise of any Warrant, to the extent (but only to the extent) that after giving effect to such issuance after exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 9.99% (the "Beneficial Ownership Limitation") of the number of shares of the combined company's Common Stock outstanding immediately after giving effect to the issuance of shares of common stock issued upon exercise of the Warrant (the "Beneficial Ownership Blocker"). The Beneficial Ownership Limitation may be changed at a holder's election upon 61 days' notice to the Issuer. Redmile Capital Offshore II Master Fund, Ltd. holds 31,803 shares of common stock issuable upon the exercise of Warrants, subject to the Beneficial Ownership Limitation. Redmile Strategic Master Fund, LP holds 55,649 shares of common stock issuable upon the exercise of Warrants, subject to the Beneficial Ownership Limitation. The address for each entity is One Letterman Drive, Building D, Suite D3-300, The Presidio of San Francisco, San Francisco, California 94129.

LEGAL MATTERS

Morgan, Lewis & Bockius LLP will pass upon the validity of Advaxis' Common Stock offered by this proxy statement/prospectus.

EXPERTS

The consolidated financial statements of Advaxis, Inc. as of October 31, 2021 and 2020 and for each of the two years in the period ended October 31, 2021 included in this proxy statement/prospectus have been so included in reliance on the report of Marcum LLP, an independent registered public accounting firm, given on the authority of such firm as experts in auditing and accounting.

The consolidated financial statements of Ayala Pharmaceuticals, Inc. included in this proxy statement/prospectus for the year ended December 31, 2021, have been audited by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements therein). Such consolidated financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Advaxis and Ayala are subject to the informational requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains Advaxis' and Ayala's filings as well as other information at *www.sec.gov*.

Advaxis also makes available free of charge on or through its website at www.advaxis.com its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after Advaxis electronically files such material with or otherwise furnishes it to the SEC. Ayala also makes available free of charge on or through its website at www.ayalapharma.com its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after Ayala electronically files such material with or otherwise furnishes it to the SEC. In addition to the information about Ayala and its subsidiaries contained in this proxy statement/prospectus, information about Ayala can be found on Ayala's website. The website addresses for the SEC, Advaxis and Ayala are inactive textual references and information on those websites is not part of this proxy statement/prospectus.

Advaxis has filed with the SEC the Registration Statement, under the Securities Act to register the shares of Advaxis Common Stock to be issued to Ayala stockholders in the Merger. This proxy statement/prospectus is a part of that Registration Statement and constitutes a prospectus of Advaxis and it will also serve as a proxy statement for the stockholders of Ayala for the Ayala Special Meeting. The Registration Statement, including the attached annexes, exhibits and schedules, contains additional relevant information about Advaxis and Advaxis Common Stock. This proxy statement/prospectus does not contain all of the information set forth in the Registration Statement because certain parts of the Registration Statement are omitted in accordance with the rules and regulations of the SEC.

Advaxis has supplied all the information contained in this proxy statement/prospectus relating to Advaxis, and Ayala has supplied all information contained in this proxy statement/prospectus relating to Ayala.

If you would like to request documents from Advaxis or Ayala, please send a request in writing or by telephone to either Advaxis or Ayala at the following addresses:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
Attn: Igor Gitelman, Interim Chief Financial Officer, Chief Accounting Officer, and VP of Finance.
Tel: (917) 940-5651

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104, Israel
Attn: Secretary
Tel: (857) 444-0553

TRADEMARK NOTICE

Advaxis Immunotherapies™ and *Lm* Technology™ are trademarks of Advaxis, Inc. in the United States. Other third-party logos and product/trade names are registered trademarks or trade names of their respective companies.

HOUSEHOLDING OF PROXY MATERIALS

The SEC's rules permit Ayala to deliver a single set of proxy materials to one address shared by two or more of Ayala's stockholders. This delivery method is referred to as "householding" and can result in significant cost savings. To take advantage of this opportunity, Ayala has delivered only one set of proxy materials to multiple stockholders who share an address, unless Ayala received contrary instructions from the impacted stockholders prior to the mailing date. Ayala agrees to deliver promptly, upon written or oral request, a separate copy of the proxy materials, as requested, to any stockholder at the shared address to which a single copy of those documents was delivered. If you prefer to receive separate copies of the proxy materials, contact Broadridge Financial Solutions, Inc. at 1-866-540-7095 or in writing at Broadridge, Householding Department, 51 Mercedes Way, Edgewood, New York 11717.

If you are currently a stockholder sharing an address with another stockholder and wish to receive only one copy of future proxy materials for your household, please contact Broadridge at the above phone number or address.

COMMUNICATIONS FROM AYALA STOCKHOLDERS

The Ayala Board will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. Ayala's Secretary is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to Ayala's directors as he considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that Ayala's Secretary and Chairman of the Ayala Board consider to be important for the directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which Ayala tends to receive repetitive or duplicative communications. Stockholders who wish to send communications on any topic to the Ayala Board should address such communications to the Board of Directors in writing: c/o Secretary, Ayala Pharmaceuticals, Inc., Oppenheimer 4, Rehovot 7670104, Israel.

AYALA STOCKHOLDERS' PROPOSALS

If the Ayala Merger Proposal is approved by the requisite vote of stockholders and the Merger is completed in the first quarter of 2023, as is currently anticipated, Ayala does not expect to hold an annual meeting of stockholders in 2023 (the "2023 Ayala Annual Meeting"). However, if the Merger is not completed in the first quarter of 2023, then Ayala may hold the 2023 Ayala Annual Meeting.

Stockholders who intend to have a proposal considered for inclusion in Ayala's proxy materials for presentation at the Ayala Annual Meeting pursuant to Rule 14a-8 under the Exchange Act must submit the proposal to Ayala's Secretary at Ayala's offices at Oppenheimer 4, Rehovot 7670104, Israel in writing not later than December 28, 2022.

Stockholders intending to present a proposal at the 2023 Ayala Annual Meeting, but not to include the proposal in Ayala's proxy statement, or to nominate a person for election as a director, must comply with the requirements set forth in Ayala's Amended and Restated Bylaws. Ayala's Amended and Restated Bylaws require, among other things, that its Secretary receive written notice from the stockholder of record of their intent to present such proposal or nomination not earlier than the 120th day and not later than the 90th day prior to the anniversary of the preceding year's annual meeting. Therefore, Ayala must receive notice of such a proposal or nomination for the 2023 Ayala Annual Meeting no earlier than February 13, 2023 and no later than March 15, 2023. The notice must contain the information required by the Amended and Restated Bylaws, a copy of which is available upon request to Ayala's Secretary. In the event that the date of the 2023 Annual Meeting of Stockholders is more than 30 days before or more than 60 days after June 13, 2023, then Ayala's Secretary must receive such written notice not earlier than the close of business on the 120th day prior to the 2023 Annual Meeting and not later than the close of business on the 90th day prior to the 2023 Annual Meeting or, if later, the close of business on 10th day following the day on which public disclosure of the date of such meeting is first made by Ayala. In addition to satisfying the foregoing requirements under Ayala's Amended and Restated Bylaws, to comply with the universal proxy rules (once they become effective), stockholders who intend to solicit proxies in support of director nominees other than Ayala's nominees must provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act no later than April 14, 2023.

We reserve the right to reject, rule out of order, or take other appropriate action with respect to any proposal that does not comply with these or other applicable requirements.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Advaxis, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Advaxis, Inc. (the "Company") as of October 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended October 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended October 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2012.

New York, NY
February 14, 2022 except, for the effects of the reverse stock split discussed in Note 3 as to which the date is June 10, 2022.

ADVAXIS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	October 31, 2021	October 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,614	$ 25,178
Deferred expenses	-	1,808
Prepaid expenses and other current assets	1,643	865
Total current assets	43,257	27,851
Property and equipment (net of accumulated depreciation)	118	2,393
Intangible assets (net of accumulated amortization)	3,354	3,261
Operating right-of-use asset (net of accumulated amortization)	40	4,839
Other assets	11	182
Total assets	$ 46,780	$ 38,526
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 87	$ 410
Accrued expenses	2,836	1,737
Current portion of operating lease liability	28	962
Deferred revenue	-	165
Common stock warrant liability	4,929	17
Total current liabilities	7,880	3,291
Operating lease liability, net of current portion	12	5,055
Total liabilities	7,892	8,346
Contingencies – Note 11		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at October 31, 2021 and 2020. Liquidation preference of $0 at October 31, 2021 and 2020.	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 1,820,452 and 975,897 shares issued and outstanding at October 31, 2021 and 2020.	2	1
Additional paid-in capital	467,486	440,917
Accumulated deficit	(428,600)	(410,738)
Total stockholders' equity	38,888	30,180
Total liabilities and stockholders' equity	$ 46,780	$ 38,526

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Year Ended October 31,	
	2021	2020
Revenue	$ 3,240	$ 253
Operating expenses:		
Research and development expenses	10,562	15,612
General and administrative expenses	11,464	11,090
Total operating expenses	22,026	26,702
Loss from operations	(18,786)	(26,449)
Other income (expense):		
Interest income	5	110
Net changes in fair value of derivative liabilities	970	-
Loss on shares issued in settlement of warrants	-	(77)
Other expense	(1)	(3)
Net loss before income tax benefit	(17,812)	(26,419)
Income tax expense	50	50
Net loss	$ (17,862)	$ (26,469)
Net loss per common share, basic and diluted	$ (11.07)	$ (34.71)
Weighted average number of common shares outstanding, basic and diluted	1,613,634	762,548

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at October 31, 2019	-	$ -	627,497	$ 1	$ 423,799	$ (384,269)	$ 39,531
Stock-based compensation	-	-	110	-	891	-	891
Tax withholdings paid on equity awards	-	-	-	-	(1)	-	(1)
Tax shares sold to pay for tax withholdings on equity awards	-	-	-	-	1	-	1
Issuance of shares to employees under ESPP Plan	-	-	176	-	7	-	7
ESPP Expense	-	-	-	-	1	-	1
Warrant exercises	-	-	423	-	2	-	2
Shares issued in settlement of warrants	-	-	37,500	-	77	-	77
Advaxis public offerings, net of offering costs	-	-	156,113	-	11,066	-	11,066
Commitment fee shares issued for equity line	-	-	13,553	-	644	-	644
Shares issued under equity line	-	-	140,525	-	4,430	-	4,430
Net Loss	-	-	-	-	-	(26,469)	(26,469)
Balance at October 31, 2020	-	$ -	975,897	$ 1	$ 440,917	$ (410,738)	$ 30,180
Stock-based compensation	-	-	69	-	566	-	566
Stock option exercises	-	-	4	-	-	-	-
Issuance of shares to employees under ESPP Plan	-	-	12	-	-	-	-
Warrant exercises	-	-	230,343	-	3,771	-	3,771
Advaxis public offerings, net of offering costs	-	-	614,127	1	22,232	-	22,233
Net Loss	-	-	-	-	-	(17,862)	(17,862)
Balance at October 31, 2021	-	$ -	1,820,452	$ 2	$ 467,486	$ (428,600)	$ 38,888

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands, except share and per share data)

	Year Ended October 31,	
	2021	2020
OPERATING ACTIVITIES		
Net loss	$ (17,862)	$ (26,469)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	566	891
Employee stock purchase plan expense	-	1
(Gain) loss on change in value of warrant liability	(970)	-
Loss on shares issued in settlement of warrants	-	77
Loss on disposal of property and equipment	1,439	-
Loss on write-down of property and equipment	-	1,060
Abandonment of intangible assets	94	1,725
Depreciation expense	387	897
Amortization of deferred offering costs	-	644
Amortization expense of intangible assets	273	337
Amortization expense of right-of-use assets	330	744
Net gain on write-off of right-of-use asset and lease liability	(116)	-
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and deferred expenses	1,030	1,113
Other assets	171	1
Accounts payable and accrued expenses	776	(2,307)
Deferred revenue	(165)	165
Operating lease liabilities	(1,392)	(819)
Net cash used in operating activities	(15,439)	(21,940)
INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	449	-
Cost of intangible assets	(460)	(748)
Net cash used in investing activities	(11)	(748)
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock and warrants	28,115	15,496
Proceeds from warrant exercises	3,771	-
Proceeds from employee stock purchase plan	-	7
Employee tax withholdings paid on equity awards	-	(1)
Tax shares sold to pay for employee tax withholdings on equity awards	-	1
Net cash provided by financing activities	31,886	15,503
Net increase (decrease) in cash and cash equivalents	16,436	(7,185)
Cash and cash equivalents at beginning of year	25,178	32,363
Cash and cash equivalents at end of year	$ 41,614	$ 25,178

The accompanying notes should be read in conjunction with the financial statements.

Supplemental Disclosures of Cash Flow Information

	Year Ended October 31,	
	2021	2020
Cash paid for taxes	$ 50	$ 50

Supplemental Schedule of Noncash Investing and Financing Activities

	Year Ended October 31,	
	2021	2020
Shares issued in settlement of warrants	$ -	$ 77
Commitment fee shares issued for equity line	$ -	$ 644
Cashless exercise of warrants	$ -	$ 2
Reassessment of the lease term	$ 43	$ -

The accompanying notes should be read in conjunction with the financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Advaxis' proprietary approach is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- Alerting and training the immune system by activating multiple pathways in Antigen-Presenting Cells ("APCs") with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment ("TME") that shields the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

Termination of Merger Agreement; Strategic Considerations

On July 4, 2021, the Company entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with Biosight Ltd. ("Biosight") and Advaxis Ltd. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Biosight was to merge with and into Merger Sub, with Biosight continuing as the surviving company and a wholly-owned subsidiary of Advaxis (the "Merger"). Immediately after the merger, Advaxis stockholders as of immediately prior to the merger were expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders were expected to own approximately 75% of the outstanding shares of the combined company.

On December 30, 2021, the Company terminated the Merger Agreement, as the Company was unable to obtain shareholder approval to complete the transaction. As announced in December 2021, the Company plans to continue to explore additional options to maximize stockholder value.

Liquidity and Management's Plans

Similar to other development stage biotechnology companies, the Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for the foreseeable future.

As of October 31, 2021, the Company had approximately $41.6 million in cash and cash equivalents. Although the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least one year from the issuance of these consolidated financial statements, the actual amount of cash that it will need to operate is subject to many factors. Over the past year, the Company has taken steps to obtain additional financing, including conducting sales of its common stock through its at-the-market ("ATM") program through A.G.P./Alliance Global Partners, the completion of a public offering in November 2020 and the completion of a registered direct offering and concurrent private placement with two healthcare-focused, institutional investors in April 2021, as further described below. The Company also received aggregate proceeds of approximately $3.8 million during the year ended October 31, 2021 upon the exercise of outstanding warrants, which were payable upon exercise.

In April 2021, the Company entered into definitive agreements with two healthcare-focused, institutional investors for the purchase of (i) 219,718 shares of common stock, (ii) 95,899 pre-funded warrants to purchase 95,899 shares of common stock and (iii) registered common share purchase warrants to purchase 140,552 shares of common stock ("Accompanying Warrants") in a registered direct offering (the "April 2021 Registered Direct Offering"). The Company also issued to the investors, in a concurrent private placement (the "April 2021 Private Placement" and together with the April 2021 Registered Direct Offering, the "April 2021 Offering"), unregistered common share purchase warrants to purchase 175,065 shares of the Company's common stock (the "Private Placement Warrants"). The Company received gross proceeds of approximately $20 million, before deducting the fees and expenses payable by the Company in connection with the April 2021 Offering.

On November 27, 2020, the Company completed an underwritten public offering of 333,333 shares of common stock and common stock warrants to purchase up to 166,674 shares of common stock (the "November 2020 Offering"). On November 24, 2020, the underwriters notified the Company that they had exercised their option to purchase an additional 50,000 shares of common stock and 25,000 warrants in full. The Company received gross proceeds of approximately $9.2 million, before deducting the fees and expenses payable by the Company in connection with the November 2020 Offering.

The Company recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used when accounting for such items as the fair value and recoverability of the carrying value of property and equipment and intangible assets (patents and licenses), determining the Incremental Borrowing Rate ("IBR") for calculating Right-Of-Use ("ROU") assets and lease liabilities, deferred expenses, deferred revenue, the fair value of options, warrants and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results may differ from these estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenue as such amounts are incurred by the collaboration partner. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. As of October 31, 2021 and 2020, the Company had cash equivalents of approximately $17.2 million and $17.1 million, respectively.

Concentration of Credit Risk

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately $41.6 million is subject to credit risk at October 31, 2021. The Company has not experienced any losses in such accounts.

Deferred Expenses

Deferred expenses consist of advanced payments made on research and development projects. Expense is recognized in the consolidated statement of operations as the research and development activity is performed.

Property and Equipment

Property and equipment are stated at cost. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to ten years.

When depreciable assets are retired or sold the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Intangible Assets

Intangible assets are recorded at cost and include patents and patent application costs, licenses and software. Intangible assets are amortized on a straight-line basis over their estimated useful lives ranging from three to 20 years. Patent application costs are written-off if the application is rejected, withdrawn or abandoned.

Impairment of Long-Lived Assets

The Company periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset(s);
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by the application of discounted cash flow models to project cash flows from the assets. In addition, the Company bases estimates of the useful lives and related amortization or depreciation expense on its subjective estimate of the period the assets will generate revenue or otherwise be used by it. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less selling costs. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

Leases

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the consolidated balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the consolidated balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Net Income (Loss) per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units and other potential common stock outstanding during the period. In the case of a net loss, the impact of the potential common stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential common stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share (as of October 31, 2020, 327,338 warrants are included in the basic earnings per share computation because the exercise price is $0):

	As of October 31,	
	2021	2020
Warrants	377,818	4,971
Stock options	11,192	12,647
Restricted stock units	-	69
Total	389,010	17,687

Research and Development Expenses

Research and development costs are expensed as incurred and include but are not limited to clinical trial and related manufacturing costs, payroll and personnel expenses, lab expenses, and related overhead costs.

Stock Based Compensation

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the consolidated statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the Black Scholes Model for the remaining awards, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

Fair Value of Financial Instruments

The carrying value of financial instruments, including cash and cash equivalents and accounts payable, approximated fair value as of the balance sheet date presented, due to their short maturities.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company used the Monte Carlo simulation model and the Black Scholes model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

Sequencing Policy

The Company adopted a sequencing policy under ASC 815-40-35, if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was due to the Company committing more shares than authorized. Certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the most recent grant date of potentially dilutive instruments. Pursuant to ASC 815, issuances of securities granted as compensation in a share-based payment arrangement are not subject to the sequencing policy.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, *"Income Taxes."* Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

Recent Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Simplification of Income Taxes (Topic 740) Income Taxes ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for public companies for annual periods beginning after December 15, 2020, including interim periods within those fiscal years. The standard will apply as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted and is not material to the financial results of the Company.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain convertible instruments, amends guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share ("EPS") calculations as a result of these changes. The standard will be effective for the Company for fiscal years beginning after December 15, 2023 and can be applied on either a fully retrospective or modified retrospective basis. Early adoption is permitted for fiscal years beginning after December 15, 2020. We are currently evaluating the impact of this standard on our consolidated financial statements.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying consolidated financial statements.

3. REVERSE STOCK SPLIT

On March 31, 2022, the Company's stockholders voted to approve an amendment to allow the Company to execute a reverse stock split of common stock within a range of 1 for 20 to 1 for 80, without reducing the authorized number of shares of the common stock, at the discretion of the Board of Directors. On June 3, 2022, the Board of Directors approved a 1 for 80 reverse stock split, which became effective on June 6, 2022. All references in this Report to number of shares, price per share and weighted average number of shares of common stock outstanding prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis, unless otherwise noted.

4. PROPERTY AND EQUIPMENT

Property and equipment consist of the following (in thousands):

	October 31,	
	2021	2020
Leasehold improvements	$ -	$ 2,335
Laboratory equipment	179	1,218
Furniture and fixtures	-	744
Computer equipment	241	409
Construction in progress	-	19
Total property and equipment	420	4,725
Accumulated depreciation and amortization	(302)	(2,332)
Net property and equipment	$ 118	$ 2,393

Depreciation expense for the years ended October 31, 2021 and 2020 was approximately $0.4 million and $0.9 million, respectively. During the year ended October 31, 2021, the Company incurred a loss on disposal of equipment of approximately $1.4 million, $0.9 million of which is reflected in the research and development expenses and $0.5 million of which is reflected in the general and administrative expenses in the consolidated statement of operations.

Management has reviewed its property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. During the years ended October 31, 2021 and 2020, the Company recorded impairment losses on idle laboratory equipment of $0 and $1.1 million, respectively, that was charged to research and development expenses in the consolidated statement of operations. Fair value for the idle assets was determined by a quoted purchase price for the assets.

5. INTANGIBLE ASSETS

Intangible assets consist of the following (in thousands):

	October 31,	
	2021	2020
Patents	$ 4,836	$ 4,479
License	777	777
Software	98	117
Total intangibles	5,711	5,373
Accumulated amortization	(2,357)	(2,112)
Net intangible assets	$ 3,354	$ 3,261

The expirations of the existing patents range from 2021 to 2039 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. Patent applications having a net book value of approximately $0.1 million and $1.7 million were abandoned and were charged to general and administrative expenses in the consolidated statement of operations for the years ended October 31, 2021 and 2020, respectively. Intangible asset amortization expense that was charged to general and administrative expense in the consolidated statement of operations was approximately $0.3 million for each of the years ended October 31, 2021 and 2020, respectively.

Management has reviewed its intangible assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the consolidated balance sheet for patents and licenses related to axalimogene filolisbac (AXAL), ADXS-HOT, ADXS-PSA and other products that are in development or out-licensed. However, if a competitor were to gain FDA approval for a treatment before the Company or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value. Lastly, if the Company is unable to raise enough capital to continue funding our studies and developing its intellectual property, the Company would likely record an impairment to certain of these assets.

At October 31, 2021, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

2022	$ 277
2023	277
2024	277
2025	277
2026	277
Thereafter	1,969
Total	$ 3,354

6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses (in thousands):

	October 31,	
	2021	2020
Salaries and other compensation	$ 55	$ 737
Vendors	2,168	671
Professional fees	613	329
Total accrued expenses	$ 2,836	$ 1,737

7. STOCKHOLDERS' EQUITY

Lincoln Park Purchase Agreement

On July 30, 2020, the Company entered into a Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Over the 36-month term of the Purchase Agreement, the Company has the right, but not the obligation, from time to time, to sell to Lincoln Park up to an aggregate amount of $20,000,000 of shares of common stock, in its sole discretion and subject to certain conditions, including that the closing price of its common stock is not below $8.00 per share, to direct Lincoln Park to purchase up to 12,500 shares (the "Regular Purchase Share Limit") of its Common Stock (each such purchase, a "Regular Purchase"). Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,000,000, unless the parties mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the Purchase Agreement): (i) the lowest sale price for the Company's common stock on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for the Company's common stock during the ten trading days prior to the purchase date.

As consideration for entering into the Purchase Agreement, the Company issued 13,553 shares of common stock to Lincoln Park as a commitment fee. The shares were valued at approximately $0.6 million and were recorded as deferred offering expenses in the consolidated balance sheet. The deferred charges were charged against paid-in capital upon future proceeds from the sale of common stock under the Lincoln Park Purchase Agreement.

From August 2020 to October 2020, Lincoln Park purchased 140,525 shares of common stock for gross proceeds of approximately $5.1 million. Approximately $50,000 of legal fees were netted against the gross proceeds.

Public Offerings

In April 2021, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors. The Purchase Agreement provided for the sale and issuance by the Company of an aggregate of 219,718 shares (the "Shares") of the Company's common stock, $0.001 par value (the "Common Stock"), at an offering price of $63.37 per Share and 95,899 pre-funded warrants to certain purchasers whose purchase of additional Shares would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 9.99% of the Company's outstanding Common Stock immediately following the consummation of the offering (the "Pre-Funded Warrants"). The Shares and Pre-Funded Warrants were sold together with warrants to purchase up to 140,552 shares of Common Stock (the "Accompanying Warrants" and together with the Shares and the Pre-Funded Warrants, the "Securities"). The Pre-Funded Warrants were sold for a purchase price of $63.29 per share and have an exercise price of $0.08 per share. The Pre-Funded Warrants were immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. Each Accompanying Warrant has an exercise price per share of $56.00, became exercisable immediately and will expire on the fifth anniversary of the original issuance date.

The Purchase Agreement also provided for a concurrent private placement (the "Private Placement") of 175,065 warrants to purchase the Company's Common Stock (the "Private Placement Warrants") with the purchasers in the Registered Offering. The Private Placement Warrants will be exercisable for an aggregate of 175,065 shares of Common Stock at any time on or after such date, if ever, that is 14 days after the Company files an amendment (the "Authorized Shares Amendment") to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares with the Delaware Secretary of State and on or prior to the date that is five years after such date. The Private Placement Warrants have an exercise price of $56.00 per share.

In November 2020, the Company closed on a public offering of 383,333 shares of its common stock at a public offering price of $24.00 per share, for gross proceeds of approximately $9.2 million, which gives effect to the exercise of the underwriter's option in full. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 191,674 shares of common stock. The warrants have an exercise price per share of $28.00, are exercisable immediately and will expire five years from the date of issuance. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $8.5 million.

In May 2020, the Company entered into a sales agreement related to an ATM equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through A.G.P./Alliance Global Partners, as sales agent. From May 2020 to October 2020, the Company sold 31,113 shares of its common stock under the ATM program for $1.583 million, or an average of $51.20 per share, and received net proceeds of $1.531 million, net of commissions of $52,000. In March 2021, the Company sold 10,826 shares of its common stock under the ATM program for $762,000, or an average of $51.20 per share, and received net proceeds of $737,000, net of commissions of $25,000.

In January 2020, the Company closed on a public offering of 125,000 shares of its common stock at a public offering price of $84.00, for gross proceeds of $10.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 62,500 shares of common stock. The warrants have an exercise price per share of $100.00, are exercisable during the period beginning on the six-month anniversary of the date of its issuance (the "Initial Exercise Date") and will expire on the fifth anniversary of the Initial Exercise Date. The warrants contain a change of control provision whereby if the change of control is within the Company's control, the warrants could be settled in cash based on the Black-Scholes value of the warrants at the option of the warrant holder. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $9.6 million.

8. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

Warrants

As of October 31, 2021, there were outstanding and exercisable warrants to purchase 30,225,397 shares of our common stock with exercise prices ranging from $0.30 to $281.25 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Summary of Warrants
$ 224.00*	4,092	July 2024	July 2019 Public Offering
$ 20.00	879	September 2024	September 2018 Public Offering
$ 28.00	57,230	November 2025	November 2020 Public Offering
$ 56.00	140,552	April 2026	April 2021 Registered Direct Offering (Accompanying Warrants)
$ 56.00	175,065	5 years after the date such warrants become exercisable, if ever	April 2021 Private Placement (Private Placement Warrants
Grand Total	377,818		

* During the year ended October 31, 2021, the cashless exercise provision of these warrants expired and the exercise price adjusted to $224.00.

As of October 31, 2020, there were outstanding warrants to purchase 398,226 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Summary of Warrants
$ -	4,092	July 2024	July 2019 Public Offering
$ 29.76	879	September 2024	September 2018 Public Offering
Grand Total	4,971		

A summary of warrant activity was as follows (In thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding and exercisable warrants at October 31, 2019	5,394	$ 6.40	4.76	$ 114,069
Issued	62,500	100.00		
Exercised *	(423)	1.60		
Exchanged	(62,500)	100.00		
Outstanding and exercisable warrants at October 31, 2020	4,971	$ 6.40	3.76	$ 110,640
Issued	603,190	38.40		
Exercised	(230,343)	16.00		
Outstanding and exercisable warrants at October 31, 2021	377,818	$ 53.49	4.63	$ 631,089

* Includes the cashless exercise of 406 warrants that resulted in the issuance of 406 shares of common stock.

As of October 31, 2021, the Company had 201,874 of its total 377,818 outstanding warrants classified as equity (equity warrants). At October 31, 2020, the Company had 4,092 of its total 4,971 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders equity section of the consolidated balance sheets.

Shares Issued for Warrants Exercises

During the year ended October 31, 2021, warrant holders from the Company's November 2020 offering exercised 134,437 warrants in exchange for 134,437 shares of the Company's common stock and warrant holders from the Company's April 2021 Offering exercised 95,399 pre-funded warrants in exchange for 95,399 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of approximately $3.8 million which were payable upon exercise.

Shares Issued in Settlement of Equity Warrants

On October 16, 2020, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 62,500 shares of our common stock at an exercise price of $100.00 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, the Company agreed to issue 37,500 shares of common stock to the investors in exchange for the warrants. The fair value of these warrants approximated the fair value of shares issued in the exchange for these warrants. The Company used the closing stock price to value the shares and Black Scholes model to value these warrants on the date of the exchange. In determining the fair warrant of the warrants issued on October 16, 2020, the Company used the following inputs in its Black-Sholes model: exercise price $100.00, stock price $32.48, expected term 4.76 years, volatility 101.18% and risk-free interest rate 0.32%. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $77,000 as the fair value of the shares issued exceeded the fair value of warrants exchanged.

Warrant Liability

As of October 31, 2021, the Company had 175,944 of its total 377,818 outstanding warrants from April 2021 Private Placement Offering and September 2018 Public Offering classified as liabilities (liability warrants). At October 31, 2020, the Company had 879 of its total 4,971 outstanding warrants from the September 2018 Public Offering classified as liabilities (liability warrants).

The warrants issued in the April 2021 Private Placement will become exercisable only on such day, if ever, that is 14 days after the Company files an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares. These warrants expire five years after the date they become exercisable. As of October 31, 2021, the Company does not have sufficient authorized common stock to allow for the issuance of common stock underlying these warrants. The Company did not receive stockholder authorization to increase the authorized shares from 170,000,000 to 300,000,000 shares at the stockholder's meeting held on June 3, 2021. The Company was subsequently required to file a proxy to seek an increase in the number of authorized shares and did not file such a proxy but rather elected to seek a reverse stock split to, among other things, increase the shares available. Accordingly, based on certain indemnification provisions of the securities purchase agreement, the Company concluded that liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement at October 31, 2021 and April 14, 2021 (issuance date), the Company used the following inputs in its Black Scholes model:

	October 31, 2021	April 14, 2021
Exercise Price	$ 56.00	$ 56.00
Stock Price	$ 38.80	$ 45.60
Expected Term	5.00 years	5.00 years
Volatility %	106%	106%
Risk Free Rate	1.18%	0.85%

The September 2018 Public Offering warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of October 31, 2021, the down round feature was triggered three times and the exercise price of the warrants were reduced from $1,800.00 to $20.00. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the September 2018 Public Offering warrants at October 31, 2021 and October 31, 2020, the Company used the following inputs in its Monte Carlo simulation model:

	October 31, 2021	October 31, 2020
Exercise Price	$ 24.00	$ 29.60
Stock Price	$ 38.80	$ 27.20
Expected Term	2.87 years	3.87 years
Volatility %	123%	106%
Risk Free Rate	0.77%	0.29%

At October 31, 2021 and October 31, 2020, the fair value of the warrant liability was approximately $4.9 million and $17,000, respectively. For the years ended October 31, 2021 and 2020, the Company reported income of approximately $1.0 million and $0, respectively, due to changes in the fair value of the warrant liability.

9. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the consolidated statement of operations by expense category for the years ended October 31, 2021 and 2020 (in thousands):

	Year Ended October 31,	
	2021	2020
Research and development	$ 164	$ 308
General and administrative	402	583
Total	$ 566	$ 891

Amendments

The Advaxis, Inc. 2015 Incentive Plan (the "2015 Plan") was originally ratified and approved by the Company's stockholders on May 27, 2015. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of common stock that may be issued under the 2015 Plan is 3,000 shares, plus a number of additional shares (not to exceed 542) underlying awards outstanding as of the effective date of the 2015 Plan under the prior plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

On January 1, 2020, 2,083 shares were added to the 2015 Plan.

At the Annual Meeting of Stockholders of the Company held on May 4, 2020, the Company's stockholders voted to approve an amendment to increase the number of shares authorized for issuance under the 2015 Plan from 10,972 shares to 75,000 shares.

On January 1, 2021, 2,083 shares were added to the 2015 Plan.

As of October 31, 2021, there were 64,100 shares available for issuance under the 2015 Plan.

Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the fiscal year ended October 31, 2021 and 2020 is as follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Balance at October 31, 2019	183	$ 3,809.60
Vested	(110)	4,847.20
Cancelled	(4)	7,904.00
Balance at October 31, 2020	69	$ 1,945.60
Vested	(69)	1,945.60
Balance at October 31, 2021	-	$ -

The fair value of the RSUs as of the respective vesting dates was approximately $3,000 and $5,000 for the years ended October 31, 2021 and 2020, respectively.

Employee Stock Awards

Common stock issued to executives and employees related to vested incentive retention awards and employment inducements totaled 69 shares and 110 shares during the years ended October 31, 2021 and 2020, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2021 and 2020 was approximately $67,000 and $0.2 million, respectively.

Stock Options

A summary of changes in the stock option plan for the years ended October 31, 2021 and 2020 is as follows (in thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding as of October 31, 2019	7,022	$ 5,728.92	7.34	$ 1
Granted	8,073	48.69		
Cancelled or expired	(2,426)	2,765.64		
Outstanding as of October 31, 2020	12,669	$ 2,676.78	8.04	$ 4
Granted	625	31.20		
Exercised	(4)	24.00		
Cancelled or expired	(2,098)	7,903.21		
Outstanding as of October 31, 2021	11,192	$ 1,550.26	7.8	$ 34
Vested and exercisable at October 31, 2021	5,744	$ 2,957.17	6.98	$ 15

During the year ended October 31, 2021, the Company granted stock options to purchase 625 shares of its common stock to an employee. The stock options have a ten-year term, vest over three years from the date of grant, and have an exercise price of $31.20. During the year ended October 31, 2020, the Company granted stock options to purchase 7,260 and 813 shares of its common stock to employees and directors, respectively. The stock options issued to employees have a ten-year term, vest over three years, and have an exercise price of $39.20 to $52.80. The stock options issued to directors have a ten-year term, vest over three years, and have an exercise price of $52.80.

The weighted average grant date fair value of options granted during the fiscal years ended October 31, 2021 and 2020 was $31.20 and $48.69, respectively.

The total intrinsic value of options exercised during the fiscal years ended October 31, 2021 and 2020 was $162 and $0.

Total compensation cost related to the Company's outstanding stock options, recognized in the consolidated statement of operations for the years ended October 31, 2021 and 2020 was approximately $0.5 million and $0.7 million, respectively.

As of October 31, 2021, there was approximately $0.2 million of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.61 years.

The following table summarizes information about the outstanding and exercisable stock options at October 31, 2021:

Options Outstanding					Options Exercisable			
Exercise Price Range	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value	Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value
$ 24.00-$800.00	9,109	8.43	$ 85.12	$ 27	3,661	8.23	$ 112.22	$ 15
$ 800.01-$8,000.00	1,133	6.22	$ 2,323.42	$ -	1,133	6.22	$ 2,323.42	$ -
$ 8000.01-$16,000.00	638	3.47	$ 12,963.87	$ -	638	3.47	$ 12,963.87	$ -
$16,000.01-$22,200.00	312	2.22	$ 18,178.77	$ -	312	2.22	$ 18,178.77	$ -

The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2021 and 2020 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's common stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's common stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating expected lives of the options. The Company used their own historical volatility in determining the volatility to be used. The expected term of the stock option grants was calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 107. The "simplified" method was used since the Company believes its historical data does not provide a reasonable basis upon which to estimate expected term and the Company does not have enough option exercise data from its grants issued to support its own estimate as a result of vesting terms and changes in the stock price. The expected dividend yield is zero as the Company has never paid dividends to common shareholders and does not currently anticipate paying any in the foreseeable future.

The following table provides the weighted average fair value of stock options granted to directors and employees and the related assumptions used in the Black-Scholes model:

	Year Ended	
	October 31, 2021	October 31, 2020
Expected term	6 years	5.50-6.50 years
Expected volatility	103.27%	100.27-105.21%
Expected dividends	0%	0%
Risk free interest rate	0.53%	0.36-0.62%

Employee Stock Purchase Plan

The Advaxis, Inc. 2018 Employee Stock Purchase Plan (ESPP) was approved by the Company's shareholders on March 21, 2018. The 2018 ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated exercise dates. Employees were eligible to participate in the 2018 ESPP beginning May 1, 2018. 12,500 shares of the Company's Common stock were reserved for issuance under the 2018 ESPP.

During the fiscal years ended October 31, 2021 and 2020, the Company issued 12 and 176 shares, respectively, under the 2018 ESPP. In July 2021, the ESPP was terminated.

10. LICENSING AGREEMENTS

OS Therapies LLC

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, as amended, OST will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agreed to pay Advaxis $25,000 per month ("Monthly Payment") starting on April 30, 2020 until OST achieves its funding milestone of $2,337,500. Upon receipt of the first Monthly Payment, Advaxis will initiate the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST will enter negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

Provided that OST meets its ongoing obligation to make its Monthly Payments to Advaxis for six consecutive months, Advaxis agrees to transfer, and OST agrees to take full ownership of, the IND application for ADXS31-164 in its entirety to OST, along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development. Until OST makes its Monthly Payments to Advaxis for six consecutive months, Advaxis will continue to bear the costs of the regulatory filing services related to the IND application for ADXS31-164.

Within five business days of achieving the funding milestone of $2,337,500 for the performance of the Children's Oncology Group study (knowns as the "License Commencement Date"), OST will make a non-refundable and non-creditable payment to Advaxis of $1,550,000 less the cumulative Monthly Payments previously made (the "License Commencement Payment"). Within five days following the License Commencement Date, Advaxis will provide existing drug supply "as is" to OST, and until the drug supply is supplied to OST, Advaxis will bear the storage costs for the drug product. Pursuant to the agreement, the Company is also to receive sales-based milestone payments and royalties on future product sales. In addition, the Company and OST will establish a Joint Steering Committee to oversee the R&D activities.

The promises to (1) Maintain the HER2 product until transfer to OST, (2) Provide the IND application ownership for ADX321-164 to OST, (3) Participate in the Joint Steering Committee, (4) Transfer of IP & licensing rights of ADXS31-164 and related Patents, and (5) Provide Clinical Drug Supply represent one combined performance obligation for revenue recognition purposes. The Company concluded that the transfer of the IP and licensing rights provides OST with a functional, or "right to use," license, and thus the Company will recognize the upfront fees of $1,550,000 from the license at a point in time. The revenue from the transfer of the license cannot be recognized until the transfer of the corresponding IP to OST has occurred and OST has the ability to benefit from the right to use the license. As the right to use the license begins when OST makes the upfront payment within five days of the License Commencement Date and the IP transfers to OST at that time, the upfront fees from the license will be recognized upon the transfer of the intellectual property to OST.

Since OST is making $25,000 monthly payments that will be creditable against the $1,550,000, as well as additional upfront payments not specified in the contract, the Company will receive payments prior to the performance of the single distinct performance obligation. Due to this, the Company will defer any of the monthly payments until the IP and licensing rights are transferred to OST. However, if OST terminates the contract, which they are able to do with 60-day notice, the Company would recognize any of the payments received when the contract terminates. As of October 31, 2020, OST had made payments totaling $164,653 and this has been recorded as other liabilities in the consolidated balance sheet.

From May 2020 to January 2021, the Company received an aggregate of $1,615,000 from OS Therapies upon achievement of the funding milestone set forth in the license agreement, and recorded $1,615,000 in revenue. The Company therefore transferred and OST took full ownership of the IND application for ADXS31-164 in its entirety along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development.

On April 26, 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and recorded $1,375,000 in revenue. The Company received the amount due from OS Therapies of $1,375,000 in May 2021.

Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. (GBP), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the years ended October 31, 2021 and 2020, the Company recorded $0.25 million in revenue for the annual license fee renewal. Since Advaxis has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied when the license renews.

11. CONTINGENCIES

Legal Proceedings

Atachbarian

On November 15, 2021, a purported stockholder of the Company commenced an action against the Company and certain of its directors in the U.S. District Court for the District of New Jersey, entitled Atachbarian v. Advaxis, Inc., et al., No. 3:21-cv-20006. The plaintiff alleges that the defendants breached their fiduciary duties and violated Section 14(a) and Rule 20(a) of the Securities Exchange Act of 1934 and Rule 14A-9 promulgated thereunder by allegedly failing to disclose certain matters in the Registration Statement. On December 15, 2021, pursuant to an understanding reached with the plaintiff, the Company filed a Form 8-K with the SEC in which it made certain other additional disclosures that mooted the demands asserted in the complaint. On December 17, 2021, the plaintiff filed a notice of voluntary dismissal with prejudice. On February 7, 2022, the Company reached a settlement agreement, which is recorded in general and administrative expenses in the consolidated income statement.

Purported Stockholder Claims Related to Biosight Transaction

Between September 16, 2021, and November 4, 2021, the Company received demand letters on behalf of six purported stockholders of the Company, alleging that the Company failed to disclose certain matters in the Registration Statement, and demanding that the Company disclose such information in a supplemental disclosure filed with the SEC. On October 14, 2021, the Company filed an Amendment to the Registration Statement and on November 8, 2021, the Company filed a Form 8-K with the SEC in which it made certain other additional disclosures that mooted the demands asserted in the above-referenced letters. The six plaintiffs have made a settlement demand. The Company believes it has adequately accrued for a settlement, which is recorded in general and administrative expenses in the consolidated income statement.

In addition, the Company received certain additional demands from stockholders asserting that the proxy materials filed by the Company in connection with the Merger contained alleged material misstatements and/or omissions in violation of federal law. In response to these demands, the Company agreed to make, and did make, certain supplemental disclosures to the proxy materials. At this time, the Company is unable to predict the likelihood of an unfavorable outcome.

Stendhal

On September 19, 2018, Stendhal filed a Demand for Arbitration before the International Centre for Dispute Resolution (Case No. 01-18-0003-5013) relating to the Co-development and Commercialization Agreement with Especificos Stendhal SA de CV (the “Stendhal Agreement”). In the demand, Stendhal alleged that (i) the Company breached the Stendhal Agreement when it made certain statements regarding its AIM2CERV program, (ii) that Stendhal was subsequently entitled to terminate the Agreement for cause, which it did so at the time and (iii) that the Company owes Stendhal damages pursuant to the terms of the Stendhal Agreement. Stendhal is seeking to recover $3 million paid to the Company in 2017 as support payments for the AIM2CERV clinical trial along with approximately $0.3 million in expenses incurred. Stendhal is also seeking fees associated with the arbitration and interest. The Company has answered Stendhal’s Demand for Arbitration and denied that it breached the Stendhal Agreement. The Company also alleges that Stendhal breached its obligations to the Company by, among other things, failing to make support payments that became due in 2018 and that Stendhal therefore owes the Company $3 million. Advaxis is also seeking fees associated with the arbitration and interest.

From October 21-23, 2019, an evidentiary hearing for the arbitration was conducted. On April 1, 2020, the Arbitrator issued a final award denying Stendhal's claim in full. The Arbitrator found that the Company had not repudiated the Agreement and did not owe Stendhal damages, fees, or interest associated with the arbitration. The Arbitrator also denied the Company's claim that Stendhal breached its obligations to the Company. The parties were ordered to bear their own attorneys' fees and evenly split administrative fees and expenses for the arbitration.

12. LEASES

Operating Leases

The Company leased its corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that was set to expire in November 2025. The Company had the option to renew the lease term for two additional five-year terms. The renewal periods were not included the lease term for purposes of determining the lease liability or right-of-use asset. The Company provided a security deposit of approximately $182,000, which was recorded as other assets in the consolidated balance sheet as of October 31, 2020.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company does not have sufficient insight to determine an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized a synthetic credit rating model to determine a benchmark for its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for the lease.

- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

- Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.

- Variable lease payments, such as common area maintenance, real estate taxes, and property insurance are not included in the determination of the lease's right-of-use asset or lease liability.

On March 26, 2021, the Company entered into a Lease Termination and Surrender Agreement with respect to this lease agreement. The Lease Termination and Surrender Agreement provides for the early termination of the lease, which became effective on March 31, 2021. In connection with the early termination of the lease, the Company was required to pay a $1,000,000 termination payment. The unapplied security deposit totaling approximately $182,000 was credited against the termination fee for a net payment of approximately $818,000. The Company wrote off of the remaining right-of-use asset of approximately $4.5 million and lease liability of approximately $5.6 million. After consideration of the termination payment and write off of remaining right-of-use asset and lease liability, the Company recorded a net gain of approximately $0.1 million.

On March 25, 2021, the Company entered into a new lease agreement for its corporate office/lab with base rent of approximately $29,000 per year, plus other expenses. The lease expires on March 25, 2022 and the Company has the option to renew the lease for one additional successive one-year term upon six months written notice to the landlord. This new lease was accounted for as a short-term lease at inception, and the Company elected not to recognize a right-of-use asset and lease liability. In September 2021, the Company exercised its option to renew the lease, extending the lease term until March 25, 2023. Since the renewed lease term exceeds one-year, the lease no longer qualifies for the short-term lease exception, resulting in the recognition of a right-of-use asset and operating lease liability of approximately $43,000.

Supplemental balance sheet information related to leases as of October 31 was as follows (in thousands):

	October 31, 2021	October 31, 2020
Operating leases:		
Operating lease right-of-use assets	$ 40	$ 4,839
Operating lease liability	$ 28	$ 962
Operating lease liability, net of current portion	12	5,055
Total operating lease liabilities	$ 40	$ 6,017

Supplemental lease expense related to leases was as follows (in thousands):

Lease Cost (in thousands)	Statements of Operations Classification	For the Fiscal Year Ended October 31, 2021	For the Fiscal Year Ended October 31, 2020
Operating lease cost	General and administrative	$ 1,302	$ 1,158
Short-term lease cost	General and administrative	14	320
Variable lease cost	General and administrative	180	547
Total lease expense		$ 1,496	$ 2,025

Other information related to leases where the Company is the lessee is as follows:

	October 31, 2021	October 31, 2020
Weighted-average remaining lease term	1.4 years	5.1 years
Weighted-average discount rate	3.79%	6.5%

Supplemental cash flow information related to operating leases was as follows:

	For the Fiscal Year Ended October 31, 2021	For the Fiscal Year Ended October 31, 2020
Cash paid for operating lease liabilities	$ 547	$ 1,233

Future minimum lease payments under non-cancellable leases as of October 31, 2021 were as follows:

Fiscal Year ending October 31,	
2022	$ 29
2023	12
Total minimum lease payments	41
Less: Imputed interest	(1)
Total	$ 40

13. INCOME TAXES

The income tax provision (benefit) consists of the following (in thousands):

	October 31, 2021	October 31, 2020
Federal		
Current	$ -	$ -
Deferred	141	(4,578)
State and Local		
Current	-	-
Deferred	131	(1,445)
Foreign		
Current	50	50
Deferred	-	-
Change in valuation allowance	(272)	(6,023)
Income tax provision (benefit)	$ 50	$ 50

The Company has U.S. federal net operating loss carryovers ("NOLs") of approximately $314.8 million and $299.2 million at October 31, 2021 and 2020, respectively, available to offset taxable income. The Company has $56.0 million of NOLs which do not expire, the remainder of which are subject to expiration through 2038. The Company conducted an Internal Revenue Code Section 382 analysis through October 31, 2019. Based on that analysis, some NOLs incurred through October 31, 2019 are subject to limitation and will expire. Subsequent period NOLs have not been studied for the Internal Revenue Code Section 382 limitation. The Company also has New Jersey State Net Operating Loss carryovers of approximately $153.7 million and $137.6 million as of October 31, 2021 and 2020, respectively, available to offset future taxable income through 2041. Utilization of New Jersey NOLs may be similarly limited.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon future generation for taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the information available, management believes that significant uncertainty exists with respect to future realization of the deferred tax assets and has therefore established a full valuation allowance.

The Company evaluated the provisions of ASC 740 related to the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. ASC 740 prescribes a comprehensive model for how a company should recognize, present, and disclose uncertain positions that the company has taken or expects to take in its tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the net benefit recognized and measured pursuant to the interpretation are referred to as "unrecognized benefits." A liability is recognized (or amount of net operating loss carry forward or amount of tax refundable is reduced) for unrecognized tax benefit because it represents an enterprise's potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740.

If applicable, interest costs related to the unrecognized tax benefits are required to be calculated and would be classified as other expense in the consolidated statement of operations. Penalties would be recognized as a component of general and administrative expenses in the consolidated statement of operations.

No interest or penalties on unpaid tax were recorded during the years ended October 31, 2021 and 2020, respectively. As of October 31, 2021, and 2020, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the fiscal year ended October 31, 2018.

The Company's deferred tax assets (liabilities) consisted of the effects of temporary differences attributable to the following (in thousands):

	Years Ended	
	October 31, 2021	October 31, 2020
Deferred Tax Assets		
Net operating loss carryovers	$ 32,971	$ 28,553
Stock-based compensation	4,566	10,132
Research and development credits	11,371	10,742
Capitalized R&D costs	14,536	13,822
Adoption of ASC 842 – Lease Liability	11	1,691
Other deferred tax assets	92	224
Total deferred tax assets	$ 63,547	$ 65,164
Valuation allowance	(62,573)	(62,845)
Deferred tax asset, net of valuation allowance	$ 974	$ 2,319
Deferred Tax Liabilities		
Adoption of ASC 842 – ROU Asset	(11)	(1,360)
Patent cost	(943)	(917)
Other deferred tax liabilities	(20)	(42)
Total deferred tax liabilities	$ (974)	$ (2,319)
Net deferred tax asset (liability)	$ -	$ -

The expected tax (expense) benefit based on the statutory rate is reconciled with actual tax expense benefit as follows:

	Years Ended	
	October 31, 2021	October 31, 2020
US Federal statutory rate	21.00%	21.00%
State income tax, net of federal benefit	(0.73)	5.48
Merger costs	(1.68)	0.00
Other permanent differences	(0.02)	(0.05)
Research and development credits	3.09	1.73
Warrant Liability	1.14	0.00
Foreign taxes	(0.28)	(0.19)
Change in valuation allowance	1.52	(22.82)
Stock option expirations	(24.32)	(5.33)
Income tax (provision) benefit	(0.28)%	(0.19)%

The "Foreign taxes" income tax expense in the consolidated statement of operations for both the years ended October 31, 2021 and 2020 pertain to a Taiwan Excise tax of $50,000 levied in connection with the GBP Revenue.

14. FAIR VALUE

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of October 31, 2021 and October 31, 2020:

October 31, 2021	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	$ 17,153	$ -	$ -	$ 17,153
Common stock warrant liability, warrants exercisable at $24.00 through September 2024	-	-	27	27
Common stock warrant liability, warrants exercisable at $56.00 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants)	-	-	4,902	4,902
Total	$ 17,153	$ -	$ 4,929	$ 22,082

October 31, 2020	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	$ 17,149	$ -	$ -	$ 17,149
Common stock warrant liability, warrants exercisable at $29.76 through September 2024	-	-	17	17
	$ 17,149	$	$ 17	$ 17,166

The following table sets forth a summary of the changes in the fair value of the Company's warrant liabilities:

	Year Ended October 31,	
	2021	2020
Beginning balance	$ 17	$ 19
Warrants issued	5,882	-
Warrant exercises	-	(2)
Change in fair value	(970)	-
Ending balance	$ 4,929	$ 17

15. EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) Plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to approximately $0.1 million for each of the years ended October 31, 2021 and 2020, respectively. These amounts were charged to the consolidated statement of operations. The employer contributions vest immediately.

16. SUBSEQUENT EVENTS

On January 31, 2022, the Company closed on an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D convertible redeemable preferred stock. The shares to be sold have an aggregate stated value of $5,000,000. Each share of the Series D preferred stock has a purchase price of $4.75, representing an original issue discount of 5% of the stated value. The shares of Series D preferred stock are convertible into shares of the Company's common stock, upon the occurrence of certain events, at a conversion price of $20.00 per share. The conversion, at the option of the stockholder, may occur at any time following the receipt of the stockholders' approval for a reverse stock split. The Company will be permitted to compel conversion of the Series D preferred stock after the fulfillment of certain conditions and subject to certain limitations. The Series D preferred stock will also have a liquidation preference over the common stock, and may be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. The Company and the holders of the Series D preferred stock will also enter into a registration rights agreement to register the resale of the shares of common stock issuable upon conversion of the Series D preferred stock. Total gross proceeds from the offering, before deducting the financial advisor's fees and other estimated offering expenses, are $4.75 million.

ADVAXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	July 31, 2022 (Unaudited)	October 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,150	$ 41,614
Prepaid expenses and other current assets	1,667	1,643
Total current assets	29,817	43,257
Property and equipment (net of accumulated depreciation)	73	118
Intangible assets (net of accumulated amortization)	181	3,354
Operating right-of-use asset (net of accumulated amortization)	19	40
Other assets	11	11
Total assets	$ 30,101	$ 46,780
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 90	$ 87
Accrued expenses	1,510	2,836
Current portion of operating lease liability	19	28
Common stock warrant liability	287	4,929
Total current liabilities	1,906	7,880
Operating lease liability, net of current portion	-	12
Total liabilities	1,906	7,892
Contingencies – Note 8		
Series D convertible preferred stock- $0.001 par value; 0 shares authorized, 0 shares issued and outstanding at July 31, 2022 and October 31, 2021.	-	-
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding at July 31, 2022 and October 31, 2021.	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 1,815,951 and 1,820,452 shares issued and outstanding at July 31, 2022 and October 31, 2021.	2	2
Additional paid-in capital	466,561	467,486
Accumulated deficit	(438,368)	(428,600)
Total stockholders' equity	28,195	38,888
Total liabilities and stockholders' equity	$ 30,101	$ 46,780

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except share and per share data)

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2022	2021	2022	2021
Revenue	$ -	$ 250	$ 250	$ 3,240
Operating expenses:				
Research and development expenses	2,233	1,703	5,371	8,616
General and administrative expenses	2,053	2,678	6,331	9,038
Intangible asset impairment	3,005	-	3,005	-
Total operating expenses	7,291	4,381	14,707	17,654
Loss from operations	(7,291)	(4,131)	(14,457)	(14,414)
Other income (expense):				
Interest income, net	50	1	57	3
Net changes in fair value of derivative liabilities	276	846	4,685	1,814
Other income (expense)	2	-	(3)	229
Net loss before income taxes	(6,963)	(3,284)	(9,718)	(12,368)
Income tax expense	-	50	50	50
Net loss	$ (6,963)	$ (3,334)	$ (9,768)	$ (12,418)
Accretion of discount and redemption feature of convertible preferred stock	-	-	(1,025)	-
Income available to common stockholders	(6,963)	(3,334)	(10,793)	(12,418)
Net loss per common share, basic and diluted	$ (3.83)	$ (1.83)	$ (5.93)	$ (8.04)
Weighted average number of common shares outstanding	1,817,761	1,820,452	1,819,545	1,543,927

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine Months Ended July 31,	
	2022	2021
OPERATING ACTIVITIES		
Net loss	$ (9,768)	$ (12,418)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	74	511
Gain on change in value of warrants	(4,642)	(1,814)
Gain on change in value of preferred stock redemption liability	(43)	-
Loss on disposal of property and equipment	-	1,530
Abandonment of intangible assets	159	90
Impairment charges on intangible assets	3,005	-
Depreciation expense	45	366
Amortization expense of intangible assets	210	203
Amortization of right-of-use asset	21	327
Net gain on write-off of right-of-use asset and lease liability	-	(116)
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and deferred expenses	(24)	488
Other assets	-	171
Accounts payable and accrued expenses	(1,323)	513
Deferred revenue	-	(165)
Operating lease liabilities	(21)	(1,389)
Net cash used in operating activities	(12,307)	(11,703)
INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	-	219
Cost of intangible assets	(201)	(323)
Net cash used in investing activities	(201)	(104)
FINANCING ACTIVITIES		
Net proceeds of issuance of Series D preferred stock	4,312	-
Net proceeds of issuance of common stock and warrants	-	28,115
Fractional shares cashed out	(18)	-
Redemption of Series D preferred stock	(5,250)	-
Warrant exercises	-	3,771
Net cash (used in) provided by financing activities	(956)	31,886
Net (decrease) increase in cash and cash equivalents	(13,464)	20,079
Cash and cash equivalents at beginning of period	41,614	25,178
Cash and cash equivalents at end of period	$ 28,150	$ 45,257
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for taxes	$ 50	$ 50
SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES		
Reclassification of preferred stock redemption liability into equity upon redemption of preferred stock	44	-
Accretion of discount and redemption feature of convertible preferred stock	1,025	-

The accompanying notes should be read in conjunction with the financial statements.

1. NATURE OF OPERATIONS

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Advaxis' proprietary approach is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- Alerting and training the immune system by activating multiple pathways in Antigen-Presenting Cells ("APCs") with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment ("TME") that shields the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

COVID-19

On March 11, 2020, the World Health Organization characterized the outbreak of the novel coronavirus ("COVID-19") as a global pandemic and recommended containment and mitigation measures. Since then, extraordinary actions have been taken by international, federal, state, and local public health and governmental authorities to contain and combat the outbreak and spread of COVID-19 in regions throughout the world. The continued impact of the COVID-19 pandemic cannot be predicted at this time.

Liquidity and Capital Resources

Liquidity and Management's Plans

Similar to other development stage biotechnology companies, the Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for the foreseeable future.

As of July 31, 2022, the Company had approximately $28.2 million in cash and cash equivalents. Although the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least one year from the issuance of these consolidated financial statements, the actual amount of cash that it will need to operate is subject to many factors.

The Company recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation/Estimates

The accompanying unaudited interim condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information, and in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and the accompanying unaudited interim condensed consolidated balance sheet as of July 31, 2022 has been derived from the Company's October 31, 2021 audited financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements furnished include all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods presented.

Operating results for interim periods are not necessarily indicative of the results to be expected for the full year. The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates include the timelines associated with revenue recognition on upfront payments received, fair value and recoverability of the carrying value of property and equipment and intangible assets, fair value of warrant liability, grant date fair value of options, deferred tax assets and any related valuation allowance and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could materially differ from these estimates.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the financial statements of the Company as of and for the fiscal year ended October 31, 2021 and notes thereto contained in this proxy statement/prospectus.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

Restricted Cash

On January 31, 2022, the Company transferred $5,250,000 into an escrow fund to fund a potential Series D preferred stock redemption. On April 6, 2022, the Series D convertible preferred stock was redeemed utilizing the entire amount held in the escrow fund.

Convertible Preferred Stock

Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For share-based derivative financial instruments, the Company used the Monte Carlo simulation model, the Black Scholes model and a binomial model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months after the balance sheet date.

Net Income (Loss) per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units and other potential common stock outstanding during the period. In the case of a net loss, the impact of the potential common stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential common stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table below sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share:

	As of July 31,	
	2022	2021
Warrants	377,818	377,818
Stock options	11,118	12,892
Total	388,936	390,710

Reverse Stock Split

On March 31, 2022, the Company's stockholders voted to approve an amendment to allow the Company to execute a reverse stock split of common stock within a range of 1 for 20 to 1 for 80, without reducing the authorized number of shares of the common stock, at the discretion of the Board of Directors. On June 3, 2022, the Board of Directors approved a 1 for 80 reverse stock split, which became effective on June 6, 2022. All references in this Report to number of shares, price per share and weighted average number of shares of common stock outstanding prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis, unless otherwise noted.

Recent Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Simplification of Income Taxes (Topic 740) Income Taxes ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for public companies for annual periods beginning after December 15, 2020, including interim periods within those fiscal years. The Company adopted this standard effective November 1, 2021 and it is not material to the financial results of the Company.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain convertible instruments, amends guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share ("EPS") calculations as a result of these changes. The standard will be effective for the Company for fiscal years beginning after December 15, 2023 and can be applied on either a fully retrospective or modified retrospective basis. Early adoption is permitted for fiscal years beginning after December 15, 2020. The Company adopted this standard effective November 1, 2021 and it is not material to the financial results of the Company.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying condensed consolidated financial statements.

3. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following (in thousands):

	July 31, 2022	October 31, 2021
Laboratory equipment	$ 179	$ 179
Computer equipment	241	241
Total property and equipment	420	420
Accumulated depreciation	(347)	(302)
Net property and equipment	$ 73	$ 118

Depreciation expense for the three months ended July 31, 2022 and 2021 was approximately $13,000 and $50,000, respectively. Depreciation expense for the nine months ended July 31, 2022 and 2021 was approximately $45,000 and $366,000, respectively. During the nine months ended July 31, 2021, the Company incurred a loss on disposal of equipment of approximately $1,530,000, $968,000 of which is reflected in the research and development expenses and $562,000 of which is reflected in the general and administrative expenses in the condensed consolidated statement of operations.

4. INTANGIBLE ASSETS

Intangible assets, net consisted of the following (in thousands):

	July 31, 2022	October 31, 2021
Patents	$ 275	$ 4,836
License	44	777
Software	98	98
Total intangibles	417	5,711
Accumulated amortization	(236)	(2,357)
Intangible assets	$ 181	$ 3,354

The expiration dates of the existing patents range from 2022 to 2039 but the expiration dates can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to further pursue the application. Patent applications having a net book value of approximately $29,000 and $21,000 were abandoned and were charged to general and administrative expenses in the condensed consolidated statement of operations for the three months ended July 31, 2022 and 2021, respectively. Patent applications having a net book value of approximately $159,000 and $90,000 were abandoned and were charged to general and administrative expenses in the condensed consolidated statement of operations for the nine months ended July 31, 2022 and 2021, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the condensed consolidated statement of operations aggregated approximately $70,000 and $68,000 for the three months ended July 31, 2022 and 2021, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the condensed consolidated statement of operations aggregated approximately $210,000 and $203,000 for the nine months ended July 31, 2022 and 2021, respectively.

Management reviews its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents related to ADXS-HPV (AXAL), ADXS-HOT, ADXS-PSA, ADXS-HER2 and other products that are in development, and the *Lm* technology licensed from the University of Pennsylvania. There are various scenarios under which an impairment charge may be recorded, which include if a competitor were to gain FDA approval for a similar treatment before the Company, if future clinical trials fail to meet the targeted endpoints, or if a drug application is rejected or fails to be issued. Lastly, if the Company is unable to raise enough capital to continue funding its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

During the three months ended July 31, 2022, the Company identified the following indicators of impairment under ASC 360 indicating that the patents and license carrying amounts might not be recoverable:

- Adverse changes in the business climate for biotechnology companies, particularly raising capital; and
- A significant reduction in the Company's market capitalization during the nine months ended July 31, 2022.

The Company performed an impairment test under ASC 350 on its patents owned and in-licensed intellectual property. Under this test a fair value of the relevant asset is compared with the carrying amount of such asset. Fair value is calculated using a discounted cash flow analysis. Cash flows are discounted using a weighted average cost of capital derived from comparable companies, which reflects the costs of borrowing as well as the associated risk. The results of the impairment test indicated that the carrying value of the patents owned and in-licensed intellectual property exceeded the fair value. During the three months ended July 31, 2022, the Company recorded an impairment charge for patents owned and in-licensed intellectual property of approximately $3,005,000 in its condensed consolidated statement of operations.

As of July 31, 2022, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

	Fiscal year ending October 31,
2022 (Remaining)	$ 24
2023	94
2024	63
Total	$ 181

5. ACCRUED EXPENSES:

The following table summarizes accrued expenses included in the condensed consolidated balance sheets (in thousands):

	July 31, 2022	October 31, 2021
Salaries and other compensation	$ 116	$ 55
Vendors	851	1,968
Professional fees	343	613
Other	200	200
Total accrued expenses	$ 1,510	$ 2,836

6. LEASES

Operating Leases

The Company previously leased a corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that was set to expire in November 2025. On March 26, 2021, the Company entered into a Lease Termination and Surrender Agreement with respect to this lease agreement. The Lease Termination and Surrender Agreement provides for the early termination of the lease, which became effective on March 31, 2021. In connection with the early termination of the lease, the Company was required to pay a $1,000,000 termination payment. The unapplied security deposit totaling approximately $182,000 was credited against the termination fee for a net payment of approximately $818,000. The Company wrote off of the remaining right-of-use asset of approximately $4,512,000 and lease liability of approximately $5,628,000. After consideration of the termination payment and write off of the remaining right-of-use asset and lease liability, the Company recorded a net gain of approximately $116,000.

On March 25, 2021, the Company entered into a new one-year lease agreement for its corporate office/lab with base rent of approximately $29,000 per year, plus other expenses. This lease was accounted for as a short-term lease at inception, and the Company elected not to recognize a right-of-use asset and lease liability. In September 2021, the Company exercised its option to renew the lease, extending the lease term until March 25, 2023. Since the renewed lease term exceeded one-year, the lease no longer qualified for the short-term lease exception, resulting in the recognition of a right-of-use asset and operating lease liability of approximately $43,000.

Supplemental balance sheet information related to leases was as follows (in thousands):

	July 31, 2022	October 31, 2021
Operating leases:		
Operating lease right-of-use assets	$ 19	$ 40
Operating lease liability	$ 19	$ 28
Operating lease liability, net of current portion	-	12
Total operating lease liabilities	$ 19	$ 40

Supplemental lease expense related to leases was as follows (in thousands):

Lease Cost (in thousands)	Statements of Operations Classification	For the Three Months Ended July 31, 2022	For the Nine Months Ended July 31, 2022
Operating lease cost	General and administrative	$ 7	$ 22
Variable lease cost	General and administrative	17	36
Total lease expense		$ 24	$ 58

Lease Cost (in thousands)	Statements of Operations Classification	For the Three Months Ended July 31, 2021	For the nine Months Ended July 31, 2021
Operating lease cost	General and administrative	$ -	$ 1,301
Short-term lease cost	General and administrative	12	16
Variable lease cost	General and administrative	4	165
Total lease expense		$ 16	$ 1,482

Other information related to leases where the Company is the lessee is as follows:

	July 31, 2022	October 31, 2021
Weighted-average remaining lease term	0.7 years	1.4 years
Weighted-average discount rate	3.79%	3.79%

Supplemental cash flow information related to operating leases was as follows:

	For the Nine Months Ended July 31, 2022	For the Nine Months Ended July 31, 2021
Cash paid for operating lease liabilities	$ 22	$ 1,363

Future minimum lease payments under non-cancellable leases as of July 31, 2022 were as follows:

Fiscal Year ending October 31,	
2022 (Remaining)	$ 7
2023	13
Total minimum lease payments	20
Less: Imputed interest	1
Total	$ 19

7. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

Warrants

As of July 31, 2022 and October 31, 2021, there were outstanding and exercisable warrants to purchase 377,818 shares of our common stock with exercise prices ranging from $20.00 to $224.00 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Type of Financing
$ 20.00	879	September 2024	September 2018 Public Offering
$ 224.00	4,092	July 2024	July 2019 Public Offering
$ 28.00	57,230	November 2025	November 2020 Public Offering
$ 56.00	140,552	April 2026	April 2021 Registered Direct Offering (Accompanying Warrants)
$ 56.00	175,065	5 years after the date such warrants become exercisable, if ever	April 2021 Private Placement (Private Placement Warrants)
Grand Total	377,818		

As of July 31, 2022 and October 31, 2021, the Company had 201,874 of its total 377,818 outstanding warrants classified as equity (equity warrants).

Warrant Liability

As of July 31, 2022 and October 31, 2021, the Company had 175,944 of its total 377,818 outstanding warrants from an April 2021 private offering of common stock and warrants (the "April 2021 Private Placement") and a September 2018 public offering of common stock and warrants (the "September 2018 Public Offering") classified as liabilities (liability warrants).

The warrants issued in the April 2021 Private Placement will become exercisable only on such day, if ever, that is 14 days after the Company files an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares. These warrants expire five years after the date they become exercisable. As of July 31, 2022, the Company did not have sufficient authorized common stock to allow for the issuance of common stock underlying these warrants. The Company did not receive stockholder authorization to increase the authorized shares from 170,000,000 to 300,000,000 shares at the stockholder's meeting commenced on June 3, 2021. The Company was subsequently required to file a proxy to seek an increase in the number of authorized shares and did not file such a proxy but rather elected to seek a reverse stock split to, among other things, increase the shares available. Accordingly, based on certain indemnification provisions of the securities purchase agreement, the Company concluded that liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement at July 31, 2022 and October 31, 2021, the Company used the following inputs in its Black Scholes model:

	July 31, 2022	October 31, 2021
Exercise Price	$ 56.00	$ 56.00
Stock Price	$ 3.73	$ 38.80
Expected Term	5.00 years	5.00 years
Volatility %	112%	106%
Risk Free Rate	2.70%	1.18%

The September 2018 Public Offering warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of July 31, 2022, the down round feature was triggered four times and the exercise price of the warrants were reduced from $1,800.00 to $20.00. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the September 2018 Public Offering warrants at July 31, 2022 and October 31, 2021, the Company used the following inputs in its Monte Carlo simulation model:

	July 31, 2022	October 31, 2021
Exercise Price	$ 20.00	$ 24.00
Stock Price	$ 3.73	$ 38.80
Expected Term	2.12 years	2.87 years
Volatility %	104%	123%
Risk Free Rate	2.89%	0.77%

At July 31, 2022 and October 31, 2021, the fair value of the warrant liability was approximately $287,000 and $4,929,000, respectively. For the three months ended July 31, 2022 and 2021, the Company reported income of approximately $276,000 and $846,000, respectively, due to changes in the fair value of the warrant liability. For the nine months ended July 31, 2022 and 2021, the Company reported income of approximately $4,642,000 and $1,814,000, respectively, due to changes in the fair value of the warrant liability.

8. COMMITMENTS AND CONTINGENCIES

Atachbarian

On November 15, 2021, a purported stockholder of the Company commenced an action against the Company and certain of its directors in the U.S. District Court for the District of New Jersey, entitled Atachbarian v. Advaxis, Inc., et al., No. 3:21-cv-20006. The plaintiff alleges that the defendants breached their fiduciary duties and violated Section 14(a) and Rule 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder by allegedly failing to disclose certain matters in its Registration Statement on Form S-4 (Commission File No. 333-259065 (the "Registration Statement") filed in connection with a proposed merger with Biosight Ltd. (the "Previously Proposed Merger"). On December 15, 2021, pursuant to an understanding reached with the plaintiff, the Company made certain other additional disclosures that mooted the demands asserted in the complaint. On December 17, 2021, the plaintiff filed a notice of voluntary dismissal with prejudice. On February 7, 2022, the Company and the plaintiff reached a settlement agreement, which is recorded in general and administrative expenses in the condensed consolidated statement of operations.

Purported Stockholder Claims Related to Biosight Transaction

Between September 16, 2021, and November 4, 2021, the Company received demand letters on behalf of six purported stockholders of the Company, alleging that the Company failed to disclose certain matters in the Registration Statement, and demanding that the Company disclose such information in a supplemental disclosure filed with the SEC. On October 14, 2021, the Company filed an amendment to the Registration Statement and on November 8, 2021, the Company made certain other additional disclosures that mooted the demands asserted in the above-referenced letters. The six plaintiffs have made settlement demands. On May 20, 2022, the Company and one of the plaintiffs have reached a settlement agreement, which is recorded in general and administrative expenses in the condensed consolidated statement of operations. The Company believes it has adequately accrued for settlements with the other five shareholders, which is recorded in accrued expenses in the condensed consolidated balance sheet.

In addition, the Company received certain additional demands from stockholders asserting that the proxy materials filed by the Company in connection with the Previously Proposed Merger contained alleged material misstatements and/or omissions. Certain stockholders also demanded books and records of the Company pursuant to Delaware law. In response to these demands, the Company agreed to make, and did make, certain supplemental disclosures to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs reached settlement agreements, which is recorded in general and administrative expenses in the condensed consolidated statement of operations.

Purported Stockholder Claims Related to Series D Convertible Preferred Stock Offering

On February 17, 2022, the Company received a letter on behalf of purported stockholders of the Company, demanding certain books and records pursuant to Delaware law regarding the proposed issuance of super voting preferred stock. The Company agreed to provide certain books and records to the stockholders and agreed to make, and did make, a supplemental disclosure to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs reached settlement agreements, which is recorded in general and administrative expenses in the condensed consolidated statement of operations.

9. TEMPORARY EQUITY

Series D Convertible Preferred Stock Offering

On January 31, 2022, the Company consummated an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D convertible redeemable preferred stock (the "Series D Preferred Stock"). The shares, which have since been redeemed in accordance with their terms as described below, and are thus no longer outstanding as of July 31, 2022, had an aggregate stated value of $5,000,000. Each share of the Series D preferred stock had a purchase price of $4.75, representing an original issue discount of 5% of the stated value. The shares of Series D Preferred Stock were convertible into shares of the Company's common stock, upon the occurrence of certain events, at a conversion price of $20.00 per share. The conversion, at the option of the stockholder, could occur at any time following the receipt of the stockholders' approval for a reverse stock split. The Company was permitted to compel conversion of the Series D Preferred Stock after the fulfillment of certain conditions and subject to certain limitations. The Series D Preferred Stock also had a liquidation preference over the shares of common stock, and could be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. Total net proceeds from the offering, after deducting the financial advisor's fees and other estimated offering expenses, were approximately $4.3 million.

Since the Series D preferred stock had a redemption feature at the option of the holder, it was classified as temporary equity. At the January 31, 2022 issuance date, the Series D preferred stock was recorded on the balance sheet at approximately $4,225,000, which is the $4,312,000 net proceeds less the $87,000 value of the bifurcated preferred stock redemption liability (see below).

On April 6, 2022, the holders of all 1,000,000 outstanding shares of the Series D Preferred Stock exercised their right to cause the Company to redeem all of such shares at a price per share equal to 105% of the stated value per share of $5.00, and such shares were redeemed accordingly. The $1,025,000 accretion of the Series D convertible preferred stock to its redemption value was recorded as a reduction in additional paid-in capital (see Note 10).

Preferred Stock Redemption Liability

The Company evaluated the preferred stock redemption feature under ASC 815. Since the preferred stock redemption feature is not considered to be clearly and closely related to the preferred stock host and the redemption feature meets the four characteristics of a derivative under ASC 815, the preferred stock redemption feature is required to be bifurcated from the preferred stock host and valued as a liability. The Company utilized a binomial model to calculate the fair value of the preferred stock redemption feature at issuance.

In measuring the preferred stock redemption liability at April 6, 2021 (redemption date) and January 31, 2022 (issuance date), the Company used the following inputs in its binomial model:

	April 6, 2022	January 31, 2022
Exercise Price	$ 20.00	$ 20.00
Stock Price	$ 9.04	$ 10.88
Volatility %	96%	105%
Risk Free Rate	1.25%	1.00%

At April 6, 2022 and January 31, 2022, the fair value of the preferred stock redemption liability was approximately $44,000 and $87,000, respectively. On April 6, 2022, the Series D convertible preferred stock was redeemed, and the $44,000 preferred stock redemption liability was reclassified into other paid-in capital (see Note 10). For the three months and nine months ended July 31, 2022, the Company reported income of approximately $0 and $44,000, respectively, due to a change in the fair value of the preferred stock redemption liability.

10. STOCKHOLDERS' EQUITY

A summary of the changes in stockholders' equity for the nine months ended July 31, 2022 and 2021 is presented below (in thousands, except share data):

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance at November 1, 2020	-	$ -	975,897	$ 1	$ 440,917	$ (410,738)	$ 30,180
Stock-based compensation	-	-	-	-	236	-	236
Advaxis public offerings, net of offering costs	-	-	383,333	1	8,549	-	8,550
Warrant exercises	-	-	92,375	-	2,586	-	2,586
Net loss	-	-	-	-	-	(3,977)	(3,977)
Balance at January 31, 2021	-	$ -	1,451,605	$ 2	$ 452,288	$ (414,715)	$ 37,575
Stock-based compensation	-	-	69	-	215	-	215
Stock option exercises	-	-	4	-	-	-	-
Advaxis public offerings, net of offering costs	-	-	230,794	-	13,683	-	13,683
Warrant exercises	-	-	137,968	-	1,185	-	1,185
Issuance of shares to employees under ESPP Plan	-	-	12	-	-	-	-
Net loss	-	-	-	-	-	(5,107)	(5,107)
Balance at April 30, 2021	-	$ -	1,820,452	$ 2	$ 467,371	$ (419,822)	$ 47,551
Stock-based compensation	-	-	-	-	60	-	60
Net loss	-	-	-	-	-	(3,334)	(3,334)
Balance at July 31, 2021	-	$ -	1,820,452	$ 2	$ 467,431	$ (423,156)	$ 44,277

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance at November 1, 2021	-	$ -	1,820,452	$ 2	$ 467,486	$ (428,600)	$ 38,888
Stock-based compensation	-	-	-	-	26	-	26
Net loss	-	-	-	-	-	(365)	(365)
Balance at January 31, 2022	-	$ -	1,820,452	$ 2	$ 467,512	$ (428,965)	$ 38,549
Stock-based compensation	-	-	-	-	23	-	23
Accretion of discount and redemption feature of convertible preferred stock	-	-	-	-	(1,025)	-	(1,025)
Convertible preferred stock redemption	-	-	-	-	44	-	44
Net loss	-	-	-	-	-	(2,440)	(2,440)
Balance at April 30, 2022	-	$ -	1,820,452	$ 2	$ 466,554	$ (431,405)	$ 35,151
Stock-based compensation	-	-	-	-	25	-	25
Fractional shares cashed out	-	-	(4,501)	-	(18)	-	(18)
Net loss	-	-	-	-	-	(6,963)	(6,963)
Balance at July 31, 2022	-	-	1,815,951	2	466,561	(438,368)	28,195

11. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the condensed consolidated statements of operations (in thousands):

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2022	2021	2022	2021
Research and development	$ 12	$ 29	$ 36	$ 142
General and administrative	13	31	38	369
Total	$ 25	$ 60	$ 74	$ 511

Stock Options

A summary of changes in the stock option plan for the nine months ended July 31, 2022 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value (in thousands)
Outstanding as of October 31, 2021	11,192	$ 1,550.26	7.80	$ 34
Cancelled or expired	(74)	22,200.00		
Outstanding as of July 31, 2022	11,118	$ 1,412.82	7.06	$ -
Vested and exercisable at July 31, 2022	7,490	$ 2,077.20	6.64	$ -

The following table summarizes information about the outstanding and exercisable options at July 31, 2022:

	Options Outstanding			Options Exercisable		
Exercise Price Range	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price
$ 24.00-$50.00	4,241	7.86	$ 32.53	1,964	7.69	$ 30.40
$ 50.01-$100.00	4,174	7.74	$ 53.33	2,824	7.73	$ 53.58
$ 100.01-20,664.00	2,703	4.75	$ 5,677.84	2,703	4.75	$ 5,677.84

As of July 31, 2022, there was approximately $77,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of 0.94 years.

Potential Acceleration of Stock Options

In the event of a merger transaction, similar to the Previously Proposed Merger Agreement, all of the Chief Executive Officer's 624 unvested stock options as of July 31, 2022, pursuant to his employment agreement, would accelerate.

12. LICENSING AGREEMENTS

OS Therapies LLC

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, as amended, OST will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agreed to pay Advaxis $25,000 per month ("Monthly Payment") starting on April 30, 2020 until it achieved its funding milestone of $2,337,500. Upon receipt of the first Monthly Payment, Advaxis initiated the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST will enter negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

In December 2020 and January 2021, the Company received an aggregate of $1,615,000 from OS Therapies upon achievement of the funding milestone set forth in the license agreement and recorded $1,615,000 in revenue. The Company therefore transferred, and OST took full ownership of, the IND application for ADXS31-164 in its entirety along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development.

In April 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and recorded $1,375,000 in revenue. The Company received the amount due from OS Therapies of $1,375,000 in May 2021.

Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. ("GBP"), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the nine months ended July 31, 2022 and 2021, the Company recorded $250,000 in revenue for the annual license fee renewal. Since Advaxis has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied when the license renews.

13. FAIR VALUE

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

● Level 1 — Quoted prices in active markets for identical assets or liabilities.

● Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.

● Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of July 31, 2022 and October 31, 2021 (in thousands):

Fair Value Measured at July 31, 2022

	Level 1	Level 2	Level 3	Total
Financial assets at fair value:				
Cash equivalents (money market funds)	$ 17,183	$ -	$ -	$ 17,183
Total Financial Assets at Fair Value	**$ 17,183**	**$ -**	**$ -**	**$ 17,183**
Financial liabilities at fair value:				
Common stock warrant liability, warrants exercisable at $20.00 through September 2024	$ -	$ -	$ 2	$ 2
Common stock warrant liability, warrants exercisable at $56.00 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants)	-	-	285	285
Total financial liabilities at fair value	**$ -**	**$ -**	**$ 287**	**$ 287**

Fair Value Measured at October 31, 2021

	Level 1	Level 2	Level 3	Total
Financial assets at fair value:				
Cash equivalents (money market funds)	$ 17,153	$ -	$ -	$ 17,153
Total Financial Assets at Fair Value	**$ 17,153**	**$ -**	**$ -**	**$ 17,153**
Financial liabilities at fair value:				
Common stock warrant liability, warrants exercisable at $24.00 through September 2024	$ -	$ -	$ 27	$ 27
Common stock warrant liability, warrants exercisable at $56.00 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants)	-	-	4,902	4,902
Total financial liabilities at fair value	**$ -**	**$ -**	**$ 4,929**	**$ 4,929**

The following table presents changes in Level 3 liabilities measured at fair value (in thousands) for the nine months ended July 31, 2022. Unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category.

	Preferred Stock Redemption Liability	Warrant Liabilities	**Total**
Fair value at October 31, 2021	**$ -**	**$ 4,929**	**$ 4,929**
Additions	87	-	87
Change in fair value	(43)	(4,642)	(4,685)
Redemption	(44)	-	(44)
Fair value at July 31, 2022	**$ -**	**$ 287**	**$ 287**

14. SUBSEQUENT EVENTS

Merger with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Company entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with Ayala Pharmaceuticals, Inc. ("Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis. Under the terms of the agreement, the Merger Sub will merge with and into Ayala, with Ayala continuing as the surviving company and a wholly-owned subsidiary of Advaxis (the "Merger"). Immediately after the merger, existing Advaxis stockholders are expected to own approximately 37.5% of the outstanding shares of the combined company and former Ayala shareholders are expected to own approximately 62.5% of the outstanding shares of the combined company. The merger will be accounted for a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Ayala issued and outstanding immediately prior to the Effective Time will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share, equal to the exchange ratio, 0.1874 shares of Advaxis common stock per Ayala share.

If the Merger Agreement is terminated under certain circumstances, Advaxis or Ayala, as applicable, will be required to pay the other party a termination fee up to $600,000.

Series E Preferred Stock

On December 1, 2022, Advaxis filed a certificate of designation (the "Certificate of Designation") with the Secretary of State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the shares of Advaxis' Series E Preferred Stock (the "Series E Preferred Stock"). The Certificate of Designation provides that ten (10) shares of Series E Preferred Stock will have 200,000,000 votes each and will vote together with the outstanding shares of the Advaxis Common Stock as a single class exclusively with respect to any proposal to amend the Advaxis Charter to change the name of Advaxis and to effect a reverse stock split of the Advaxis Common Stock. Also on December 1, 2022, the Company issued all ten (10) authorized shares of Series E Preferred Stock. The holder of these shares has agreed to vote all of such shares on any proposal to amend the Advaxis Charter to change the name of Advaxis and to effect a reverse stock split of the Advaxis Common Stock in the same proportion as shares of Advaxis Common Stock are voted on such proposal. The Series E Preferred Stock otherwise has no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series E Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of Advaxis. The Series E Preferred Stock has no rights with respect to any distribution of assets of Advaxis, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of Advaxis, whether voluntarily or involuntarily. The holder of the Series E Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding shares of Series E Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by the Advaxis Board in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Advaxis Charter implementing a reverse stock split. Upon such redemption, the holder of the Series E Preferred Stock will receive consideration of $1,000 per share in cash.

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Report of Independent Registered Public Accounting Firm
To the Shareholders and the Board of Directors of

AYALA PHARMACEUTICALS, INC.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Ayala Pharmaceuticals, Inc. (the Company) as of December 31, 2021 and 2020, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a negative cash flows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KOST FORER GABBAY & KASIERER

A Member of Ernst & Young Global

We have served as the Company's auditor since 2017.

Tel-Aviv, Israel

March 28, 2022

AYALA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and Cash Equivalents	$ 36,982	$ 42,025
Short-Term Restricted Bank Deposits	122	90
Trade Receivables	-	681
Prepaid Expenses and Other Current Assets	2,636	1,444
Total Current Assets	39,740	44,240
Long-Term Assets:		
Other Assets	267	305
Property and Equipment, Net	1,120	1,283
Total Long-Term Assets	1,387	1,588
Total Assets	$ 41,127	$ 45,828
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Trade Payables	$ 3,214	$ 3,726
Other Accounts Payables	3,258	3,151
Total Current Liabilities	6,472	6,877
Long-Term Liabilities:		
Long-Term Rent Liability	497	553
Total Long-Term Liabilities	$ 497	$ 553
Stockholders' Equity:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at December 31, 2021 and 2020; 14,080,383 and 12,824,463 shares issued at December 31, 2021 and 2020, respectively; 13,956,035 and 12,728,446 shares outstanding at December 31, 2021 and 2020, Respectively.	$ 139	$ 128
Additional Paid-in Capital	145,160	109,157
Accumulated Deficit	(111,141)	(70,887)
Total Stockholders' Equity	34,158	38,398
Total Liabilities and Stockholders' Equity	$ 41,127	$ 45,828

The accompanying notes are an integral part of the consolidated financial statements.

AYALA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except shares and per shares data)

	Year ended December 31, 2021	Year ended December 31, 2020
Revenue from License Agreement	$ 3,506	$ 3,708
Cost of Revenue	(3,506)	(3,708)
Gross Profit	—	—
Research and Development	$ 29,941	$ 22,406
General and Administrative	9,277	7,371
Operating Loss	(39,218)	(29,777)
Financial income (expenses), net	(260)	56
Loss before taxes on income	(39,478)	(29,721)
Taxes on Income	(776)	(425)
Net Loss	$ (40,254)	$ (30,146)
Net Loss per Share attributable to Common Stockholders, Basic and Diluted	$ (2.80)	$ (3.06)
Weighted Average Shares Used to Compute Net Loss per Share, Basic and Diluted	14,398,905	9,860,610

The accompanying notes are an integral part of the consolidated financial statements.

AYALA PHARMACEUTICALS, INC.

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars in thousands (except share amounts)

	Convertible Preferred Stock									
	Series A Preferred Stock		Series B Preferred Stock		Total	Common Stock		Additional paid-in	Accumulated	Total Stockholders' (Deficit)
	Number	Amount	Number	Amount	Amount	Number	Amount	capital	Deficit	Equity
Balance as of December 31, 2019	3,679,778	$ 23,823	3,750,674	$ 29,550	$ 53,373	4,998,874	$ 51	$ 1,770	$ (40,741)	$ (38,920)
Conversion of Preferred Stock into Common stock	(3,679,778)	(23,823)	(3,750,674)	(29,550)	(53,373)	3,715,222	37	53,336	—	53,373
Issuance of Common Stock, Initial Public Offering, net of Issuance Cost of $2,730	—	—	—	—	—	3,940,689	39	52,202	—	52,241
Exercise of Stock Option	—	—	—	—	—	54,999	1	280	—	281
Stock Based Compensation	—	—	—	—	—	18,662	*	1,569		1,569
Net Loss	—	—	—	—	—	—	—	—	(30,146)	(30,146)
Balance as of December 31, 2020	—	$ —	—	$ —	$ —	12,728,446	$ 128	$ 109,157	$ (70,887)	$ 38,398
Proceeds from Issuance of common stock and warrants, net of issuance cost of $1,724	—	—	—	—	—	333,333	3	23,259	—	23,262
Proceeds from Issuance of common stock net of issuance cost of $438	—	—	—	—	—	827,094	8	9,959	—	9,967
Exercise of Stock Options	—	—	—	—	—	18,328	*	101	—	101
Stock Based Compensation	—	—	—	—	—	48,834	*	2,684	—	2,684
Net Loss	—	—	—	—	—	—	—	—	(40,254)	(40,254)
Balance as of December 31, 2021	—	$ —	—	$ —	$ —	13,956,035	$ 139	$ 145,160	$ (111,141)	$ 34,158

* Represents an amount lower than $1.

The accompanying notes are an integral part of the consolidated financial statements.

AYALA PHARMACEUTICALS, INC.

STATEMENTS OF CONSOLIDATED CASH FLOWS

U.S. dollars in thousands

	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash Flows from Operating Activities:		
Net Loss	$ (40,254)	$ (30,146)
Adjustments to reconcile Net Loss to Net Cash used in Operating Activities:		
Shared Based Compensation	2,684	1,569
Depreciation	168	182
Increase in Prepaid Expenses and other Assets	(1,174)	(1,029)
Decrease (Increase) in trade receivables	681	(212)
Increase in Trade Payables	(512)	451
Increase in other Accounts Payable	51	1,644
Net Cash used in Operating Activities	(38,356)	(27,541)
Cash Flows from Investing Activities:		
Proceeds from Maturities of Long-Term Deposits	—	226
Purchase of Property and Equipment	(5)	(45)
Net Cash provided by (used in) Investing Activities	(5)	181
Cash Flows from Financing Activities:		
Exercise of Stock Options	101	281
Issuance of shares and warrants, net	23,262	—
Proceeds from Issuance of Shares, net	9,967	52,641
Net Cash provided by Financing Activities	33,330	52,922
Increase (Decrease) in Cash and Cash Equivalents and Restricted Cash	(5,031)	25,562
Cash and Cash Equivalents and Restricted Cash at Beginning of the Year	42,370	16,808
Cash and Cash Equivalents and Restricted Cash at End of the Year	$ 37,339	$ 42,370
Supplemental Disclosure of Non-Cash Financing Activities		
Non-cash Deferred Offering Costs	$ -	$ 400
Supplemental Disclosures of Cash Flow Information:		
Cash Received for Interest	$ 12	$ 58
Cash Paid for Income Taxes	$ 209	$ 300
Cash Received for Income Taxes	$ 32	$ -

	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash and Cash Equivalents	$ 36,982	$ 42,025
Restricted Cash	122	90
Restricted Cash in Other Assets	235	255
Cash and Cash Equivalents and Restricted Cash at End of the Year	$ 37,339	$ 42,370

The accompanying notes are an integral part of the consolidated financial statements.

1. General

a) Ayala Pharmaceuticals, Inc. (the "Company") was incorporated in November 2017. The Company is a clinical stage oncology company dedicated to developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. The Company's current portfolio of product candidates, AL101 and AL102, target the aberrant activation of the Notch pathway with gamma secretase inhibitors.

b) In 2017, the Company entered into an exclusive worldwide license agreement with respect to AL101 and AL102. See note 5.

c) The Company's lead product candidates, AL101 and AL102, have completed preclinical and Phase 1 studies. AL102 is currently being evaluated in a pivotal Phase 2/3 trial (RINGSIDE) in patients with Desmoids tumors and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BMCA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. AL101 is currently being evaluated in a Phase 2 trial (ACCURACY) in patients with R/M ACC bearing Notch-activating mutations is ongoing.

d) The Company has a wholly-owned Israeli subsidiary, Ayala-Oncology Israel Ltd. (the "Subsidiary"), which was incorporated in November 2017.

Initial Public Offering and Other Transactions

On May 12, 2020, the Company completed the sale of shares of its common stock in its IPO. In connection with the IPO, the Company issued and sold 3,940,689 shares of its common stock, par value $0.01 per share ("Common Stock") including 274,022 shares associated with the partial exercise on June 4, 2020 of the underwriters' option to purchase additional shares, at a price to the public of $15.00 per share, resulting in net proceeds to the Company of approximately $52.2 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. All shares issued and sold were registered pursuant to a registration statement on Form S-1 (File No. 333-236942), as amended, declared effective by the U.S. Securities and Exchange Commission (the "Commission") on May 7, 2020.

In connection with the IPO, the Company effected a one-for-two reverse stock split of its Common Stock which became effective on May 4, 2020. Upon the closing of the IPO, all of the outstanding shares of Series A preferred stock and Series B preferred stock automatically converted into an aggregate of 3,715,222 shares of Common Stock. Subsequent to the closing of the IPO, there were no preferred shares outstanding.

On February 19, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, the company agreed to sell (i) an aggregate of 333,333 shares of our common stock (the "Private Placement Shares"), par value $0.01 per share, together with warrants to purchase an aggregate of 116,666 shares of its Common Stock with an exercise price of $18.10 per share (the "Common Warrants"), for an aggregate purchase price of $4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of its Common Stock with an exercise price of $0.01 per share (the "Pre-Funded Warrants" and collectively with the Common Warrants, the "Private Placement Warrants"), together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of $19,986,661.67 (collectively, the "Private Placement"). The Private Placement closed on February 23, 2021.

In June 2021, the Company entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which the Company may, from time to time, issue and sell Common Stock with an aggregate value of up to $200.0 million in "at-the-market" offerings, under its Registration Statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the "ATM"). Sales of Common Stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for its Common Stock. Pursuant to the Sales Agreement, during the year ended December 31, 2021, the Company sold a total of 827,094 shares of Common Stock for total gross proceeds of approximately $10.4 million.

Going Concern

The Company has incurred recurring losses since inception as a research and development organization and has an accumulated deficit of $111.1 million as of December 31, 2021. For the year ended December 31, 2021, the Company used $38.4 million of cash in operations. The Company has relied on its ability to fund its operations through public and private equity financings. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. As of December 31, 2021, the Company had approximately $37.3 million in cash and cash equivalents and restricted cash, which, without additional funding, the Company believes will not be sufficient to meet its obligations within the next twelve months from the date of issuance of these consolidated financial statements. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. As such, those factors raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Therefore, the consolidated financial statements for the year ended December 31, 2021 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

2. Significant Accounting Policies

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The significant accounting policies followed in the preparation of the consolidated financial statements, are as follows:

Use of Estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements. Actual results could differ from those estimates.

Consolidated Financial Statements in U.S. Dollars

A substantial portion of the Company's financing activities, including equity transactions and cash investments, are incurred in U.S. dollars. The Company's management believes that the U.S. dollar is the currency of the primary economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the U.S. dollar.

A subsidiary's functional currency is the currency of the primary economic environment in which the subsidiary operates; normally, that is the currency of the environment in which a subsidiary primarily generates and expends cash. In making the determination of the appropriate functional currency for a subsidiary, the Company considers cash flow indicators, local market indicators, financing indicators and the subsidiary's relationship with both the parent company and other subsidiaries. For subsidiaries that are primarily a direct and integral component or extension of the parent entity's operations, the U.S. dollar is the functional currency.

The Company has determined the functional currency of its foreign subsidiary is the U.S. Dollar. The foreign operation is considered a direct and integral part or extension of the Company's operations. The day-to-day operations of the foreign subsidiary are dependent on the economic environment of the U.S. Dollar.

Accordingly, monetary accounts maintained in currencies other than the U.S. dollar are remeasured into U.S. dollars in accordance with Statement of the Accounting Standard Codification ("ASC") No. 830 "Foreign Currency Matters" ("ASC No. 830"). All transaction gains and losses of the remeasured monetary balance sheet items are reflected in the statements of operations as financial income or expenses as appropriate.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and the Subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

Cash and Cash Equivalents and Short-term restricted bank deposits

The Company considers all highly liquid certificates of deposits with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts in the United States and are stated at fair value. Short-term restricted bank deposits consist of a bank deposit accounts that serves as collateral for a credit card agreement and lease agreements at one of the Company's financial institutions.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, at the following annual rates:

Computers and Software	33%
Lab Equipment	15%
Office Furniture and Equipment	7%

Leasehold improvements are amortized on a straight-line basis over the shorter of the assets' estimated useful life or the remaining term of the lease.

Maintenance and repair costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company's long-lived assets are reviewed for impairment in accordance with ASC No. 360, "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets are expected to generate are less than the carrying value of the assets, the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values. During the years ended December 31, 2021, and 2020, no impairment indicators have been identified.

Accrued Post-Employment Benefit

Under Israeli employment laws, employees of the Company are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. According to Section 14, these employees are entitled to monthly payments made by the Company on their behalf with insurance companies.

Payments in accordance with Section 14 release the Company from any future severance payments with respect to those employees. The obligation to make the monthly deposits is expensed as incurred. In addition, the aforementioned deposits are not recorded as an asset in the consolidated balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments. Severance costs amounted to approximately $0.3 million and $0.2 million for the year ended December 31, 2021 and 2020, respectively.

The Company maintains a 401(k) retirement savings plan for its U.S. employees. Each eligible employee may elect to contribute a portion of the employee's compensation to the plan. As of December 31, 2021, and 2020, the Company has matched 100% of all employee contributions, up to 6% of the employee's base salary.

Fair Value of Financial Instruments:

The Company measures and discloses the fair value of financial assets and liabilities in accordance with ASC Topic 820, "Fair Value Measurement." Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data are available.

Restricted bank deposits, trade receivables, trade payables are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include payroll and personnel expenses, consulting costs, external contract research and development expenses, raw materials, drug product manufacturing costs, and allocated overhead including depreciation, rent, and utilities. Research and development costs that are paid in advance of performance are classified as a prepaid expense and amortized over the service period as the services are provided.

Acquired In-Process Research and Development

In an asset acquisition, the initial costs of rights to in-process research and development projects acquired are expensed as R&D in the consolidated statements of operations unless the in-process research and development has an alternative future use. In a business combination, the fair value of in-process research and development is capitalized as an indefinite-lived intangible asset, regardless of whether the in-process research and development asset has an alternative future use.

Clinical Trial Costs

Clinical trial costs are a component of research and development expenses. The Company bases its expenses related to Clinical Research Organization ("CRO") on the services received, and efforts expanded pursuant to agreements with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In instances where payments made to CROs exceed the level of services provided and result in a prepayment of the research and development expenses. For reoccurring services fees, the Company calculates the time period over which services will be performed and the level of effort to be expanded in each period. If the actual timing of the performance of services varies from the calculation, the Company adjusts the accrual or amount of prepaid expenses accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Patent Costs

Legal and related patent costs are expensed as incurred as their realization is uncertain. Costs related to patent registration are classified as general and administrative expenses, and costs related to acquired patents are classified as research and development expenses in the accompanying consolidated statements of operations.

Contingent Liabilities

The Company accounts for its contingent liabilities in accordance with ASC No. 450, "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of December 31, 2021, and 2020, the Company is not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". This standard prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value, if it is more likely than not that some portion of the entire deferred tax asset will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740-10, "Income Taxes". Accounting guidance addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements, under which a Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position.

The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. Bank deposits are held by accredited financial institutions and these deposits may at times be in excess of insured limits. Money Market funds are of Prime A and only invested in government issued securities. The Company limits its credit risk associated with cash and cash equivalents by placing them with financial institutions that it believes are of high-quality credit rating. The Company has not experienced any losses on its deposits of cash or cash equivalents.

Company's trade receivables are from one customer as of December 31, 2021, and December 31, 2020. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored on an ongoing basis. The Company grants credit of 45 days to this one customer.

Stock-Based Compensation

The Company measures its stock-based payment awards made to employees, directors, and non-employee service providers based on estimated fair values. The fair value of each option award is estimated on the grant date using the Black-Scholes option pricing model. The Company recognizes compensation expenses based on the accelerated method over the requisite service period. The Company recognizes forfeitures of awards as they occur.

The Black-Scholes option pricing model requires a number of assumptions, of which the most significant are share price, expected volatility, expected option term (the time from the grant date until the options are exercised or expire), risk-free rate, and expected divided rate. Share price is estimated based on third party valuation (see also Note 9). After the IPO, the fair value of each ordinary share was based on the closing price of the Company's publicly traded ordinary shares as reported on the date of the grant.

Expected volatility

As the Company has a short trading history for its ordinary shares, the expected volatility is derived from the average historical share volatilities of several unrelated public companies within the Company's industry that the Company considers to be comparable to its own business over a period equivalent to the option's expected term.

Expected Dividend Yield

The Company has historically not paid dividends and has no foreseeable plans to pay dividends, therefore the Company uses an expected dividend yield of 0%.

Risk-Free Interest Rate

The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent expected term.

Expected Term The expected option term is calculated for options granted to employees and directors using the "simplified" method. Under this approach, the expected term is presumed to be the midpoint between the weighted average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options expire. The expected option term for options granted to non-employees is based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the share options granted and the results of operations of the Company.

Restricted shares are value as fair value of shares on date of grant.

Basic and Diluted Net Loss per Share

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding together with the number of additional shares of Common Stock that would have been outstanding if all potentially dilutive shares of Common Stock had been issued. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of Common Stock are anti-dilutive.

Segment Information

Financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment. Operating segments are defined as components of an enterprise in which separate financial information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and assessing performance.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, which applies to all contracts with customers. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct.

Customer option to acquire additional goods or services gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract.

In a contract with multiple performance obligations, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations.

The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration the Company expect to be entitled to receive in exchange for those goods or services.

In December 2018, the Company entered into an Evaluation Option to acquire License Agreement (the "Novartis Agreement") with Novartis International Pharmaceutical Limited ("Novartis") for which the company is paid for its research and development costs. For additional details regarding the Novartis Agreement, refer to Note 5.

The Company concluded that there is one distinct performance obligation under the Novartis Agreement: Research and development services, obligation which is satisfied over time.

Revenue associated with the research and development services in the amount of $3.5 million and $3.7 million was recognized in 2021 and 2020 respectively.

The Company concluded that progress towards completion of the research and development performance obligation related to the Novartis Agreement is best measured in an amount proportional to the expenses incurred from the total estimated expenses. The Company periodically reviews and updates its estimates, when appropriate, which may adjust revenue recognized for the period. The transaction price to be recognized as revenue under the Novartis Agreement consists of the reimbursable research and development costs.

Recently Issued Accounting Pronouncements Not Yet Adopted

As an "emerging growth company," the Jumpstart Our Business Startups Act ("JOBS Act") allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act. The adoption dates discussed below reflects this election.

In February 2016, the FASB issued ASU 2016-02—Leases, requiring the recognition of lease assets and liabilities on the balance sheet. The standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The standard will be effective for the Company for fiscal years beginning after December 15, 2021. The Company is currently evaluating the impact of adopting this new guidance on its financial statements.

In June 2016, the FASB issued ASU No. 2016-13 (Topic 326), Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments, which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The guidance will be effective for the Company for fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently evaluating the effect that ASU 2016-13 will have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). The final guidance issued by the FASB for convertible instruments eliminates two of the three models in ASC 470-20 that require separate accounting for embedded conversion features. Separate accounting is still required in certain cases. Additionally, among other changes, the guidance eliminates some of the conditions for equity classification in ASC 815-40-25 for contracts in an entity's own equity. The guidance also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of share settlement for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

3. Property and Equipment, net

Property and Equipment, net consists of the following:

	December 31, 2021	December 31, 2020
	(in thousands)	
Cost:		
Computers and Software	$ 73	$ 73
Lab Equipment	294	293
Office Furniture and Equipment	146	142
Leasehold Improvements	1,105	1,105
	1,618	**1,613**
Less: Accumulated Depreciation	498	330
Property and Equipment, Net	**$ 1,120**	**$ 1,283**

Depreciation expenses for the years ended December 31, 2021, and 2020 was approximately $168 and $182, respectively.

4. Other account payables

Other account payables consist of the following:

	December 31, 2021	December 31, 2020
	(in thousands)	
Accrued Professional Fees	$ 291	$ 657
Accrued Research and Development Expenses	56	101
Tax Provision	1,150	780
Accrued Payroll and Employee Benefits	1,761	1,613
Total Accrued Expenses	$ 3,258	$ 3,151

5. Commitments and Contingent Liabilities *Lease*

The Subsidiary rents its facilities under an operating lease agreement, which expired in November 2019.

In January 2019, the Company signed a new lease agreement. The term of the lease is for 63 months and includes an option to extend the lease for an additional 60 months. As part of the agreement, the lessor also provided the Company with finance in in the amount of approximately $0.5 million paid in arrears for of leasehold improvements. The financing was recorded as a Long-Term Rent Liability. The minimum rental payments under operating leases as of December 31, 2021, are as follows (in thousands):

Year ended December 31,	(in thousands)
2022	360
2023	360
2024	120
	$ 840

The Subsidiary obtained a bank guarantee in the amount of approximately $0.2 million for its new office lease agreement.

The subsidiary leasing expense for the years ended December 2021 and 2020 was $0.3 million and $0.3 million, respectively.

Asset Transfer and License Agreement with Bristol-Myers Squibb Company.

In November 2017, the Company entered into a license agreement, or the BMS License Agreement, with Bristol-Myers Squibb Company, or BMS, under which BMS granted the Company a worldwide, non-transferable, exclusive, sublicensable license under certain patent rights and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102, or the BMS Licensed Compounds, and products containing AL101 or AL102, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

Under the BMS License Agreement, the Company is obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product. The Company has sole responsibility for, and bear the cost of, conducting research and development and preparing all regulatory filings and related submissions with respect to the BMS Licensed Compounds and/or BMS Licensed Products. BMS has assigned and transferred all INDs for the BMS Licensed Compounds to the Company. The Company is also required to use commercially reasonable efforts to obtain regulatory approvals in certain major market countries for at least one BMS Licensed Product, as well as to effect the first commercial sale of and commercialize each BMS Licensed Product after obtaining such regulatory approval. The Company has sole responsibility for, and bear the cost of, commercializing BMS Licensed Products. For a limited period of time, the Company may not, engage directly or indirectly in the clinical development or commercialization of a Notch inhibitor molecule that is not a BMS Licensed Compound.

As consideration of the rights granted by BMS to the Company under the BMS License Agreement, the Company paid BMS a payment of $6 million and issued to BMS 1,125,929 shares of Series A Preferred Stock valued at approximately $7.3 million. The payment and transfer of intellectual property occurred in November 2017 at the time the BMS License Agreement was executed (the "Effective Date").

The Company is required to pay BMS payments upon the achievement of certain development or regulatory milestone events of up to $95 million in the aggregate with respect to the first BMS Licensed Compound to achieve each such event and up to $47 million in the aggregate with respect to each additional BMS Licensed Compound to achieve each such event. The Company is also obligated to pay BMS payments of up to $50 million in the aggregate for each BMS Licensed Product that achieves certain sales-based milestone events and tiered royalties on net sales of each BMS Licensed Product by the Company or its affiliates or sublicensees at rates ranging from a high single-digit to low teen percentage, depending on the total annual worldwide net sales of each such Licensed Product. If the Company sublicenses or assigns any rights to the licensed patents, the BMS Licensed Compounds and/or the BMS Licensed Products, the Company is required to share with BMS a portion of all consideration received from such sublicense or assignment, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced BMS Licensed Compound or BMS Licensed Product that is subject to the applicable sublicense or assignment, but such portion may be reduced based on the milestone or royalty payments that are payable by the Company to BMS under the BMS License Agreement.

Under the terms of the BMS Agreement, the Company was obligated to issue to BMS additional shares of preferred stock as would be required for BMS to maintain its 8% equity ownership in Company, subject to certain exceptions. This right terminated upon the closing of the sale of the Company's Series B Preferred Stock. The Company estimates the fair value of this anti-dilution commitment using the probability weighted expected return method ("PWERM"). At the date of BMS Agreement, the Company recorded liability associated with the anti-dilution right in the amount of approximately $0.5 million, according to its fair value. For the year ended December 31, 2018, the Company recorded an income of approximately $0.5 million for the reassessment of the liability, within financial income, net, in the consolidated statement of operations.

The Company accounted for the acquisition of the rights granted by BMS as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred and value of shares issued to BMS as research and development expense in the consolidated statement of operations as incurred since the acquired the rights granted by BMS represented in-process research and development and had no alternative future use.

The Company accounts for contingent consideration payable upon achievement of sales milestones in such asset acquisitions when the underlying contingency is resolved.

The BMS License Agreement remains in effect, on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis, until the expiration of royalty obligations with respect to a given BMS Licensed Product in the applicable country. Royalties are paid on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis from the first commercial sale of a particular BMS Licensed Product in a country until the latest of

10 years after the first commercial sale of such BMS Licensed Product in such country, (b) when such BMS Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such BMS Licensed Product in such country. Any inventions, and related patent rights, invented solely by either party pursuant to activities conducted under the BMS License Agreement shall be solely owned by such party, and any inventions, and related patent rights, conceived of jointly by the Company and BMS pursuant to activities conducted under the BMS License Agreement shall be jointly owned by the Company and BMS, with BMS's rights thereto included in the Company's exclusive license. The Company has the first right—with reasonable consultation with, or participation by, BMS—to prepare, prosecute, maintain and enforce the licensed patents, at the Company's expense.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to the Company (a) for insolvency-related events involving the Company, (b) for the Company's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, for the Company's failure to fulfill its obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if the Company or its affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. The Company has the right to terminate the BMS License Agreement for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Project has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if the Company reasonably determine that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products.

Upon termination of the BMS License Agreement in its entirety by the Company for convenience or by BMS, the Company grants an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of its patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay the Company a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/ or BMS Licensed Products.

Option and License Agreement with Novartis International Pharmaceutical Ltd.

In December 2018, the Company entered into an evaluation, option and license agreement, or the Novartis Option Agreement, with Novartis International Pharmaceutical Limited, or Novartis, pursuant to which Novartis agreed to conduct certain studies to evaluate AL102 in combination with its B-cell maturation antigen, or BCMA, therapies in multiple myeloma, and the Company agreed to supply AL102 for such studies. All supply and development costs associated with such evaluation studies are fully borne by Novartis.

Under the Novartis Option Agreement, the Company granted Novartis an exclusive option to obtain an exclusive (including as to the Company and its affiliates), sublicensable (subject to certain terms and conditions), worldwide license and sublicense (as applicable) under certain patent rights and know-how controlled by the Company (including applicable patent rights and know-how that are licensed from BMS pursuant to the BMS License Agreement) to research, develop, manufacture (subject to the Company's non-exclusive right to manufacture and supply AL102 or the Novartis Licensed Product for Novartis) and commercialize AL102 or any pharmaceutical product containing AL102 as the sole active ingredient, or the Novartis Licensed Product, for the diagnosis, prophylaxis, treatment, or prevention of multiple myeloma in humans. The Company also granted Novartis the right of first negotiation for the license rights to conduct development or commercialization activities with respect to the use of AL102 for indications other than multiple myeloma. Additionally, from the exercise by Novartis of its option until the termination of the Novartis Option Agreement, the Company may not, either itself or through its affiliates or any other third parties, directly or indirectly research, develop or commercialize certain BCMA-related compounds for the treatment of multiple myeloma.

According to the agreement, Novartis shall pay the Company a low eight figure option exercise fee in order to exercise its option and activate its license, upon which the Company will be eligible to receive development, regulatory and commercial milestone payments of up to $245 million in the aggregate and tiered royalties on net sales of Novartis Licensed Products by Novartis or its affiliates or sublicensees at rates ranging from a mid-single-digit to low double-digit percentage, depending on the total annual worldwide net sales of Novartis Licensed Products. Royalties will be paid on a country-by-country and Novartis Licensed Product-by-Novartis

Licensed Product basis from the first commercial sale of a particular Novartis Licensed Product in a country until the latest of (a) 10 years after the first commercial sale of such Novartis Licensed Product in such country, (b) when such Novartis Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such Novartis Licensed Product in such country. Contemporaneously with the Novartis Option Agreement, the Company entered into a stock purchase agreement and associated investment agreements, or the SPA, with Novartis' affiliate, Novartis Institutes for BioMedical Research, Inc., or NIBRI, pursuant to which NIBRI acquired a $10 million equity stake in the Company.

Novartis shall own any inventions, and related patent rights, invented solely by it or jointly with the Company in connection with activities conducted pursuant to the Novartis Option Agreement. The Company will maintain first right to prosecute and maintain any patents licensed to Novartis, both before and after its exercise of its option. The Company maintain the first right to defend and enforce its patents prior to Novartis's exercise of its option, upon which Novartis gains such right with respect to patents included in the license.

The option granted to Novartis will remain in effect until the earlier of (a) 60 days following the last visit of the last subject in the evaluation studies, the termination of the Novartis Option Agreement, or (c) 36 months following the delivery by the Company to Novartis of sufficient amounts of clinical evaluation materials to conduct the anticipated clinical studies. The Novartis Option Agreement remains in effect until such time as no Novartis Licensed Product is being developed or commercialized by Novartis, its affiliates, or sublicensees (including distributors or commercial partners), unless terminated earlier. The Company has the right to terminate the Novartis Option Agreement (a) for Novartis's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (b) for Novartis's failure to use commercially reasonable efforts to develop or commercialize AL102 and/or the Novartis Licensed Product not remedied within four months following written notice to Novartis. Novartis has the right to terminate the Novartis Option Agreement (a) in its entirety or on a country-by-country basis for convenience, upon 60 days written notice to us, (b) for Company's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (c) upon immediate written notice to the Company for insolvency-related events involving the Company.

6. Fair Value Measurements

As of December 31, 2021, the Company had no financial liabilities measured at fair value.

The following tables summarize the fair value measurements of our financial instruments as of December 31, 2021:

	Fair Value Measurements at December 31, 2021			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($in thousands)		
Cash equivalents:				
Money market funds	$ 32,900	$ —	$ —	$ 32,900
Total cash equivalents	$ 32,900	$ —	$ —	$ 32,900

The following tables summarize the fair value measurements of our financial instruments as of December 31, 2020:

	Fair Value Measurements at December 31, 2020			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($in thousands)		
Cash equivalents:				
Money market funds	$ 35,900	$ —	$ —	$ 35,900
Total cash equivalents	$ 35,900	$ —	$ —	$ 35,900

7. Common Stock

The Common Stock confer upon the holders the right vote in annual and special meetings of the Company, and to participate in the distribution of the surplus assets of the Company upon liquidation of the Company, after the distribution of the preferred stock liquidation preference. No dividends have been declared as of December 31, 2021 and 2020.

On May 12, 2020, the Company completed the sale of shares of its Common Stock in its IPO. In connection with the IPO, the Company issued and sold 3,940,689 shares of Common Stock, including 274,022 shares associated with the partial exercise on June 4, 2020 of the underwriters' option to purchase additional shares, at a price to the public of $15.00 per share, resulting in net proceeds to the Company of approximately $52.8 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. All shares issued and sold were registered pursuant to a registration statement on Form S-1 (File No. 333-236942), as amended, declared effective by the U.S. Securities and Exchange Commission (the "Commission") on May 7, 2020.

In connection with the IPO, the Company effected a one-for-two reverse stock split of its Common Stock which became effective on May 4, 2020. Upon the closing of the IPO, all of the outstanding shares of Series A preferred stock and Series B preferred stock automatically converted into an aggregate of 3,715,222 shares of Common Stock. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding, and amended the authorized capital stock of the company to (i) 200,000,000 shares of Common Stock (ii) 10,000,000 shares of Preferred Stock.

On February 19, 2021, we entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, we agreed to issue (i) an aggregate of 333,333 shares of our common stock (the "Private Placement Shares"), par value $0.01 per share, together with warrants to purchase an aggregate of 116,666 shares of our common stock with an exercise price of $18.10 per share (the "Common Warrants"), for an aggregate purchase price of $4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of our common stock with an exercise price of $0.01 per share (the "Pre-Funded Warrants" and collectively with the Common Warrants, the "Private Placement Warrants"), together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of $19,986,661.67 (collectively, the "Private Placement"). The Private Placement closed on February 23, 2021. The Company had issuance costs of approximately $1.715 million. The Private Placement closed on February 23, 2021. The warrants were classified as a component of permanent equity pursuant to ASC 480 "Distinguishing Liabilities from Equity" and ASC 815 "Derivatives and Hedging." As of December 31, 2021, the 1,799,999 warrants are all outstanding.

In June 2021, we entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $200.0 million in "at-the-market" offerings, under our Registration Statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the "ATM"). Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for our common stock. Pursuant to the Sales Agreement, during the twelve months ended December 31, 2021, the Company issued a total of 827,094 shares of common stock for total gross proceeds of approximately $10.4 million.

Total shares of Common Stock reserved for issuance are summarized as follows:

	December 31, 2021	December 31, 2020
Options Outstanding	900,789	695,674
Warrants for common shares of the company.	1,799,999	
Shares available for future option grants	593,040	387,736
Total shares of Common Stock reserved for Issuance	3,293,828	1,083,410

Composition of Capital Stock:

	December 31, 2021		December 31, 2020	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
Shares of USD 0.01 par value:				
Common Stock	200,000,000	13,956,035*	200,000,000	12,728,446*

* Does not include 124,348 and 96,017 shares of restricted Common Stock issued but not outstanding in 2021 and 2020, respectively.

8. Stock-Based Plans

In 2017, the Company's board of directors adopted the 2017 Stock Incentive Plan (the "Plan"). According to the Plan, share awards, including restricted stock, restricted stock units or other stock-based awards, or options to purchase shares may be granted to employees, directors, consultants and other service providers of the Company or any affiliate of the Company.

As of December 31, 2021, a total of 1,841,040 shares of Common Stock were authorized for issuance in accordance with the provisions of the 2017 Plan, of which 593,040 shares were then available for future awards (whether as share awards or as options to purchase shares of common stock of the Company). Each option granted under the Plan expires no later than 10 years from the date of grant. The options vest primarily over four to five years of employment.

The following table set forth the parameters used in the computation of the fair value of options granted to employees:

	Year ended December 31,	
	2021	2020
Expected volatility	80%	80%
Expected dividends	0%	0%
Expected term (in years)	6.34	6.34
Risk free rate	0.50%-1.08%	0.47%-2.03%

Expected Volatility:

As the Company was privately owned in part of 2020, there was not sufficient historical volatility for the expected term of the stock options. Therefore, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable publicly traded companies which were selected based upon industry similarities.

Expected term (years):

Expected term represents the period that the Company's option grants are expected to be outstanding. There is not sufficient historical share exercise data to calculate the expected term of the stock options. Therefore, the Company elected to utilize the simplified method to value option grants. Under this approach, the weighted-average expected life is presumed to be the average of the shortest vesting term and the contractual term of the option.

Risk-free interest rate:

The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Expected dividend yield:

The Company does not anticipate paying any dividends in the foreseeable future.

The Company recorded stock-based compensation for the period indicated as follows (in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
Research and Development	$ 1,097	$ 509
General and Administrative	1,587	1,060
Total Stock-Based Compensation	$ 2,684	$ 1,569

The Company recognizes compensation expenses for the value of its awards granted based on the accelerated method over the requisite service period of each of the awards.

A summary of the Company's stock option activity granted to employees under the Plan is as follows:

	Year ended December 31, 2021			
	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at Beginning of Year	695,674	$ 6.07	7.25	$ 1,695,276
Granted	295,470	10.99		
Exercised	(18,328)	5.50		$ 55,133
Forfeited	(70,527)	9.78		
Expired	(1,500)	5.10		
Outstanding, December 31, 2021	900,789	$ 7.41	7.78	$ 991,878
Exercisable Options, December 31, 2021	476,303	$ 5.93	7.12	$ 1,230,643

The weighted-average grant date per-share fair value of stock options granted during 2021 and 2020 was $7.98 and $6.07, respectively. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2021 and 2020 was $55 and $280, respectively. As of December 31, 2021, there was approximately $1.1 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 0.93 years.

Company's restricted shares:

In February 2018, the Company granted 83,165 restricted shares to an employee and an officer of the Company. In the case of the officer, the restricted shares vest over two years starting November 15, 2017, and in the case of the other employee, the restricted shares vest over four years starting November 15, 2017.

In December 2019, the Company granted 59,597 restricted shares to two officers of the Company. The restricted shares vest over four years starting December 24, 2019.

In May 2020, the Company granted 58,651 restricted shares to two officers of the Company. The restricted shares vest over four years starting May 7, 2020.

The following table summarizes information relating to restricted shares, as well as changes to such awards during the fiscal years ended December 31, 2021 and 2020:

	Year ended December 31, 2021	**Year ended December 31, 2020**
Outstanding at beginning of Year	101,929	65,847
Granted	71,253	58,651
Forfeited	—	(3,907)
Vested	(48,834)	(18,662)
Outstanding at end of Year	124,348	101,929

The weighted average fair values at grant date of restricted shares granted for the years ended December 31, 2021 and 2020 was $11.26 and $15.00, per share respectively.

The total fair value of shares vested during each of 2021 and 2020 was approximately $0.2 million. As of December 31, 2021, the Company had approximately $1.8 million of unrecognized compensation expense related to non-vested restricted shares, expected to be recognized over a weighted average period of 1.73 years.

Restricted shares are subject to a repurchase right by the Company on certain occasions. Under the repurchase right, the Company may reacquire restricted shares, for no consideration, if certain conditions occur including the employees' end of service with the Company.

9. Taxes on Income

The Company records income tax expense related to profits realized in the United States and realized by its subsidiary in Israel.

United States:

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "U.S. Tax Reform"); a comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes, most of which are effective for tax years beginning after December 31, 2017, include several key tax provisions that might impact the Company, among others: (i) a permanent reduction to the statutory federal corporate income tax rate from 35% (top rate) to 21% (flat rate) effective for tax years beginning after December 31, 2017 (ii) a new tax deduction in the amount of 37.5% of "foreign derived intangible income" that effectively reduces the federal corporate tax on certain qualified foreign derived sales/licenses/leases and service income in excess of a base amount to 13.125% (as compared to the regular corporate income tax rate of 21%); (iii) stricter limitation on the tax deductibility of business interest expense; (iv) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) (v) a one-time deemed repatriation tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate and (vi) an expansion of the U.S. controlled foreign corporation ("CFC") anti deferral starting with the CFC's first tax year beginning in 2018 intended to tax in the U.S. "global intangible low-taxed income" ("GILTI").

The Company recorded loss from continuing operations, before taxes on income for the period indicated as follows (in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
United States	$ (39,018)	$ (29,698)
Israel	(460)	(23)
Net loss before tax	$ (39,478)	$ (29,721)

Income tax expense is summarized as follows (in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020
Current:		
Federal	$ —	$
State		—
Foreign	776	426
	$ 776	$ 426
Deferred:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	$ —	$ —
Income tax expense	$ 776	$ 426

The effective income tax rate differed from the amount computed by applying the federal statutory rate to our loss before income taxes as follows:

	Year ended December, 31 2021	Year ended December, 31 2020
U.S. federal tax provision at statutory rate	21.00%	21.00%
State and local tax, net of federal benefit	4.01	4.64
Foreign rate differences	(0.09)	(0.07)
Non-deductible stock compensation	(1.43)	(1.11)
Section 951A GILTI	0.00	(0.85)
Effect of other permanent differences	(0.07)	(0.07)
Uncertain tax positions	(0.66)	(0.52)
Change in valuation allowance	(34.39)	(26.65)
Federal Tax Reform Rate Change	0.00	0.00
Tax Credits	6.01	—
Provision to Return	3.95	—
Other adjustments	(0.30)	2.20
Effective tax rate	(1.97)%	(1.43)%

Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	As of December 31, 2021	As of December 31, 2020
Deferred tax assets:		
Federal net operating loss carryforwards	$ 22,614	$ 12,752
Intangible assets	3,402	651
Accrued expenses	3,011	3,022
Other	169	—
Total deferred tax assets	29,196	16,425
Valuation allowance	(29,196)	(16,425)
Net deferred tax assets	$ —	$ —

As of December 31, 2021, the Company has provided a valuation allowance of approximately $29.2 million in respect of the Company's deferred tax assets resulting from tax loss carryforwards and other temporary differences. Realization of deferred tax assets is dependent upon future earnings, if any, the time and amount of which are uncertain. As the Company is still in its development stage and has not yet generated revenues, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to their recoverable amounts.

Available Carryforward Tax Losses

As of December 31, 2021, we had net operating loss carryforwards, or NOLs, of $91.6 million for federal income tax purposes and $57.7 million for state income tax purposes, which may be available to offset our future taxable income, if any, and begin to expire in various amounts in 2037 and 2038, respectively, provided that NOLs generated in tax years ending after December 31, 2017 will not be subject to expiration. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. If the U.S. Internal Revenue Service challenges our determinations with respect to the existence of previous ownership changes or the effects thereof, or if we undergo an ownership change, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Sections 382 and 383 of the Code. In addition, for taxable years beginning after December 31, 2020, utilization of federal NOLs generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year, after taking into account utilization of NOLs generated in years beginning before January 1, 2018 and determined without regard to such NOL deduction. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability. The reduction of the corporate tax rate under recently-enacted U.S. tax legislation may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us.

In addition, as of December 31, 2021, the Company had federal Orphan Drug research and development credit carryforwards of approximately $618 thousand and $33, respectively. If not utilized, the federal tax carryforwards which expire in 2039.

Uncertain Tax Positions

The Company has reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of December 31, 2021, and 2020, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of approximately $0.9 and $0.6 million, respectively. As of December 31, 2021, the Company has not accrued penalties for uncertain tax positions. A reconciliation of the Company's unrecognized tax benefits is below:

	2021 (in thousands)	2020 (in thousands)
Uncertain tax position at the beginning of year	$ 581	$ 424
Additions for uncertain tax position of prior years (foreign exchange and interest)	17	3
Additions for tax positions of current year	260	153
Uncertain tax position at the end of the year	$ 858	$ 581

The Company remains subject to examination until the statute of limitations expires for each respective tax jurisdiction. The statute of limitations is currently open for 2017, 2018, 2019, 2020 and 2021 for all tax jurisdictions.

Israel:

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years) which reduces the corporate income tax rate from 25% to 24% effective from January 1, 2017, and to 23% effective from January 1, 2018.

The Israeli corporate income tax rate was 23% in 2021 and 2020. Income not eligible for Preferred Enterprise benefits is taxed at the regular corporate tax rates as described above.

10. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of the loss per share for the period presented (in thousands, except for share data):

	Year ended December 31, 2021	Year ended December 31, 2020
Numerator:		
Net loss	$ 40,254	$ 30,146
Denominator:		
Weighted-average number of shares used to compute net loss per share, basic and diluted	14,398,905	9,860,610

The calculation of basic and diluted Loss Per Share includes 1,333,333 and 1,155,555 weighted average warrants with an exercise price of $0.01 for the year ended December 31, 2021, respectively.

The following potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect: 466,666 shares of common stock and 900,789 options outstanding to purchase common stock as of December 31, 2021.

The following potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect: 3,679,778 shares of Series A Preferred Stock, and 3,750,674 shares of Series B Preferred Stock, that were converted on IPO and 695,674 options outstanding to purchase common stock as of December 31, 2020.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	September 30, 2022 (Unaudited)	December 31, 2021
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 11,195	$ 36,982
Short-term Restricted Bank Deposits	110	122
Trade Receivables	129	-
Prepaid Expenses and other Current Assets	1,598	2,636
Total Current Assets	13,032	39,740
LONG-TERM ASSETS:		
Other Assets	$ 229	$ 267
Property and Equipment, Net	999	1,120
Total Long-Term Assets	1,228	1,387
Total Assets	**$ 14,260**	**$ 41,127**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 2,326	$ 3,214
Other Accounts Payables	3,379	3,258
Total Current Liabilities	5,705	6,472
LONG TERM LIABILITIES:		
Long-term Rent Liability	396	497
Total Long-Term Liabilities	$ 396	$ 497
STOCKHOLDERS' STOCKHOLDERS' EQUITY:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at December 31, 2021 and September 30, 2022; 14,820,727 and 14,080,383 shares issued at September 30, 2022 and December 31, 2021, respectively; 14,301,984 and 13,956,035 shares outstanding at September 30, 2022 and December 31, 2021, respectively	$ 139	$ 139
Additional Paid-in Capital	147,586	145,160
Accumulated Deficit	(139,566)	(111,141)
Total Stockholders' Equity	8,159	34,158
Total Liabilities and Stockholders' Equity	**$ 14,260**	**$ 41,127**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues from licensing agreement	$ 91	$ 625	$ 587	$ 2,360
Cost of services	(91)	(625)	(497)	(2,360)
Gross profit	-	-	90	-
Operating expenses:				
Research and development	7,196	7,368	20,279	22,414
General and administrative	2,885	2,198	7,586	7,037
Operating loss	(10,081)	(9,566)	(27,775)	(29,451)
Financial Income (Loss), net	(1)	(63)	(141)	(177)
Loss before income tax	(10,082)	(9,629)	(27,916)	(29,628)
Taxes on income	(106)	(167)	(509)	(577)
Net loss	(10,188)	(9,796)	(28,425)	(30,205)
Net Loss per share, basic and diluted	$ (0.66)	$ (0.68)	$ (1.85)	$ (2.14)
Weighted average common shares outstanding, basic and diluted	**15,482,809**	**14,483,629**	**15,365,342**	**14,130,993**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share and per share amounts)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	12,728,446	$ 128	$ 109,157	$ (70,887)	$ 38,398
Share based compensation	36,990	-	1,964	-	1,964
Exercise of stock options	8,186	-	54	-	54
Proceeds from Issuance of common stocks and warrants, net of Issuance Cost of $1,665	333,333	3	23,319	-	23,322
Proceeds from Issuance of common stocks, net of Issuance Cost of $337	442,407	4	5,847		5,851
Net Loss	-	-	-	(30,205)	(30,205)
Balance as of September 30, 2021	**13,549,362**	**$ 135**	**140,341**	**$ (101,092)**	**$ 39,384**
Balance as of June 30, 2021	**13,092,925**	**131**	**133,925**	**(91,296)**	**42,760**
Share based compensation	11,844	-	545	-	545
Exercise of stock options	2,186	-	24	-	24
Proceeds from Issuance of common stocks net of Issuance Cost of $337	442,407	4	5,847	-	5,851
Net Loss	-	-	-	(9,796)	(9,796)
Balance as of September 30, 2021	**13,549,362**	**$ 135**	**$ 140,341**	**$ (101,092)**	**$ 39,384**
Balance as of December 31, 2021	**13,956,035**	**139**	**145,160**	**(111,141)**	**34,158**
Share based compensation	35,532	-	1,914	-	1,914
Proceeds from issuance of common stock, net of issuance costs of $16	310,417		512		512
Net Loss	-	-		(28,425)	(28,425)
Balance as of September 30, 2022	**14,301,984**	**$ 139**	**$ 147,586**	**$ (139,566)**	**$ 8,159**
Balance as of June 30, 2022	**13,984,622**	**139**	**146,602**	**(129,378)**	**17,363**
Share based compensation	11,845	-	516	-	516
Proceeds from issuance of common stock, net of issuance costs of $14	305,517	-	468	-	468
Net Loss	-	-	-	(10,188)	(10,188)
Balance as of September 30, 2022	**14,301,984**	**$ 139**	**$ 147,586**	**$ (139,566)**	**$ 8,159**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (28,425)	$ (30,205)
Adjustments to Reconcile Net Loss to Net Cash used in Operating Activities:		
Shared Based Compensation	$ 1,914	$ 1,964
Depreciation	121	140
(Increase) decrease in Prepaid Expenses and Other Assets	1,045	(1,546)
(Increase) decrease in Trade Receivables	(129)	308
Decrease in Trade Payables	(888)	(993)
Increase (Decrease) in other Accounts Payable	20	(232)
Net Cash used in Operating Activities	(26,342)	(30,564)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of Property and Equipment	-	(5)
Net Cash provided by (used in) Investing Activities	-	(5)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Issuance of Shares, net	-	6,007
Issuance of shares and warrants, net	512	23,322
Exercise of Stock Options	-	54
Net Cash provided by Financing Activities	512	29,383
Decrease in Cash and Cash Equivalents and Restricted Bank Deposits	25,830	1,186
Cash and Cash Equivalents and Restricted Bank Deposits at Beginning of the period	37,339	42,370
Cash and Cash Equivalents and Restricted Bank Deposits at End of the period	11,509	$ 41,184
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
Non-cash deferred issuance costs	$ -	$ 156
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash Received for Interest	$ 63	$ -
Tax Paid in Cash	$ 182	$ 128

Reconciliation of cash, cash equivalents and restricted bank deposits

	September 30, 2022	**September 30, 2021**
Cash and Cash Equivalents	$ 11,195	$ 40,840
Restricted Bank Deposits	110	120
Restricted Bank Deposits in Other Assets	204	224
Cash and Cash Equivalents and Restricted Bank Deposits at End of the Period	$ 11,509	$ 41,184

See accompanying notes to unaudited condensed consolidated financial statements

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES

General

a) Ayala Pharmaceuticals, Inc. (the "Company") was incorporated in November 2017. The Company is a clinical stage oncology company dedicated to developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. The Company's current portfolio of product candidates, AL101 and AL102, target the aberrant activation of the Notch pathway with gamma secretase inhibitors.

b) In 2017, the Company entered into an exclusive worldwide license agreement with respect to AL101 and AL102. See note 4.

c) The Company's lead product candidates, AL101 and AL102, have completed preclinical and Phase 1 studies. AL102 is currently being evaluated in a pivotal Phase 2/3 trial (RINGSIDE) in patients with Desmoids tumors and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BMCA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. AL101 is currently being evaluated in a Phase 2 trial (ACCURACY) in patients with R/M ACC bearing Notch-activating mutations is ongoing.

d) The Company has a wholly-owned Israeli subsidiary, Ayala-Oncology Israel Ltd. (the "Subsidiary"), which was incorporated in November 2017.

Certain Transactions

On February 19, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, the Company agreed to sell (i) an aggregate of 333,333 shares of the Company's common stock (the "Common Stock"), par value $0.01 per share (the "Private Placement Shares"), together with warrants to purchase an aggregate of 116,666 shares of its Common Stock with an exercise price of $18.10 per share (the "Common Warrants"), for an aggregate purchase price of $4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of its Common Stock with an exercise price of $0.01 per share (the "Pre-Funded Warrants" and collectively with the Common Warrants, the "Private Placement Warrants"), together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of $19,986,661.67 (collectively, the "Private Placement"). The Private Placement closed on February 23, 2021.

In June 2021, the Company entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which the Company may, from time to time, issue and sell Common Stock with an aggregate value of up to $200.0 million in "at-the-market" offerings (the "ATM"), under its registration statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the "ATM Registration Statement"). Sales of Common Stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for its Common Stock. Pursuant to the Sales Agreement, during the year ended December 31, 2021, the Company sold a total of 827,094 shares of Common Stock for total net proceeds of approximately $10.0 million. During the three and nine months ended September 30, 2022, the Company sold a total of 305,517 and 310,417 shares of Common Stock for total net proceeds of approximately $468 thousand and $512 thousand, respectively.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

Going Concern

The Company has incurred recurring losses since inception as a research and development organization and has an accumulated deficit of $139.6 million as of September 30, 2022. For the nine months ended September 30, 2022, the Company used approximately $26.3 million of cash in operations. The Company has relied on its ability to fund its operations through public and private equity financings. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. As of September 30, 2022, the Company had approximately $11.5 million in cash and cash equivalents and restricted bank deposits, which, without additional funding, the Company believes will not be sufficient to meet its obligations within the next twelve months from the date of issuance of these condensed consolidated financial statements. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all. If the Company is unable to obtain funding, the Company would be forced to delay, reduce, or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. As such, those factors raise substantial doubt about the Company's ability to continue as a going concern.

The unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Therefore, the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2022, do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed for the year ended December 31, 2021 (the "Annual Report") with the Securities and Exchange Commission (the "SEC"). The Company's significant accounting policies have not changed materially from those included in Note 2 of the Company's consolidated financial statements for the year ended December 31, 2021, included in the Company's Annual Report, unless otherwise stated.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements. Actual results could differ from those estimates.

Net Loss per Share

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding together with the number of additional shares of Common Stock that would have been outstanding if all potentially dilutive shares of Common Stock had been issued. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of Common Stock are anti-dilutive.

The calculation of basic and diluted loss per share includes 1,333,333 warrants with an exercise price of $0.01 for the three and nine months ended September 30, 2022.

The calculation of basic and diluted loss per share includes 1,333,333 and 1,091,158 weighted average warrants with an exercise price of $0.01 for the three and nine month ended September 30, 2021, respectively.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

The calculation of diluted loss per share does not include 583,332 Warrants and 1,141,927 options outstanding to purchase common stock with anti-dilutive effect for the three and nine months ended September 30, 2022.

The calculation of diluted loss per share does not include 583,332 Warrants and 913,194 options outstanding to purchase common stock with anti-dilutive effect for the three and nine month ended September 30, 2021.

Newly Issued Accounting Pronouncements

As an "emerging growth company," the Jumpstart Our Business Startups Act ("JOBS Act") allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act. The adoption dates discussed below reflects this election.

In February 2016, the FASB issued ASU 2016-02—Leases, requiring the recognition of lease assets and liabilities on the balance sheet. The standard:

(a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The standard is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company estimates the change in liabilities of $4.3 million and change in assets of $4.2 million.

In June 2016, the FASB issued ASU No. 2016-13 (Topic 326), Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments, which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The guidance will be effective for the Company for fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company believes Adoption of the standard will not have a material impact on the financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing a variety of exceptions within the framework of ASC 740. These exceptions include the exception to the incremental approach for intra-period tax allocation in the event of a loss from continuing operations and income or a gain from other items (such as other comprehensive income), and the exception to using general methodology for the interim period tax accounting for year-to-date losses that exceed anticipated losses. The guidance will be effective for the Company beginning January 1, 2022, and interim periods in fiscal years beginning January 1, 2023. Early adoption is permitted. The Company believes Adoption of the standard will not have a material impact on the financial statements.

Recently issued and adopted pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity (ASU 2020-06), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. This guidance also eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020. The Company elected to early adopt ASU 2020-06 on January 1, 2022. Adoption of the standard did not have a material impact on the financial statements.

NOTE 2—REVENUES

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, which applies to all contracts with customers. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct.

Customer option to acquire additional goods or services gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract.

In a contract with multiple performance obligations, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations.

The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration the Company expects to be entitled to receive in exchange for those goods or services.

In December 2018, the Company entered into an evaluation, option and license agreement (the "Novartis Agreement") with Novartis International Pharmaceutical Limited ("Novartis") for which the Company is paid for its research and development costs.

The Company concluded that there is one distinct performance obligation under the Novartis Agreement: Research and development services, an obligation which is satisfied over time.

Revenue associated with the research and development services in the amounts of approximately $91 thousand and $0.6 million were recognized in the three months ended September 30, 2022, and 2021, respectively and $0.6 million and $2.4 million were recognized in the nine months ended September 30, 2022, and 2021, respectively.

The Company concluded that progress towards completion of the research and development performance obligation related to the Novartis Agreement is best measured in an amount proportional to the expenses relative to the total estimated expenses. The Company periodically reviews and updates its estimates, when appropriate, which may adjust revenue recognized for the period. Most of the company's revenues derive from the Novartis Agreement, for which revenues consist of reimbursable research and development costs. On June 2, 2022, Novartis informed the Company that Novartis does not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the agreement.

NOTE 3—TAX

The Company has reviewed the tax positions taken, or to be taken, in its tax returns for all tax years currently open to examination by a taxing authority. As of September 30, 2022 and 2021, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of $1.3 million and $0.9 million, respectively, which were classified as other long-term liabilities. As of September 30, 2022 and 2021, the Company accrued interest related to uncertain tax positions of $71 thousand and $46 thousand, respectively. The interest is recorded as part of financial expenses. These uncertain tax positions would impact the Company's effective tax rate, if recognized. A reconciliation of the Company's unrecognized tax benefits is below:

	Nine months ended September 30, 2022	Year ended December 31, 2021
	(in thousands)	
Uncertain tax position at the beginning of the period	$ 858	$ 581
Additions for uncertain tax position of prior years (foreign exchange and interest)	19	17
Additions for tax positions of current period	470	260
Uncertain tax position at the end of the period	$ 1,347	$ 858

The Company files U.S. federal, various U.S. state and Israeli income tax returns. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. In the United States and Israel, the 2017 and subsequent tax years remain subject to examination by the applicable taxing authorities as of September 30, 2022.

NOTE 4—COMMITMENTS AND CONTINGENT

Liabilities Lease

In January 2019, the Subsidiary signed a new lease agreement. The term of the lease is for 63 months and includes an option to extend the lease for an additional 60 months. As part of the agreement, the lessor also provided the Company with finance in in the amount of approximately $0.5 million paid in arrears for of leasehold improvements. The financing was recorded as a Long-Term Rent Liability. In September 2020, the Company signed a new lease agreement. The term of the lease is for 30 months. The minimum rental payments under operating leases as of September 30, 2022, are as follows (in thousands):

Year ended December 31,	
2022	103
2023	409
2024	145
	$ 657

The Subsidiary obtained a bank guarantee in the amount of approximately $0.2 million for its new office lease agreement.

Asset Transfer and License Agreement with Bristol-Myers Squibb Company.

In November 2017, the Company entered into a license agreement, or the BMS License Agreement, with Bristol-Myers Squibb Company, or BMS, under which BMS granted the Company a worldwide, non-transferable, exclusive, sublicensable license under certain patent rights and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102, or the BMS Licensed Compounds, and products containing AL101 or AL102, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

Under the BMS License Agreement, the Company is obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product. The Company has sole responsibility for, and bear the cost of, conducting research and development and preparing all regulatory filings and related submissions with respect to the BMS Licensed Compounds and/or BMS Licensed Products. BMS has assigned and transferred all INDs for the BMS Licensed Compounds to the Company. The Company is also required to use commercially reasonable efforts to obtain regulatory approvals in certain major market countries for at least one BMS Licensed Product, as well as to affect the first commercial sale of and commercialize each BMS Licensed Product after obtaining such regulatory approval. The Company has sole responsibility for, and bear the cost of, commercializing BMS Licensed Products. For a limited period of time, the Company may not, engage directly or indirectly in the clinical development or commercialization of a Notch inhibitor molecule that is not a BMS Licensed Compound.

NOTE 4—COMMITMENTS AND CONTINGENT (continued):

The Company is required to pay BMS payments upon the achievement of certain development or regulatory milestone events of up to $95 million in the aggregate with respect to the first BMS Licensed Compound to achieve each such event and up to $47 million in the aggregate with respect to each additional BMS Licensed Compound to achieve each such event. The Company is also obligated to pay BMS payments of up to $50 million in the aggregate for each BMS Licensed Product that achieves certain sales-based milestone events and tiered royalties on net sales of each BMS Licensed Product by the Company or its affiliates or sublicensees at rates ranging from a high single-digit to low teen percentage, depending on the total annual worldwide net sales of each such Licensed Product. If the Company sublicenses or assigns any rights to the licensed patents, the BMS Licensed Compounds and/or the BMS Licensed Products, the Company is required to share with BMS a portion of all consideration received from such sublicense or assignment, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced BMS Licensed Compound or BMS Licensed Product that is subject to the applicable sublicense or assignment, but such portion may be reduced based on the milestone or royalty payments that are payable by the Company to BMS under the BMS License Agreement.

The Company accounted for the acquisition of the rights granted by BMS as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred and value of shares issued to BMS as research and development expense in the consolidated statement of operations as incurred since the acquired the rights granted by BMS represented in-process research and development and had no alternative future use.

The Company accounts for contingent consideration payable upon achievement of sales milestones in such asset acquisitions when the underlying contingency is resolved.

The BMS License Agreement remains in effect, on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis, until the expiration of royalty obligations with respect to a given BMS Licensed Product in the applicable country. Royalties are paid on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis from the first commercial sale of a particular BMS Licensed Product in a country until the latest of 10 years after the first commercial sale of such BMS Licensed Product in such country, (b) when such BMS Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such BMS Licensed Product in such country. Any inventions, and related patent rights, invented solely by either party pursuant to activities conducted under the BMS License Agreement shall be solely owned by such party, and any inventions, and related patent rights, conceived of jointly by the Company and BMS pursuant to activities conducted under the BMS License Agreement shall be jointly owned by the Company and BMS, with BMS's rights thereto included in the Company's exclusive license. The Company has the first right—with reasonable consultation with, or participation by, BMS—to prepare, prosecute, maintain and enforce the licensed patents, at the Company's expense.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to the Company (a) for insolvency-related events involving the Company, (b) for the Company's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, for the Company's failure to fulfill its obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if the Company or its affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. The Company has the right to terminate the BMS License Agreement (a) for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Project has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS's material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if the Company reasonably determine that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products.

Upon termination of the BMS License Agreement in its entirety by the Company for convenience or by BMS, the Company grants an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of its patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay the Company a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/ or BMS Licensed Products.

Option and License Agreement with Novartis International Pharmaceutical Ltd.

In December 2018, the Company entered into an evaluation, option and license agreement, or the Novartis Option Agreement, with Novartis International Pharmaceutical Limited, or Novartis, pursuant to which Novartis agreed to conduct certain studies to evaluate AL102 in combination with its B-cell maturation antigen, or BCMA, therapies in multiple myeloma, and the Company agreed to supply AL102 for such studies. All supply and development costs associated with such evaluation studies were fully borne by Novartis.

NOTE 4—COMMITMENTS AND CONTINGENT (continued):

Under the Novartis Option Agreement, the Company granted Novartis an exclusive option to obtain an exclusive (including as to the Company and its affiliates), sublicensable (subject to certain terms and conditions), worldwide license and sublicense (as applicable) under certain patent rights and know-how controlled by the Company (including applicable patent rights and know-how that are licensed from BMS pursuant to the BMS License Agreement) to research, develop, manufacture (subject to the Company's non-exclusive right to manufacture and supply AL102 or the Novartis Licensed Product for Novartis) and commercialize AL102 or any pharmaceutical product containing AL102 as the sole active ingredient, or the Novartis Licensed Product, for the diagnosis, prophylaxis, treatment, or prevention of multiple myeloma in humans. The Company also granted Novartis the right of first negotiation for the license rights to conduct development or commercialization activities with respect to the use of AL102 for indications other than multiple myeloma. Additionally, from the exercise by Novartis of its option until the termination of the Novartis Option Agreement, the Company was not able to, either itself or through its affiliates or any other third parties, directly or indirectly research, develop or commercialize certain BCMA-related compounds for the treatment of multiple myeloma.

According to the agreement, Novartis was obligated to pay the Company a low eight figure option exercise fee in order to exercise its option and activate its license, upon which the Company would have been eligible to receive development, regulatory and commercial milestone payments of up to $245 million in the aggregate and tiered royalties on net sales of Novartis Licensed Products by Novartis or its affiliates or sublicensees at rates ranging from a mid-single-digit to low double-digit percentage, depending on the total annual worldwide net sales of Novartis Licensed Products. Royalties were paid on a country-by-country and Novartis Licensed Product-by-Novartis Licensed Product basis from the first commercial sale of a particular Novartis Licensed Product in a country until the latest of (a) 10 years after the first commercial sale of such Novartis Licensed Product in such country, (b) when such Novartis Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such Novartis Licensed Product in such country. Contemporaneously with the Novartis Option Agreement, the Company entered into a stock purchase agreement and associated investment agreements, or the SPA, with Novartis' affiliate, Novartis Institutes for BioMedical Research, Inc., or NIBRI, pursuant to which NIBRI acquired a $10 million equity stake in the Company.

Novartis owned any inventions, and related patent rights, invented solely by it or jointly with the Company in connection with activities conducted pursuant to the Novartis Option Agreement. The Company maintain first right to prosecute and maintain any patents licensed to Novartis, both before and after its exercise of its option. The Company maintained the first right to defend and enforce its patents prior to Novartis's exercise of its option, upon which Novartis gains such right with respect to patents included in the license.

The option granted to Novartis will remain in effect until the earlier of (a) 60 days following the last visit of the last subject in the evaluation studies, the termination of the Novartis Option Agreement, or (c) 36 months following the delivery by the Company to Novartis of sufficient amounts of clinical evaluation materials to conduct the anticipated clinical studies. The Novartis Option Agreement remains in effect until such time as no Novartis Licensed Product is being developed or commercialized by Novartis, its affiliates, or sublicensees (including distributors or commercial partners), unless terminated earlier. The Company has the right to terminate the Novartis Option Agreement (a) for Novartis's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (b) for Novartis's failure to use commercially reasonable efforts to develop or commercialize AL102 and/or the Novartis Licensed Product not remedied within four months following written notice to Novartis. Novartis has the right to terminate the Novartis Option Agreement (a) in its entirety or on a country-by-country basis for convenience, upon 60 days written notice to us, (b) for Company's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (c) upon immediate written notice to the Company for insolvency-related events involving the Company. On June 2, 2022, Novartis informed the Company that Novartis does not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the agreement.

NOTE 5—SUBSEQUENT EVENTS

Agreement and Plan of Merger

On October 18, 2022, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Advaxis, Inc., a Delaware corporation ("Advaxis"). The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) each share of the common stock, par value $0.01 per share, of the Company (the "Ayala Common Stock") issued and outstanding immediately prior to the Merger shall be automatically converted into the right to receive 0.1874 shares (as such amount may be adjusted as provided in the Merger Agreement "Exchange Ratio") of the common stock, par value $0.001 per share, of Advaxis (the "Advaxis Common Stock"), (iii) each outstanding option to purchase shares of the Ayala Common Stock (each, an " Ayala Option") will be substituted and converted automatically into an option (each, an "Advaxis Replacement Option") to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the effective time of the Merger, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the effective time of the Merger, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iv) each restricted stock unit of the Company (each, an "Ayala RSU") outstanding immediately prior to the effective time of the Merger, whether or not vested, will be substituted and converted automatically into a restricted stock unit award of Advaxis with respect to a number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the effective time of the Merger by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

Upon completion of the Merger, the Company's stockholders will own approximately 62.5% of the combined company's outstanding common stock and Advaxis stockholders will own approximately 37.5%, subject to the terms of the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (i) approval of the Merger Agreement and the Transactions by the Company's stockholders (the "Ayala Stockholder Approval"); (ii) the effectiveness of a registration statement on Form S-4 filed by Advaxis registering the shares of Advaxis Common Stock to be issued in connection with the Merger; (iii) receipt of all required state securities or "blue sky" authorizations for the issuance of such shares of Advaxis Common Stock, except for such authorizations the lack of receipt of which would not reasonably be expected to have a material adverse impact on any of the parties to the Merger Agreement or their respective affiliates; (iv) the absence of any law or judgment of a governmental entity of competent jurisdiction that is in effect and restrains, enjoins, or otherwise prohibits consummation of the Merger; (v) the absence of a material adverse effect on the business, financial condition or results of operations of, respectively, (a) the Company and its subsidiaries, taken as a whole or (b) Advaxis and its subsidiaries, taken as a whole; (vi) the accuracy of the Company's and Advaxis's representations and warranties, subject to specified materiality qualifications; (vii) compliance by the Company and Advaxis with its respective covenants in the Merger Agreement in all material respects; and (viii) delivery of customary closing documents, including a customary officer certificate from the Company and Advaxis.

The Merger Agreement provides that the payment of a $600,000 termination fee will be payable to either sides if the merger does not go through.

Closing of the Merger is expected to occur during the first quarter of 2023. The representations, warranties, agreements and covenants of the parties set forth in the Merger Agreement will terminate at the Closing.

Annex A

Execution Version

AGREEMENT AND PLAN OF MERGER

among

ADVAXIS, INC.,

AYALA PHARMACEUTICALS, INC.

and

DOE MERGER SUB, INC.

Dated as of October 18, 2022

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Indemnified Persons	Section 5.11(a)
IRB	Section 3.16(i)
Proxy Statement/Prospectus	Section 5.4
Merger	Recitals
Merger Consideration	Section 2.1(a)(i)
Merger Sub	Preamble
Parent	Preamble
Parent Balance Sheet	Section 4.7
Parent Board	Recitals
Parent Certifications	Section 4.6(a)
Parent Common Stock	Section 4.3(a)
Parent Disclosure Schedule	Article IV
Parent SEC Documents	Section 4.6(a)
Parent Share Issuance	Section 4.4(a)
Parties	Preamble
Party	Preamble
Payor	Section 7.8(a)
Pre-Closing Period	Section 5.1(a)
Recipient	Section 7.8(a)
Registration Statement	Section 5.4
Reports	Section 3.16(e)
Representatives	Section 5.2(a)
Sensitive Data	Section 3.15.(g)
Shares	Recitals
Surviving Company	Section 1.1
Termination Date	Section 7.2(a)
Uncertificated Shares	Section 2.1(a)(ii)
Willful Breach	Section 7.7

AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (hereinafter referred to as this "**Agreement**"), dated as of October 18, 2022, among Ayala Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), Advaxis, Inc., a Delaware corporation ("**Parent**"), and Doe Merger Sub, Inc., a Delaware corporation and a wholly owned Subsidiary of Parent ("**Merger Sub**"). Parent, Merger Sub and the Company are each sometimes referred to herein as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. The Parties wish to effect a business combination through the merger of Merger Sub with and into the Company, with the Company being the surviving corporation (the "**Merger**").

B. In connection with the Merger, each outstanding share of common stock, par value $0.01 per share, of the Company ("**Shares**") issued and outstanding immediately prior to the Effective Time shall be cancelled and each holder of Shares shall have the right to receive the Merger Consideration upon the terms and subject to the conditions set forth in this Agreement and in accordance with the General Corporation Law of the State of Delaware (the "**DGCL**") (other than Shares to be cancelled in accordance with Section 2.1(a)(iii)).

C. The board of directors of the Company (the "**Company Board**") has (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) resolved to recommend the adoption of this Agreement by the Company's stockholders (the "**Company Board Recommendation**").

D. The board of directors of Parent (the "**Parent Board**") has (i) determined that the Contemplated Transactions, including the Merger and the Parent Share Issuance, are advisable and in the best interests of Parent and its stockholders and (ii) approved and declared advisable this Agreement and the Contemplated Transactions.

E. The board of directors of Merger Sub, by resolutions duly adopted, has (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of Merger Sub and its sole stockholder and (ii) approved and declared advisable this Agreement and the Contemplated Transactions.

F. Concurrently with the execution and delivery of this Agreement, and as a condition and inducement to Parent's willingness to enter into this Agreement, certain stockholders of the Company have entered into an agreement with Parent (the "**Company Voting Agreement**") pursuant to which each such stockholder has agreed, among other things, to vote the Shares it holds in favor of this Agreement, the Merger and the other Contemplated Transactions.

G. For U.S. federal income Tax purposes, it is intended that (i) the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "**Code**") (such treatment, the "**Intended Tax Treatment**") and (ii) this Agreement be, and it is hereby adopted as a "plan of reorganization" within the meaning of Treasury Regulations Section 1.368-2(g).

NOW, THEREFORE, in consideration of the premises, and of the representations, warranties, covenants and agreements contained herein, the Parties hereby agree as follows:

ARTICLE I
THE MERGER; CLOSING; SURVIVING COMPANY

1.1. The Merger. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company and the separate corporate existence of Merger Sub shall thereupon cease. The Company shall be the surviving company in the Merger (sometimes hereinafter referred to as the "**Surviving Company**"), and the separate corporate existence of the Company with all its rights, privileges, immunities, powers and franchises shall continue unaffected by the Merger, except as set forth in Article II. The Merger shall have the effects specified in this Agreement and the DGCL.

1.2. Closing. The closing of the Merger (the "**Closing**") shall take place (a) via electronic exchange of required Closing documentation, as soon as reasonably practicable, and in no event later than three Business Days following the day on which the last to be satisfied or waived of each of the conditions set forth in Article VI (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of those conditions) shall have been satisfied or waived in accordance with this Agreement or (b) at such other place and time and/or on such other date as the Company and Parent may otherwise agree in writing (the date on which the Closing occurs, the "**Closing Date**").

1.3. Effective Time. Upon the Closing, the Company and Parent will cause the certificate of merger with respect to the Merger in the form attached hereto as Exhibit A (the "**Certificate of Merger**") to be executed, acknowledged and filed with the Secretary of State of the State of Delaware as provided in the DGCL. The Merger shall become effective at the time when the Certificate of Merger has been duly filed with the Secretary of State of the State of Delaware, or at such later time as may be agreed upon by the Parties in writing and set forth in the Certificate of Merger in accordance with the DGCL (the "**Effective Time**").

1.4. The Certificate of Incorporation. At the Effective Time, the certificate of incorporation of the Company shall be amended and restated in its entirety as set forth in Exhibit B hereto and as so amended and restated shall be the Certificate of Incorporation of the Surviving Company (the "**Certificate of Incorporation**"), until thereafter amended as provided therein or by applicable Law.

1.5. The Bylaws. At the Effective Time, the bylaws of the Company shall be amended and restated to conform to the bylaws of Merger Sub (except that references to the name of Merger Sub shall be replaced with the name of the Company) (the "**Bylaws**"), and as so amended and restated shall be the Bylaws of the Surviving Company until thereafter amended as provided therein or by applicable Law.

1.6. Directors of Parent. The Parties shall take all actions necessary so that the directors and officers of Parent, each to hold office in accordance with Parent's Organizational Documents, shall be as set forth in Section 5.14 after giving effect to the provisions of Section 5.14, or such other Persons as shall be mutually agreed upon by Parent and the Company until their successors have been duly elected or appointed and qualified or until their earlier death, resignation or removal in accordance with the Certificate of Incorporation and the Bylaws.

1.7. Directors and Officers of the Surviving Company. The Parties shall take all actions necessary so that immediately after the Effective Time, the directors and officers of the Surviving Company shall be as set forth on Exhibit C under the heading "Directors and Officers – Surviving Company" until their successors have been duly elected or appointed and qualified or until their earlier death, resignation or removal in accordance with the Certificate of Incorporation and the Bylaws.

ARTICLE II
EFFECT OF THE MERGER ON SECURITIES; EXCHANGE

2.1. Effect on Capital Stock.

(a) At the Effective Time, as a result of the Merger and without any action on the part of the holder of any capital stock of the Company, Parent or Merger Sub:

(i) Merger Consideration. Each Share issued and outstanding immediately prior to the Effective Time (other than Shares held in treasury, if any (each such Share, an "**Excluded Share**" and, collectively, "**Excluded Shares**")) shall be automatically converted into the right to receive a number of shares of Parent Common Stock equal to the Exchange Ratio (the aggregate shares of Parent Common Stock issued by applying the Exchange Ratio in accordance with this Section 2.1, the "**Merger Consideration**").

(ii) At the Effective Time, all of the Shares (other than Excluded Shares) shall cease to be outstanding, shall be cancelled and shall cease to exist, and (A) each certificate (a "**Certificate**") formerly representing any of the Shares (other than Excluded Shares) and (B) each book-entry account formerly representing any uncertificated Shares ("**Uncertificated Shares**") (other than Excluded Shares) shall thereafter represent only the right to receive the Merger Consideration, any distributions or dividends payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Parent Common Stock payable pursuant to Section 2.2(e), without interest, in each case to be issued or paid in consideration therefor upon surrender of such Certificate in accordance with Section 2.2, in the case of certificated Shares, and upon receipt by the Exchange Agent of an "agent's message" in customary form in accordance with Section 2.2(h) in the case of Uncertificated Shares.

(iii) Cancellation of Excluded Shares. Each Excluded Share shall, by virtue of the Merger and without any action on the part of the Company, Parent, Merger Sub or the holder thereof, cease to be outstanding, shall be cancelled without payment of any consideration therefor and shall cease to exist.

(b) Merger Sub. Each share of common stock, par value $0.01 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and become one validly issued, fully paid and nonassessable share of common stock, $0.01 par value per share, of the Surviving Company, and such converted shares shall constitute the only outstanding shares of capital stock of the Surviving Company.

(c) Adjustments to Exchange Ratio. If, between the time of calculating the Exchange Ratio and the Effective Time, the outstanding shares of Company Capital Stock or Parent Common Stock shall have been changed into, or exchanged for, a different number of shares or a different class, by reason of any stock dividend, subdivision, reclassification, recapitalization, split, combination or exchange of shares or other like change, the Exchange Ratio shall, to the extent necessary, be equitably adjusted to reflect such change to the extent necessary to provide the holders of Company Capital Stock, Parent Common Stock, Company Options, Company RSUs and Company Warrants with the same economic effect as contemplated by this Agreement prior to such stock dividend, subdivision, reclassification, recapitalization, split, combination or exchange of shares or other like change; provided, however, that nothing herein will be construed to permit the Company or Parent to take any action with respect to Company Capital Stock or Parent Common Stock, respectively, that is prohibited or not expressly permitted by the terms of this Agreement.

2.2. Exchange of Certificates.

(a) Exchange Agent and Exchange Fund. Prior to the Effective Time, Parent shall designate a bank or trust company reasonably acceptable to the Company as the exchange agent in connection with the Merger (the "**Exchange Agent**"). The Exchange Agent shall also act as the agent for the Company's stockholders for the purpose of receiving and holding their Certificates and Uncertificated Shares and shall obtain no rights or interests in the shares represented thereby. At the Closing, Parent shall issue and cause to be deposited with the Exchange Agent: (i) evidence of book-entry shares representing non-certificated shares of Parent Common Stock issuable pursuant to Section 2.1(a); and (ii) cash sufficient to make payments in lieu of fractional shares in accordance with Section 2.2(e). The shares of Parent Common Stock and cash amounts so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares of Parent Common Stock, are referred to collectively as the "**Exchange Fund**."

(b) Exchange Procedures. Promptly after the Effective Time (and in any event within five Business Days thereafter), the Exchange Agent shall mail to each holder of record of Shares represented by a Certificate (other than holders of Excluded Shares) or Uncertificated Shares (i) a letter of transmittal in customary form specifying that delivery shall be effected, and risk of loss and title to the Certificates shall pass, only upon delivery of the Certificates (or affidavits of loss in lieu of the Certificates as provided in Section 2.2(g)) or Uncertificated Shares to the Exchange Agent, such letter of transmittal to be in such form and have such other provisions as Parent and the Company may reasonably agree, and (ii) instructions for surrendering the Certificates (or affidavits of loss in lieu of the Certificates as provided in Section 2.2(g)) or Uncertificated Shares (including instructions for sending an "agent's message" in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request)) to the Exchange Agent. Upon surrender of a Certificate (or affidavit of loss in lieu of the Certificate as provided in Section 2.2(g)) to the Exchange Agent in accordance with the terms of such letter of transmittal or with respect to Uncertificated Shares receipt of an "agent's message" in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request) by the Exchange Agent, the holder of such Certificate or Uncertificated Share shall be entitled to receive in exchange therefor non-certificated shares of Parent Common Stock in book-entry form and cash in lieu of any fractional share of Parent Common Stock pursuant to Section 2.2(e) and any dividends or other distributions pursuant to Section 2.2(c), less any required Tax withholdings as provided in Section 2.4. The Certificate or Uncertificated Share so surrendered shall forthwith be cancelled. Until due surrender of the Certificates or Uncertificated Shares, each Certificate and Uncertificated Share shall be deemed, from and after the Effective Time, to represent only the right to receive shares of Parent Common Stock (and cash in lieu of any fractional share of Parent Common Stock pursuant to Section 2.2(e)). In the event of a transfer of ownership of Shares that is not registered in the transfer records of the Company, the applicable portion of Merger Consideration to be exchanged upon due surrender of the Certificate or Uncertificated Share pursuant to Section 2.1(a) may be issued and paid to such transferee if the Certificate formerly representing such Shares is presented to the Exchange Agent, accompanied by all documents required to evidence and effect such transfer and to evidence that any applicable stock transfer Taxes have been paid or are not applicable.

(c) Distributions with Respect to Unexchanged Shares. All shares of Parent Common Stock to be issued pursuant to the Merger shall be deemed issued and outstanding as of the Effective Time and whenever a dividend or other distribution is declared by Parent in respect of the Parent Common Stock, the record date for which is after the Effective Time, that declaration shall include dividends or other distributions in respect of all shares of Parent Common Stock issuable in the Merger. No dividends or other distributions in respect of the Parent Common Stock issued pursuant to the Merger shall be paid to any holder of any un-surrendered Certificate or Uncertificated Share until such Certificate (or affidavit of loss in lieu thereof as provided in Section 2.2(g)) or Uncertificated Share is surrendered for exchange in accordance with this Article II. Subject to the effect of applicable Laws, following surrender of any such Certificate (or affidavit of loss in lieu thereof as provided in Section 2.2(g)) or Uncertificated Share, there shall be issued and/or paid to the holder of the whole shares of Parent Common Stock issued in exchange therefor, without interest thereon, (A) at the time of such surrender, the dividends or other distributions with a record date after the Effective Time theretofore payable with respect to such whole shares of Parent Common Stock and not paid and (B) at the appropriate payment date, the dividends or other distributions payable with respect to such whole shares of Parent Common Stock with a record date after the Effective Time, but with a payment date subsequent to surrender.

(d) Transfers. From and after the Effective Time, there shall be no transfers on the stock transfer books of the Company of the Shares that were outstanding immediately prior to the Effective Time.

(e) Fractional Shares. No certificate or scrip representing fractional shares of Parent Common Stock shall be issued upon the surrender for exchange of Certificates or Uncertificated Shares, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a stockholder of Parent. The Exchange Agent, acting as agent for the holders of Shares otherwise entitled to receive fractional shares of Parent Common Stock, will aggregate all fractional shares of Parent Common Stock that would otherwise have been required to be distributed and cause them to be sold in the open market for the accounts of such holders. Notwithstanding any other provision of this Agreement, each holder of Shares who would otherwise have been entitled to receive a fraction of a share of Parent Common Stock shall receive, in lieu thereof, cash, rounded to the nearest whole cent and without interest, in an amount equal to the proceeds from such sale by the Exchange Agent, if any, less any brokerage commissions or other fees, transfer Taxes or other out-of-pocket transaction costs, as well as any expenses of the Exchange Agent incurred from the sale of such fractional shares of Parent Common Stock in accordance with such holder's fractional interest in the aggregate number of shares of Parent Common Stock sold.

(f) Termination of Exchange Fund. Any portion of the Exchange Fund (including the proceeds of any investments of the Exchange Fund) that remains unclaimed by the holders of Shares for 180 days after the Effective Time shall be delivered, at Parent's option, to Parent. Any holder of Shares (other than Excluded Shares) who has not theretofore complied with Section 2.2(b) shall thereafter look only to Parent for delivery of any shares of Parent Common Stock, payment of cash in lieu of fractional shares and any dividends and other distributions in respect of the Parent Common Stock to be issued or paid pursuant to the provisions of this Article II (after giving effect to any required Tax withholdings as provided in Section 2.4) upon due surrender of its Certificates (or affidavits of loss in lieu of the Certificates as provided in Section 2.2(g)) or Uncertificated Shares, without any interest thereon. Notwithstanding the foregoing, none of the Surviving Company, Parent, Exchange Agent or any other Person shall be liable to any former holder of Shares for any amount properly delivered to a public official pursuant to applicable abandoned property, escheat or similar Laws. To the fullest extent permitted by Law, immediately prior to the date any Merger Consideration would otherwise escheat to or become the property of any Governmental Entity, such Merger Consideration shall become the property of the Surviving Company, free and clear of all claims or interest of any Person previously entitled thereto.

(g) Lost, Stolen or Destroyed Certificates. In the event any Certificate shall have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the Person claiming such Certificate to be lost, stolen or destroyed, and, if required by Parent or the Exchange Agent, the posting by such Person of a bond in such reasonable amount as Parent or the Exchange Agent, as applicable, may direct as indemnity against any claim that may be made against it with respect to such Certificate, the Exchange Agent will issue in exchange for such lost, stolen or destroyed Certificate, the cash in lieu of fractional shares, shares of Parent Common Stock and any dividends and other distributions in respect of the Parent Common Stock that would have been issuable or payable pursuant to the provisions of this Article II (after giving effect to any required Tax withholdings as provided in Section 2.4) had such lost, stolen or destroyed Certificate been surrendered.

(h) Uncertificated Shares. Any holder of Uncertificated Shares shall not be required to deliver a Certificate or an executed letter of transmittal to the Exchange Agent to receive the Merger Consideration, any dividends or other distributions payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Parent Common Stock payable pursuant to Section 2.2(e) that such holder is entitled to receive pursuant to this Article II in respect of such Uncertificated Shares. In lieu thereof, each registered holder of one or more Uncertificated Shares whose Shares were converted into the right to receive the Merger Consideration, any distributions or dividends payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Parent Common Stock payable pursuant to Section 2.2(e), shall, upon receipt by the Exchange Agent of an "agent's message" in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request), be entitled to receive, and the Surviving Company shall cause the Exchange Agent to pay and deliver as soon as reasonably practicable after the Effective Time, the Merger Consideration, any dividends or other distributions payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Parent Common Stock payable pursuant to Section 2.2(e) for each Uncertificated Share, and the Uncertificated Shares of such holder shall forthwith be cancelled. No interest will be paid or accrued on any amount payable to a holder of Uncertificated Shares.

2.3. Treatment of Equity Awards and Warrants.

(a) At the Effective Time, each Company Option that is outstanding and unexercised immediately prior to the Effective Time shall, without any action on the part of Parent, the Company or the holder thereof, cease to represent a right to acquire Shares and shall be substituted and converted automatically into a Parent option award to purchase the number of shares of Parent Common Stock (each, an "**Adjusted Option**") equal to the product obtained by *multiplying* (i) the number of Shares subject to the Company Option immediately prior to the Effective Time, by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share. Each Adjusted Option shall have an exercise price per share of Parent Common Stock equal to (x) the per share exercise price for Shares subject to the corresponding Company Option immediately prior to the Effective Time, *divided by* (y) the Exchange Ratio, rounded up to the nearest whole cent. Each Adjusted Option shall otherwise be subject to the same terms and conditions applicable to the corresponding Company Option under the applicable Company Stock Incentive Plan and the agreements evidencing grants thereunder, including vesting terms and provisions.

(b) At the Effective Time, each Company RSU that is outstanding immediately prior to the Effective Time, whether or not vested or issuable, shall, as of the Effective Time, automatically and without any action on the part of the holder thereof, be substituted and converted automatically into a Parent restricted stock unit award with respect to a number of shares of Parent Common Stock (each, an "**Adjusted RSU**") equal to the product obtained by multiplying (i) the total number of Shares subject to such Company RSU immediately prior to the Effective Time by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share. Each Adjusted RSU shall otherwise be subject to the same terms and conditions applicable to the corresponding Company RSU under the applicable Company Stock Incentive Plan and the agreements evidencing grants thereunder, including vesting terms.

(c) Further Action. At or prior to the Effective Time, the Company and the Company Board shall adopt any resolutions and take any actions which are reasonably necessary to effectuate the treatment of the Company RSUs and Company Options (collectively, the "**Company Equity Awards**") set forth in this Section 2.3. At the Effective Time, Parent (i) shall assume the Company Equity Awards in accordance with the terms of this Section 2.3 and (ii) may, in its sole discretion, assume sponsorship of the Company Stock Incentive Plan, provided that references to the Company in the Company Stock Incentive Plan and award agreements for the Company Equity Awards shall thereupon be deemed reference to Parent and references to Shares therein shall be deemed references to Parent Common Stock with appropriate equitable adjustments in accordance with the terms of the Company Stock Incentive Plan to reflect the Contemplated Transactions.

(d) At the Effective Time, each warrant that is outstanding and unexercised immediately prior to the Effective Time (a "**Company Warrant**") shall be treated in accordance with its terms.

(e) Notwithstanding anything to the contrary in the foregoing, in all cases, the exercise price of, and the number of Parent Common Stock subject to, each Adjusted Option shall be determined as necessary to comply with Sections 424 and 409A of the Code.

2.4. Withholding Rights. Each of Parent, the Merger Sub, the Company, Surviving Company and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable to Persons pursuant to this Agreement any amounts it is required to deduct and withhold with respect to the making of such payment under the Code or any other applicable state, local or foreign Tax Law. To the extent that amounts are so withheld and timely remitted by Parent, the Merger Sub, the Company, the Surviving Company or the Exchange Agent, as the case may be, to the applicable Governmental Entity, such amounts shall be treated for all purposes of this Agreement as having been paid to such Person in respect of which such deduction and withholding was made. The Parties shall cooperate in good faith to eliminate or reduce any such deduction or withholding (including through the request and provision of any statements, forms or other documents to reduce or eliminate any such deduction or withholding) to the extent permitted by applicable Law.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to Parent as set forth in the statements contained in this Article III except as set forth in the Company SEC Documents filed with, or furnished to, the SEC prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature) or in the disclosure letter delivered by the Company to Parent at or before the execution and delivery of this Agreement (the "**Company Disclosure Schedule**"). The Company Disclosure Schedule shall be arranged in numbered and lettered sections corresponding to the numbered and lettered sections contained in this Article III, and the disclosure in any section of the Company Disclosure Schedule shall be deemed to qualify other sections in this Article III to the extent that it is reasonably apparent on the face of such disclosure that such disclosure also qualifies or applies to such other sections.

3.1. Organizational Documents. The Company has made available to Parent accurate and complete copies of the Organizational Documents of the Company and each of its Subsidiaries in effect as of the date of this Agreement. Neither the Company nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

3.2. Due Organization; Subsidiaries.

(a) The Company is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions.

(b) The Company is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Company Material Adverse Effect.

(c) The Company has no Subsidiaries, except for the entities identified in Section 3.2(c) of the Company Disclosure Schedule; and neither the Company nor any of the entities identified in Section 3.2(c) of the Company Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other entity other than the entities identified in Section 3.2(c) of the Company Disclosure Schedule. Each of the Company's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Company Material Adverse Effect.

(d) Neither the Company nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither the Company nor any of its Subsidiaries has agreed or is obligated to make or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other entity. Neither the Company nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other entity.

3.3. Capitalization.

(a) The authorized capital stock of the Company as of the date of this Agreement consists of 200,000,000 shares of common stock, par value $0.01 per share ("**Company Common Stock**"), of which 14,833,327 shares have been issued and are outstanding as of the close of business on the Reference Date, and 10,000,000 shares of preferred stock, par value $0.01 per share ("**Company Preferred Stock**"), of which no shares have been issued and are outstanding as of the date of this Agreement. The Company does not hold any shares of its capital stock in its treasury.

(b) Section 3.3(b) of the Company Disclosure Schedule lists, as of the Reference Date, (A) each holder of issued and outstanding Company Warrants, (B) the number and type of shares subject to each Company Warrant, (C) the exercise price of each Company Warrant and (D) the termination date of each Company Warrant.

(c) All of the outstanding shares of Company Common Stock have been duly authorized and validly issued and are fully paid and nonassessable. None of the outstanding shares of Company Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Company Common Stock is subject to any right of first refusal in favor of the Company. Except as contemplated herein and as set forth in Section 3.3(c)(i) of the Company Disclosure Schedule, there is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Common Stock. Except as set forth in Section 3.3(c)(ii) of the Company Disclosure Schedule, the Company is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Common Stock or other securities.

(d) Except for the Company Stock Incentive Plan, the Company does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, the Company has (i) reserved 2,404,255 shares of Company Common Stock for issuance under the Company Stock Incentive Plan, of which 132,450 shares have been issued and are currently outstanding, of which no shares are subject to the Company's right of repurchase, 1,141,927 shares have been reserved for issuance upon exercise of Company Options previously granted and currently outstanding under the Company Stock Incentive Plan and 470,257 shares remain available for future issuance pursuant to the Company Stock Incentive Plan.

(e) Except for the Company Warrants and the Company Options, and as otherwise set forth in Section 3.3(e) of the Company Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of the Company or any of its Subsidiaries; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of the Company or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company or any of its Subsidiaries.

(f) All outstanding shares of Company Common Stock, Company Options, Company Warrants and other securities of the Company have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

3.4. Authority; Binding Nature of Agreement.

(a) The Company has all requisite corporate power and authority to execute and deliver this Agreement and, subject to receipt of the Company Stockholder Approval, to perform its obligations hereunder and to consummate the Contemplated Transactions. The Company Board (at a meeting duly called and held or by written consent in lieu of a meeting) has: (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions, and (iii) subject to Section 5.2, resolved to recommend the adoption of this Agreement by the Company's stockholders at the Company Stockholders Meeting. This Agreement has been duly executed and delivered by the Company and, assuming the due authorization, execution and delivery by Parent, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except, in each case, as enforcement may be limited by bankruptcy, insolvency, reorganization or similar Laws affecting creditors' rights generally and by general principles of equity (the "**Bankruptcy and Equity Exception**"). Prior to the execution of the Company Voting Agreements, the Company Board approved the Company Voting Agreement and the transactions contemplated thereby.

(b) Except for the adoption of this Agreement by the affirmative vote of the holders of a majority of the outstanding Shares present in person or by proxy and entitled to vote thereon at the Company Stockholders Meeting (such approval, the "**Company Stockholder Approval**"), no other corporate proceedings on the part of the Company are necessary to authorize, adopt or approve, as applicable, this Agreement or to consummate the Contemplated Transactions (except for the filing of the appropriate merger documents as required by the DGCL). The Company has duly executed and delivered this Agreement and, assuming the due authorization, execution and delivery by Parent and Merger Sub, this Agreement constitutes its legal, valid and binding obligation, enforceable against the Company in accordance with its terms, except, in each case, as enforcement may be limited by the Bankruptcy and Equity Exception.

3.5. Non-Contravention; Consents. Subject to (i) obtaining the Company Stockholder Approval, (ii) the filing of the Certificate of Merger required by the DGCL, (iii) (A) the filing with the SEC of the Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement and the Contemplated Transactions and (iv) such Consents, registrations, declarations, notices or filings as are required to be made or obtained under the securities or "blue sky" laws of various states in connection with the issuance of the shares of Parent Common Stock to be issued as the Merger Consideration, neither (x) the execution, delivery or performance of this Agreement by the Company, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of the Company or any of its Subsidiaries;

(b) contravene, conflict with or result in a violation of, or give any Governmental Entity the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which the Company or any of its Subsidiaries, or any of the assets owned or used by the Company or any of its Subsidiaries, is subject, except as would not reasonably be expected to be material to the Company or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company or its Subsidiaries, except as would not reasonably be expected to be material to the Company or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Company Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Company Material Contract; (iii) accelerate the maturity or performance of any Company Material Contract; or (iv) cancel, terminate or modify any term of any Company Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Lien upon or with respect to any asset owned or used by the Company or any of its Subsidiaries (except for Permitted Liens).

(f) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) (A) the filing with the SEC of the Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions and (iii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither the Company nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Entity in connection with (x) the execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions. Assuming the accuracy of the representation set forth in Section 4.5(f), the Company Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Company Voting Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Company Voting Agreements or any of the Contemplated Transactions.

3.6. SEC Documents; Financial Statements.

(a) Other than such documents that can be obtained on the SEC's website at www.sec.gov, the Company has delivered or made available to Parent accurate and complete copies of all registration statements, proxy statements, Company Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by the Company with the SEC since May 12, 2020 (the "**Company SEC Documents**"). Since the date of the Company Balance Sheet, all material statements, reports, schedules, forms and other documents required to have been filed by the Company or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Company SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Company SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (or, in the case of a Company SEC Document that is a registration statement, as amended or supplemented, if applicable, filed pursuant to the Securities Act, as of the date such registration statement or amendment became effective, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements made therein not misleading); provided, however, that no representation is made as to the accuracy of any financial projections or forward-looking statements or the completeness of any information furnished by the Company to the SEC solely for the purposes of complying with Regulation FD promulgated under the Exchange Act. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Company SEC Documents (collectively, the "**Company Certifications**") are accurate and complete and comply as to form and content with all applicable Laws. As used in this Section 3.6, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Company SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of the Company and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of the Company and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Company SEC Documents filed prior to the date hereof, there has been no material change in the Company's accounting methods or principles that would be required to be disclosed in the Company's financial statements in accordance with GAAP.

(c) As of the date of this Agreement, the Company is in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(d) The Company maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Company Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the Company's financial statements. The Company has evaluated the effectiveness of the Company's system of internal control over financial reporting as of December 31, 2021, and, to the extent required by applicable Law, presented in any applicable the Company SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. The Company has disclosed, based on its most recent evaluation of internal control over financial reporting, to the Company's auditors and audit committee (and made available to Parent a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in the Company's internal control over financial reporting. The Company has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of the Company's internal control over financial reporting.

(e) The Company maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by the Company in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure and to make the Company Certifications.

3.7. Absence of Changes. Except as set forth in Section 3.7 of the Company Disclosure Schedule and reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by Governmental Entity in connection with the COVID-19 pandemic, between the date of the Company latest consolidated unaudited balance sheet (the "**Company Balance Sheet**") and the date of this Agreement, the Company has conducted its business in the Ordinary Course of Business in all material respects (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (a) Company Material Adverse Effect or (b) action, event or occurrence that would have required the consent of Parent pursuant to Section 5.1(a) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

3.8. Absence of Undisclosed Liabilities. As of the date of this Agreement, neither the Company nor any of its Subsidiaries has any liability, debt or obligation individually or in the aggregate, of a type required to be recorded or reflected on the Company's balance sheet or disclosed in the footnotes thereto under GAAP except for liabilities, debts or obligations: (a) disclosed, reflected or reserved against in the Company Balance Sheet or disclosed in the notes thereto included in the Company SEC Documents; (b) that have been incurred by the Company or any of its Subsidiaries since the date of the Company Balance Sheet in the Ordinary Course of Business; (c) for performance of obligations of the Company or any of its Subsidiaries under the Company Material Contracts which have not resulted from a breach of such Company Material Contracts, breach of warranty, tort, infringement or violation of Law; (d) incurred in connection with the Contemplated Transactions; (e) which would not, individually or in the aggregate, reasonably be expected to be material to the Company; and (f) described in Section 3.8 of the Company Disclosure Schedule.

3.9. Title to Assets. The Company and each of its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all tangible assets reflected on the Company Balance Sheet; and (b) all other tangible assets reflected in the books and records of the Company or any of its Subsidiaries as being owned by the Company or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by the Company or its applicable Subsidiary free and clear of any Liens, other than Permitted Liens.

3.10. Legal Proceedings; Orders.

(a) As of the date of this Agreement, except as set forth in Section 3.10(a) of the Company Disclosure Schedule, to the Company's Knowledge there is no pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) the Company, (B) any of its Subsidiaries, (C) any Company Associate (in his or her capacity as such) or (D) any of the material assets owned or used by the Company or its Subsidiaries; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Except as set forth in Section 3.10(b) of the Company Disclosure Schedule, since January 1, 2020, no Legal Proceeding has been pending against the Company or any of its Subsidiaries that resulted in material liability to the Company or any of its Subsidiaries.

(c) There is no order, writ, injunction, judgment or decree to which the Company or any of its Subsidiaries, or any of the material assets owned or used by the Company or any of its Subsidiaries, is subject. To the Company's Knowledge, no officer or employee of the Company or any of its Subsidiaries is subject to any unsatisfied order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of the Company or any of its Subsidiaries or to any material assets owned or used by the Company or any of its Subsidiaries.

3.11. Contracts.

(a) Section 3.11(a) of the Company Disclosure Schedule lists the following the Company Contracts in effect as of the date of this Agreement (other than any Company Benefit Plan) (each, a "**Company Material Contract**"):

(i) a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Contract that is material to the business or operations of the Company and its Subsidiaries, taken as a whole, containing (A) any covenant limiting the freedom of the Company or any of its Subsidiaries to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provisions applicable to the Company or any of its Subsidiaries;

(iii) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $50,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any entity;

(v) each Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to material Indebtedness of the Company or any of its Subsidiaries or creating any material Liens with respect to any assets of the Company or any of its Subsidiaries;

(vi) each Contract requiring payment by or to the Company or any of its Subsidiaries after the date of this Agreement in excess of $100,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which the Company or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Company or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of the Company or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Company or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(vii) each Company Real Estate Lease;

(viii) each Contract with any Governmental Entity;

(ix) each Company Out-bound License and Company In-bound License;

(x) each Contract that is material to the business or operations of the Company and its Subsidiaries, taken as a whole, containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company or any of its Subsidiaries; or

(xi) any other Contract that is not terminable at will (with no penalty or payment) by the Company or its Subsidiaries, as applicable, and (A) which involves payment or receipt by the Company or its Subsidiaries after the date of this Agreement under any such Contract of more than $100,000 in the aggregate, or obligations after the date of this Agreement in excess of $200,000 in the aggregate, or (B) that is material to the business or operations of the Company and its Subsidiaries, taken as a whole.

(b) The Company has delivered or made available to Parent accurate and complete copies of all Company Material Contracts, including all material amendments thereto, but excluding any purchase orders issued under a Company Material Contract in the Ordinary Course of Business. There are no Company Material Contracts that are not in written form. As of the date of this Agreement, none of the Company, any of its Subsidiaries or, to the Company's Knowledge, any other party to a Company Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Company Material Contract in such manner as would permit any other party to cancel or terminate any such Company Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to the Company or its business or operations. As to the Company and its Subsidiaries, as of the date of this Agreement, each Company Material Contract is valid, binding, enforceable and in full force and effect, subject to the Bankruptcy and Equity Exception. Since the date of the Company Balance Sheet, no counterparty to a Company Material Contract has notified the Company in writing (or, to the Knowledge of the Company, otherwise) that it intends to terminate or not renew a Company Material Contract.

3.12. Employee and Labor Matters; Benefits Plans.

(a) Section 3.12(a) of the Company Disclosure Schedule is a list of all material Company Benefit Plans, including, without limitation, each such Company Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits.

(b) As applicable with respect to each material Company Benefit Plan, the Company has made available to Parent, true and complete copies of (i) each material Company Benefit Plan, including all amendments thereto, and in the case of an unwritten material Company Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Entity (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, and (vii) all notices and filings concerning IRS or United States Department of Labor or other Governmental Entity audits or investigations, including with respect to "prohibited transactions" within the meaning of Section 406 of ERISA or Section 4975 of the Code, since January 1, 2020.

(c) Each Company Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Company Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to the Company's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Company Benefit Plan or the tax exempt status of the related trust.

(e) None of the Company, any of its Subsidiaries or any Company ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code) or (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Entity involving any Company Benefit Plan, and no pending or, to the Company's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Company Benefit Plans), suits or proceedings involving any Company Benefit Plan, any fiduciary thereof or service provider thereto. All material contributions and premium payments required to have been made under any of the Company Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been made and neither the Company nor any Company ERISA Affiliate has any liability for any such unpaid contributions with respect to any Company Benefit Plan.

(g) None of the Company, any of its Subsidiaries or any Company ERISA Affiliates, nor, to the Company's Knowledge, any fiduciary, trustee or administrator of any Company Benefit Plan, has since January 1, 2020 engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Company Benefit Plan which would subject any such Company Benefit Plan, the Company, any of its Subsidiaries or the Company ERISA Affiliates to a material Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Company Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law and none of the Company, any of its Subsidiaries or any Company ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of the Company or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of the Company or any of its Subsidiaries, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Company Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Company Benefit Plan or (v) limit the right to merge, amend or terminate any Company Benefit Plan.

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to the Company and its Subsidiaries of any payment or benefit that is characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Company Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder.

(l) No Person has any "gross up" agreements with the Company or any of its Subsidiaries or other assurance of reimbursement by the Company or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) Neither the Company nor any of its Subsidiaries is a party to or bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to the Company's Knowledge, purporting to represent or seeking to represent any employees of the Company or its Subsidiaries, including through the filing of a petition for representation election.

(n) The Company and each of its Subsidiaries is, and since January 1, 2020 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including, without limitation, worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages), unemployment and workers' compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries, with respect to employees of the Company or any of its Subsidiaries, each of the Company and its Subsidiaries, since January 1, 2020: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Entity, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to the Company's Knowledge, threatened or reasonably anticipated against the Company or any of its Subsidiaries relating to any current or former employee, applicant for employment, consultant, employment agreement or Company Benefit Plan (other than routine claims for benefits). All U.S. based employees of the Company and its Subsidiaries are employed "at-will" and their employment can be terminated without advance notice or payment of severance in excess of sixty (60) days.

(o) Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries, with respect to each individual who currently renders services to the Company or any of its Subsidiaries, the Company and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, the Company has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither the Company nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(p) There is not and has not been since January 1, 2020, nor, to the Company's Knowledge, is there or has there been since January 1, 2020 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Company's Knowledge, any union organizing activity, against the Company or any of its Subsidiaries. No event has occurred, and, to the Company's Knowledge, no condition or circumstance exists, that would reasonably be expected directly or indirectly to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

3.13. Environmental Matters. The Company and each of its Subsidiaries are in compliance, and, to the Company's Knowledge, since January 1, 2020 have complied with all applicable Environmental Laws, which compliance includes the possession by the Company and its Subsidiaries of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to the Company or its business. Neither the Company nor any of its Subsidiaries has received since January 1, 2020 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Entity or other Person, that alleges that the Company or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law and, to the Company's Knowledge, there are no circumstances that would reasonably be expected to prevent or interfere with the Company's or any of its Subsidiaries' compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to the Company or its business. No current or (during the time a prior property was leased or controlled by the Company or any of its Subsidiaries) prior property leased or controlled by the Company or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of the Company or any of its Subsidiaries pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Entity is required by Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of the Contemplated Transactions.

3.14. Taxes. Except as set forth on Section 3.14 of the Company Disclosure Schedule:

(a) The Company and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Entity in any jurisdiction where the Company or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that the Company or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by the Company or any of its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of the Company and its Subsidiaries did not, as of the date of the Company Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Company Balance Sheet.

(c) All Taxes that the Company or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Entity or other Person or properly set aside in accounts for this purpose.

(d) There are no Liens for material Taxes (other than Taxes not yet due and payable) upon any of the assets of the Company or any of its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to the Company or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Entity in writing. There are no pending or ongoing, and, to the Company's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of the Company or any of its Subsidiaries. Neither the Company nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Neither the Company nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither the Company nor any of its Subsidiaries is a party to any material Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither the Company nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) installment sale or open transaction disposition made on or prior to the Closing Date; (v) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; or (vi) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date. The Company has not made any election under Section 965(h) of the Code.

(i) Neither the Company nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is the Company) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither the Company nor any of its Subsidiaries has any liability for any material Taxes of any Person (other than the Company and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither the Company nor any of its Subsidiaries (i) is a "passive foreign investment company" within the meaning of Section 1297 of the Code; or (ii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither the Company nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Neither the Company nor any of its Subsidiaries has taken any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) Neither the Company nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any pandemic response laws that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of the Company and its Affiliates (including Parent and its Subsidiaries) after the Closing Date.

(n) For purposes of this Section 3.14, each reference to the Company or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, the Company of any of its Subsidiaries.

3.15. Intellectual Property.

(a) Section 3.15(a) of the Company Disclosure Schedule identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners, for each item of Registered IP owned in whole or in part or licensed by the Company or its Subsidiaries (the "**Company Registered IP**"). Each of the patents and patent applications included in the Company Registered IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. As of the date of this Agreement, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than initial examination proceedings) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Company Registered IP is being or has been contested or challenged, except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect. To the Company's Knowledge, all Company Registered IP is in effect, valid, subsisting and enforceable. To the Company's Knowledge, all prior art publications relevant to the patentability of the claims in any issued or applied for Company Registered IP, is cited in the respective issued patents, or applications, and there is no other material prior art with respect thereto.

(b) The Company or its Subsidiaries solely owns or has rights to all right, title and interest in and to all material Company IP (other than as disclosed in Section 3.15(b) of the Company Disclosure Schedule), free and clear of all Liens other than Permitted Liens. Each Company Associate involved in the creation or development of any material Company IP, pursuant to such Company Associate's activities on behalf of the Company or its Subsidiaries, has signed a valid, enforceable written agreement containing a present assignment of all such Company Associate's rights in such material Company IP to the Company or its Subsidiaries (without further payment being owed to any such Company Associate and without any restrictions or obligations on the Company's or its Subsidiaries' ownership or use thereof) and confidentiality provisions protecting the Company IP, which, to the Company's Knowledge, has not been materially breached by such Company Associate.

(c) No funding, facilities or personnel of any Governmental Entity or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Company IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Entity or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Company IP or the right to receive royalties or other consideration for the practice of such Company IP, except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

(d) Section 3.15(d) of the Company Disclosure Schedule sets forth each license agreement pursuant to which the Company or any of its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by the Company or any of its Subsidiaries in its business as currently conducted (each a "**Company In-bound License**") or (ii) grants to any third party a license under any material Company IP or any material Intellectual Property Right licensed to the Company or any of its Subsidiaries under a Company In-bound License (each a "**Company Out-bound License**") (provided, that, the Company In-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, commercially available software-as-a-service offerings, off-the-shelf software licenses or generally available patent license agreements entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of the Company or any of its Subsidiaries; and the Company Out-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of the Company or any of its Subsidiaries).

(e) To the Company's Knowledge, the products of the Company and its Subsidiaries as currently conducted does not infringe any valid and enforceable patent of an Intellectual Property Right of any other Person, that is not a Company In-bound License, or misappropriate or otherwise violate any other Intellectual Property Right owned by any other Person, and no other Person is infringing, misappropriating or otherwise violating any Company IP or any material Intellectual Property Rights exclusively licensed to the Company or any of its Subsidiaries ("**Company In-Licensed IP**"), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect. As of the date of this Agreement, no Legal Proceeding is pending (or is threatened in writing) (A) against the Company or any of its Subsidiaries alleging that the operation of the businesses of the Company or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by the Company or any of its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of the Company IP or any Company In-Licensed IP. Since January 1, 2020, neither the Company nor any of its Subsidiaries has received any written notice or other written communication alleging that the operation of the businesses of the Company or any of its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person, except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

(f) None of the Company IP or, to the Company's Knowledge, any Company In-Licensed IP is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by the Company or any of its Subsidiaries of any such Company IP or Company In-Licensed IP.

(g) The operation of the Company's and its Subsidiaries' business are in substantial compliance with all applicable Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "**Sensitive Data**"), except to the extent that such noncompliance has not and would not reasonably be expected to have a Company Material Adverse Effect. Since January 1, 2020, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of the Company or its Subsidiaries, (ii) no violations of any security policy of the Company or its Subsidiaries regarding any such Sensitive Data, (iii) no unauthorized access or unauthorized use of any Sensitive Data used in the business of the Company or its Subsidiaries and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of the Company or its Subsidiaries or a contractor or agent acting on behalf of the Company or its Subsidiaries, in each case of (i) through (iv), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

(h) None of the Company or its Subsidiaries is now or has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate the Company or any of its Subsidiaries to grant or offer to any other Person any license or right to any Company IP.

3.16. Regulatory Matters.

(a) The Company and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all respects with all applicable Laws, including the FDCA and any other similar Laws administered or promulgated by the FDA or other comparable Governmental Entity, except for any noncompliance, either individually or in the aggregate, which would not be material to the Company. To the Company's Knowledge, no investigation, inspection, claim, suit, proceeding, audit or other action by any Governmental Entity is pending or threatened against the Company or any of its Subsidiaries.

(b) There is no agreement, judgment, injunction, order or decree binding upon the Company or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company or any of its Subsidiaries, any acquisition of material property by the Company or any of its Subsidiaries or the conduct of business by the Company or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on the Company's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(c) The Company and its Subsidiaries have at all times since January 1, 2020 held and have operated in compliance with all Governmental Authorizations that are necessary for the conduct of business of the Company and its Subsidiaries as currently being conducted (the "**Company Permits**"), except where such failures to hold or remain so in compliance would not, either individually or in the aggregate, reasonably be expected to have a Company Material Adverse Effect. All such Company Permits are valid and are in full force and effect, and will continue to be so upon consummation of the Contemplated Transactions, except as would not, either individually or in the aggregate, reasonably be expected to have a Company Material Adverse Effect. No notice, filing, or other Consent is required as a result of the Contemplated Transactions under any material Company Permit. Section 3.16(c) of the Company Disclosure Schedule identifies each Company Permit. The Company and its Subsidiaries hold all right, title and interest in and to all the Company Permits free and clear of any Lien. All fees and charges with respect to such Company Permits, as of the date hereof, have been paid in full and all filing, reporting and maintenance obligations have been completely and timely satisfied, except as would not, either individually or in the aggregate, reasonably be expected to have a Company Material Adverse Effect. The Company and each of its Subsidiaries are in material compliance with the terms of the Company Permits. To the Company's Knowledge, no Legal Proceeding is pending or threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit.

(d) To the Company's Knowledge, there are no proceedings pending or threatened with respect to an alleged material violation by the Company or any of its Subsidiaries of the FDCA or any other similar Law administered or promulgated by any comparable Governmental Entity. Neither the Company, any of its Subsidiaries nor to the Company's Knowledge, any Person providing services to the Company or any of its Subsidiaries with respect to the Company's current products or product candidates (the "**Company Products**") has received any written notice, including any warning letter, untitled letter, FDA Form-483, written notice of other adverse finding, or notice of deficiency or violation, or similar written communication from the FDA or any other Governmental Entity alleging that the Company or its Subsidiaries, their respective operations, or the Company Products are in material violation of any applicable Law or Company Permit.

(e) As required under applicable Law or pursuant to a Governmental Authorization, the Company and its Subsidiaries have maintained, filed, or furnished to the applicable Governmental Entities or Person all filings, documents, claims, reports, notices, and other submissions (the "**Reports**"), required to be maintained, filed, or furnished on a timely basis, and, at the time of maintenance, filing, or furnishing all such Reports were complete and accurate when submitted, or were subsequently updated, changed, corrected, or modified, except where the failures to so maintain, file, furnish, update, change, correct or modify would not, either individually or in the aggregate, reasonably be expected to have a Company Material Adverse Effect.

(f) Neither the Company, its Subsidiaries, nor to the Company's Knowledge, any Person providing services to the Company or its Subsidiaries has made an untrue statement of a material fact or fraudulent statement to the FDA or a Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or a Governmental Entity, or made a statement, or failed to make a statement that, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto (the "**FDA Ethics Policy**"). Neither the Company, its Subsidiaries, nor to the Company's Knowledge, any Person providing services to the Company or its Subsidiaries has ever been investigated by the FDA or other Governmental Entity for data or healthcare program fraud. Neither the Company, its Subsidiaries, nor to the Company's Knowledge, any Person providing services to the Company or its Subsidiaries is the subject of any pending or, to the Company's Knowledge, threatened investigation pursuant to the FDA Ethics Policy, or resulting from any other untrue or false statement or omission.

(g) Neither the Company, its Subsidiaries, nor, to the Company's Knowledge, any Person providing services to the Company or its Subsidiaries, nor their respective officers, directors, partners, employees, or agents have been:

(i) debarred or suspended pursuant to 21 U.S.C. § 335a;

(ii) excluded under 42 U.S.C. § 1320a-7 or any similar law, rule or regulation of any Governmental Entity;

(iii) excluded, debarred, suspended or deemed ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration;

(iv) charged, named in a complaint, convicted, or otherwise found liable in any Legal Proceeding that falls within the ambit of 21 U.S.C. § 331, 21 U.S.C. § 333, 21 U.S.C. § 334, 21 U.S.C. § 335a, 21 U.S.C. § 335b, 42 U.S.C. § 1320a - 7, 31 U.S.C. §§ 3729 – 3733, 42 U.S.C. § 1320a-7a, or any other applicable Law;

(v) disqualified or deemed ineligible pursuant to 21 C.F.R. Parts 312, 511, or 812, or otherwise restricted, in whole or in part, or subject to an assurance; or

(vi) had a pending Legal Proceeding, or otherwise received any written notice from any Governmental Entity or any Person threatening, investigating, or pursuing (i)-(v) above.

(h) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, the Company or any of its Subsidiaries, or in which the Company or any of its Subsidiaries or the Company Products have participated were and, if still pending, are being conducted in compliance in all material respects with all applicable Laws and regulations enforced by the FDA or any comparable Governmental Entity, including without limitation, 21 C.F.R. Parts 50, 54, 56, 58 and 312. To the Company's Knowledge, there are no other studies, the results of which are inconsistent with, or otherwise call into question, the results of any such studies or tests conducted by or on behalf of, or sponsored by, the Company or any of its Subsidiaries, or in which the Company or any of its Subsidiaries or the Company Products. The Company has not received written notice of any complaints, information, or adverse drug experience reports related to a Company Product that would reasonably be expected to have a Company Material Adverse Effect.

(i) Neither the Company, its Subsidiaries, nor to Parent's Knowledge, any Person providing services to the Company or its Subsidiaries has received any written notice, correspondence, or other written communications from the FDA, any other Governmental Entity, any Institutional Review Board ("**IRB**"), or other Person or board responsible for the oversight or conduct of any study conducted by or on behalf of, or sponsored by, the Company or any of its Subsidiaries, or in which the Company or any of the Company Products are participating, requiring or threatening the termination, hold, material adverse modification or suspension of any clinical study that is being or is proposed to be conducted. All clinical studies conducted or sponsored by or on behalf of the Company were and, if still pending, are being conducted in all material respects in accordance with all applicable Laws, the protocols, procedures and controls designed and approved for such studies, and in accordance with any requirement of an IRB or other Person or board responsible for review of such studies.

3.17. Insurance; Real Estate.

(a) The Company has delivered or made available to Parent accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of the Company and each of its Subsidiaries. Each of such insurance policies is in full force and effect and the Company and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2020, neither the Company nor any of its Subsidiaries has received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. The Company and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against the Company or any of its Subsidiaries for which the Company or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding or informed the Company or any of its Subsidiaries of its intent to do so.

(b) Neither the Company nor any of its Subsidiaries owns any real property. The Company has made available to Parent (a) an accurate and complete list of all real properties with respect to which the Company directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by the Company or any of its Subsidiaries, and (b) copies of all leases under which any such real property is possessed (the "**Company Real Estate Leases**"), each of which is in full force and effect, with no existing material default thereunder. The Company's or its applicable Subsidiary's use and operation of each such leased property conforms to all applicable Laws in all material respects, and the Company or its applicable Subsidiary has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Liens other than Permitted Liens.

3.18. Proxy Statement/Prospectus. None of the information supplied or to be supplied by the Company for inclusion or incorporation by reference in (a) the Registration Statement will, at the time the Registration Statement or any amendment or supplement thereto is declared effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading or (b) the Proxy Statement/Prospectus will, at the date it is first mailed to each of the Company's stockholders or at the time of the Company Stockholders Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading. The Proxy Statement/Prospectus will comply as to form in all material respects with the requirements of the Exchange Act and the rules and regulations thereunder, except that no representation is made by the Company with respect to statements made or incorporated by reference therein based on information supplied by Parent for inclusion or incorporation by reference therein.

3.19. Transactions with Affiliates. Except as set forth in the Company SEC Documents filed prior to the date of this Agreement, since the date of Company's proxy statement filed in 2022 with the SEC, no event has occurred that would be required to be reported by the Company pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

3.20. Brokers and Finders. Except for Torreya Capital, LLC, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of the Company or any of its Subsidiaries.

3.21. Opinion of Financial Advisor. As of the date of this Agreement, the Company Board has received the opinion of the Torreya Capital, LLC, as of the date of such opinion and based upon and subject to the various qualifications, assumptions, limitations and other matters set forth therein, the Exchange Ratio provided for in the Merger is fair, from a financial point of view, to holders of Shares. The Company shall, promptly following the execution of this Agreement by all Parties, furnish a copy of each such written opinion to Parent solely for informational purposes (it being agreed that none of the Parent or Merger Sub, nor any of their respective Affiliates or Representatives, shall have the right to rely on such opinion).

3.22. Anti-Bribery. None of the Company, any of its Subsidiaries or any of their respective directors, officers, employees or, to the Company's Knowledge, agents or any other Person acting on their behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action or made or failed to make any other statement, in violation of Anti-Bribery Laws except, in each case, as would not be material to the Company's business or operations. Neither the Company nor any of its Subsidiaries nor any of their respective officers, employees or agents is or has been the subject of any pending or threatened debarment or exclusionary claims, actions, proceedings, investigation or inquiry by any Governmental Entity with respect to potential violations of Anti-Bribery Laws except, in each case, as would not be material to the Company's business or operations. None of the Company, any of its Subsidiaries or any of their respective officers, employees or, to the Company's Knowledge, agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law.

3.23. Ownership of Parent Common Stock. In the past three (3) years, neither the Company nor any of its Subsidiaries has "owned" (as such term is defined in Section 203(c) of the DGCL), directly or indirectly, any shares of Parent Common Stock or other securities convertible into, exchangeable into or exercisable for shares of Parent Common Stock (other than pursuant to any employee benefit plan of the Company). There are no voting trusts or other agreements or understandings to which the Company or any its Subsidiaries is a party with respect to the voting of the capital stock or other equity interest of Parent or any of its Subsidiaries.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Parent represents and warrants to the Company as set forth in the statements contained in this Article IV except as set forth in the Parent SEC Documents filed with, or furnished to, the SEC prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature) or in the disclosure letter delivered by Parent to the Company at or before the execution and delivery by Parent of this Agreement (the "**Parent Disclosure Schedule**"). The Parent Disclosure Schedule shall be arranged in numbered and lettered sections corresponding to the numbered and lettered sections contained in this Article IV, and the disclosure in any section of the Parent Disclosure Schedule shall be deemed to qualify other sections in this Article IV to the extent that it is reasonably apparent on the face of such disclosure that such disclosure also qualifies or applies to such other sections.

4.1. Organizational Documents. Parent has made available to the Company accurate and complete copies of the Organizational Documents of Parent, Merger Sub and each of Parent's other Subsidiaries in effect as of the date of this Agreement. Neither Parent, nor Merger Sub nor any of Parent's other Subsidiaries is in material breach or violation of its respective Organizational Documents.

4.2. Due Organization; Subsidiaries.

(a) Each of Parent and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions.

(b) Parent is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Parent Material Adverse Effect.

(c) Parent has no Subsidiaries, except for the entities identified in Section 4.2(c) of the Parent Disclosure Schedule; and neither Parent nor any of the entities identified in Section 4.2(c) of the Parent Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other entity other than the entities identified in Section 4.2(c) of the Parent Disclosure Schedule. Each of Parent's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Parent Material Adverse Effect.

(d) Neither Parent nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither Parent nor any of its Subsidiaries has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other entity. Neither Parent nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other entity.

4.3. Capitalization.

(a) The authorized capital stock of Parent as of the date of this Agreement consists of (i) 170,000,000 shares of common stock, par value $0.001 per share (the "**Parent Common Stock**"), of which 1,815,951 shares have been issued and are outstanding as of the close of business on the Reference Date and (ii) 5,000,000 shares of preferred stock of Parent, par value $0.001 per share, of which no shares have been issued and are outstanding as of the date of this Agreement. Parent has authorized a sufficient number of shares of Parent Common Stock to issue the Merger Consideration. Parent does not hold any shares of its capital stock in its treasury.

(b) Section 4.3(b) of the Parent Disclosure Schedule lists, as of the Reference Date, (A) the number and type of shares subject to each Parent Warrant, (B) the exercise price of each Parent Warrant and (C) the termination date of each Parent Warrant.

(c) All of the outstanding shares of Parent Common Stock have been duly authorized and validly issued and are fully paid and nonassessable. None of the outstanding shares of Parent Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Parent Common Stock is subject to any right of first refusal in favor of Parent. The shares of Parent Common Stock issuable as Merger Consideration will be, when issued, duly authorized and validly issued and fully paid and nonassessable and all of the Adjusted Options and Adjusted RSUs to be issued pursuant to Section 2.3 will be duly authorized and validly issued, and, in each case, not subject to, or issued in violation of, any preemptive right, right of participation, right of maintenance, right of first refusal or any similar right. Except as contemplated herein and as set forth in Section 4.3(c)(i) of the Parent Disclosure Schedule, there is no Parent Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Parent Common Stock. Except as set forth in Section 4.3(c)(ii) of the Parent Disclosure Schedule, Parent is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Parent Common Stock or other securities.

(d) Except for the Parent Stock Plans, Parent does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, Parent has reserved 79,165 shares of the Parent Common Stock for issuance under the Parent Stock Plans, of which 0 shares have been issued and are currently outstanding, of which 0 shares are subject to Parent's right of repurchase and 11,118 shares have been reserved for issuance upon exercise of Parent Options previously granted and currently outstanding under the Parent Stock Plans. Parent has authorized and reserved a sufficient number of shares of Parent Common Stock to assume the Company Equity Awards at the Closing.

(e) Except for the Parent Warrants, and the Parent Options, and as otherwise set forth in Section 4.3(e) of the Parent Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Parent or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of Parent or any of its Subsidiaries; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of Parent or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Parent or any of its Subsidiaries.

(f) All outstanding shares of Parent Common Stock, the Parent Options, the Parent Warrants and other securities of Parent have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

4.4. Authority; Binding Nature of Agreement.

(a) Each of Parent and Merger Sub has all requisite corporate power and authority to execute and deliver this Agreement and, with respect to Merger Sub, the adoption of this Agreement by Parent in its capacity as sole stockholder of Merger Sub, to perform its obligations hereunder and to consummate the Contemplated Transactions. The Parent Board has adopted resolutions, by vote at a meeting duly called, (i) determining that the Contemplated Transactions, including the Merger and the issuance of shares of Parent Common Stock pursuant to this Agreement (the "**Parent Share Issuance**"), are advisable and in the best interests of Parent and its stockholders and (ii) approving and declaring advisable this Agreement and the Contemplated Transactions. As of the date of this Agreement, such resolutions have not been amended or withdrawn. This Agreement has been duly executed and delivered by Parent and Merger Sub and, assuming the due authorization, execution and delivery by the Company, constitutes the legal, valid and binding obligation of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, except, in each case, as enforcement may be limited by the Bankruptcy and Equity Exception.

(b) No other corporate proceedings on the part of Parent are necessary to authorize, adopt, or approve, as applicable, this Agreement or to consummate the Contemplated Transactions (except for the filing of the appropriate merger documents as required by the DGCL). Parent and Merger Sub have duly executed and delivered this Agreement and, assuming the due authorization, execution and delivery by the Company, this Agreement constitutes its legal, valid and binding obligation, enforceable against Parent, in accordance with its terms except, in each case, as enforcement may be limited by the Bankruptcy and Equity Exception.

4.5. Non-Contravention; Consents. Subject to (i) the filing of the Certificate of Merger required by the DGCL, (ii) (A) the filing with the SEC of the Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions, (iii) such Consents, registrations, declarations, notices or filings as are required to be made or obtained under the securities or "blue sky" laws of various states in connection with the issuance of the shares of Parent Common Stock to be issued as the Merger Consideration, neither (x) the execution, delivery or performance of this Agreement by the Company nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of Parent or any of its Subsidiaries;

(b) contravene, conflict with or result in a violation of, or give any Governmental Entity the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which Parent or any of its Subsidiaries, or any of the assets owned or used by Parent or any of its Subsidiaries, is subject, except as would not reasonably be expected to be material to Parent or its business.;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Parent or its Subsidiaries, except as would not reasonably be expected to be material to Parent or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Parent Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Parent Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Parent Material Contract; (iii) accelerate the maturity or performance of any Parent Material Contract; or (iv) cancel, terminate or modify any term of any Parent Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Lien upon or with respect to any asset owned or used by Parent or any of its Subsidiaries (except for Permitted Liens).

(f) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) (A) the filing with the SEC of the Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions and (iii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither Parent nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Entity in connection with (x) the execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent to consummate the Contemplated Transactions. The Parent Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement or any of the Contemplated Transactions.

4.6. SEC Filings; Financial Statements.

(a) Other than such documents that can be obtained on the SEC's website at www.sec.gov, Parent has delivered or made available to the Company accurate and complete copies of all registration statements, proxy statements, Parent Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Parent with the SEC since May 12, 2020 (the "**Parent SEC Documents**"). Since the date of the Company Balance Sheet, all material statements, reports, schedules, forms and other documents required to have been filed by Parent or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Parent SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (or, in the case of a Parent SEC Document that is a registration statement, as amended or supplemented, if applicable, filed pursuant to the Securities Act, as of the date such registration statement or amendment became effective, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements made therein not misleading); provided, however, that no representation is made as to the accuracy of any financial projections or forward-looking statements or the completeness of any information furnished by Parent to the SEC solely for the purposes of complying with Regulation FD promulgated under the Exchange Act. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the "**Parent Certifications**") are accurate and complete and comply as to form and content with all applicable Laws. As used in this Section 4.6, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Parent and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of Parent and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Parent SEC Documents filed prior to the date hereof, there has been no material change in Parent's accounting methods or principles that would be required to be disclosed in Parent's financial statements in accordance with GAAP.

(c) Parent maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Parent Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Parent's assets that could have a material effect on Parent's financial statements. Parent has evaluated the effectiveness of Parent's system of internal control over financial reporting as of December 31, 2021, and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and audit committee (and made available to the Company a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Parent's internal control over financial reporting. Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting.

(d) Parent maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by Parent in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to Parent's management as appropriate to allow timely decisions regarding required disclosure and to make the Parent Certifications.

4.7. Absence of Changes. Except as set forth in Section 4.7 of the Parent Disclosure Schedule and reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by Governmental Entity in connection with the COVID-19 pandemic, between the date of Parent's latest consolidated unaudited balance sheet (the "**Parent Balance Sheet**") and the date of this Agreement, Parent has conducted its business in the Ordinary Course of Business in all material respects (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (a) Parent Material Adverse Effect or (b) action, event or occurrence that would have required the consent of the Company pursuant to Section 5.1(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

4.8. Absence of Undisclosed Liabilities. As of the date of this Agreement, neither Parent nor any of its Subsidiaries has any liability, debt or obligation individually or in the aggregate, of a type required to be recorded or reflected on Parent's balance sheet or disclosed in the footnotes thereto under GAAP except for liabilities, debts or obligations: (a) disclosed, reflected or reserved against in the Parent Balance Sheet or disclosed in the notes thereto included in the Parent SEC Documents; (b) that have been incurred by Parent or any of its Subsidiaries since the date of the Parent Balance Sheet in the Ordinary Course of Business; (c) for performance of obligations of Parent or any of its Subsidiaries under Parent's material Contracts which have not resulted from a breach of such Contracts, breach of warranty, tort, infringement or violation of Law; (d) incurred in connection with the Contemplated Transactions; (e) which would not, individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect; and (f) described in Section 4.8 of the Parent Disclosure Schedule.

4.9. Legal Proceedings; Orders.

(a) As of the date of this Agreement, except as set forth in Section 4.9(a) of the Parent Disclosure Schedule, to Parent's Knowledge there is no pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Parent, (B) any of its Subsidiaries, (C) any Parent Associate (in his or her capacity as such) or (D) any of the material assets owned or used by Parent or its Subsidiaries; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Except as set forth in Section 4.9(b) of the Parent Disclosure Schedule, since January 1, 2020, no Legal Proceeding has been pending against Parent or any of its Subsidiaries that resulted in material liability to Parent or any of its Subsidiaries.

(c) There is no order, writ, injunction, judgment or decree to which Parent or any of its Subsidiaries, or any of the material assets owned or used by Parent or any of its Subsidiaries, is subject. To Parent's Knowledge, no officer or employee of Parent or any of its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Parent or any of its Subsidiaries or to any material assets owned or used by Parent or any of its Subsidiaries.

4.10. Contracts.

(a) Section 4.10(a) of the Parent Disclosure Schedule lists the following Parent Contracts in effect as of the date of this Agreement (other than any Parent Benefit Plan) (each, a "**Parent Material Contract**"):

(i) a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Contract that is material to the business or operations of Parent and its Subsidiaries, taken as a whole, containing (A) any covenant limiting the freedom of Parent or any of its Subsidiaries to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provisions applicable to Parent or any of its Subsidiaries;

(iii) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $50,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any entity;

(v) each Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to material Indebtedness of Parent or any of its Subsidiaries or creating any material Liens with respect to any assets of Parent or any of its Subsidiaries;

(vi) each Contract requiring payment by or to Parent or any of its Subsidiaries after the date of this Agreement in excess of $100,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Parent or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Parent or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Parent or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Parent or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Parent or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Company or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(vii) each Contract with any Governmental Entity;

(viii) each Contract that is material to the business or operations of Parent and its Subsidiaries, taken as a whole, containing any royalty, dividend or similar arrangement based on the revenues or profits of Parent or any of its Subsidiaries; or

(ix) any other Contract that is not terminable at will (with no penalty or payment) by Parent or its Subsidiaries, as applicable, and (A) which involves payment or receipt by Parent or its Subsidiaries after the date of this Agreement under any such Contract of more than $100,000 in the aggregate, or obligations after the date of this Agreement in excess of $200,000 in the aggregate, or (B) that is material to the business or operations of the Company and its Subsidiaries, taken as a whole.

(b) Parent has delivered or made available to the Company accurate and complete copies of all Parent Material Contracts, including all material amendments thereto, but excluding any purchase orders issued under a Parent Material Contract in the Ordinary Course of Business. There are no Parent Material Contracts that are not in written form. As of the date of this Agreement, none of Parent, any of its Subsidiaries or, to Parent's Knowledge, any other party to a Parent Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Parent Material Contract in such manner as would permit any other party to cancel or terminate any such Parent Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to Parent or its business or operations. As to Parent and its Subsidiaries, as of the date of this Agreement, each Parent Material Contract is valid, binding, enforceable and in full force and effect, subject to the Bankruptcy and Equity Exception. Since the date of the Parent Balance Sheet, no counterparty to a Parent Material Contract has notified Parent in writing (or, to the Knowledge of Parent, otherwise) that it intends to terminate or not renew a Parent Material Contract.

4.11. Employee and Labor Matters; Benefits Plans.

(a) Section 4.11(a) of Parent Disclosure Schedule is a list of all material Parent Benefit Plans, including, without limitation, each such Parent Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits.

(b) As applicable with respect to each material Parent Benefit Plan, Parent has made available to the Company, true and complete copies of (i) each material Parent Benefit Plan, including all amendments thereto, and in the case of an unwritten material Parent Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Entity (e.g., Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, and (vii) all notices and filings concerning IRS or United States Department of Labor or other Governmental Entity audits or investigations, including with respect to "prohibited transactions" within the meaning of Section 406 of ERISA or Section 4975 of the Code, since January 1, 2020.

(c) Each Parent Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Parent Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to Parent's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Parent Benefit Plan or the tax exempt status of the related trust.

(e) None of Parent, any of its Subsidiaries or any Parent ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code) or (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Entity involving any Parent Benefit Plan, and no pending or, to Parent's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Parent Benefit Plans), suits or proceedings involving any Parent Benefit Plan, any fiduciary thereof or service provider thereto. All material contributions and premium payments required to have been made under any of the Parent Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been made and neither Parent nor any Parent ERISA Affiliate has any liability for any such unpaid contributions with respect to any Parent Benefit Plan.

(g) None of Parent, any of its Subsidiaries or any Parent ERISA Affiliates, nor, to Parent's Knowledge, any fiduciary, trustee or administrator of any Parent Benefit Plan, has since January 1, 2020 engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Parent Benefit Plan which would subject any such Parent Benefit Plan, Parent, any of its Subsidiaries or Parent ERISA Affiliates to a material Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Parent Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law and none of Parent, any of its Subsidiaries or any Parent ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of Parent or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of Parent or any of its Subsidiaries, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Parent Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Parent Benefit Plan or (v) limit the right to merge, amend or terminate any Parent Benefit Plan.

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to Parent and its Subsidiaries of any payment or benefit that is characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Parent Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder.

(l) No Person has any "gross up" agreements with Parent or any of its Subsidiaries or other assurance of reimbursement by Parent or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) Neither Parent nor any of its Subsidiaries is a party to or bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to Parent's Knowledge, purporting to represent or seeking to represent any employees of Parent or its Subsidiaries, including through the filing of a petition for representation election.

(n) Parent and each of its Subsidiaries is, and since January 1, 2020 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including, without limitation, worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages), unemployment and workers' compensation, leaves of absence, and hours of work. Except as would not be reasonably likely to result in a material liability to Parent or any of its Subsidiaries, with respect to employees of Parent or any of its Subsidiaries, each of Parent and its Subsidiaries, since January 1, 2020: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Entity, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to Parent's Knowledge, threatened or reasonably anticipated against Parent or any of its Subsidiaries relating to any current or former employee, applicant for employment, consultant, employment agreement or Parent Benefit Plan (other than routine claims for benefits). All U.S. based employees of Parent and its Subsidiaries are employed "at-will" and their employment can be terminated without advance notice or payment of severance in excess of sixty (60) days.

(o) Except as would not be reasonably likely to result in a material liability to Parent or any of its Subsidiaries, with respect to each individual who currently renders services to Parent or any of its Subsidiaries, Parent and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Parent has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither Parent nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(p) There is not and has not been since January 1, 2020, nor, to Parent's Knowledge, is there or has there been since January 1, 2020 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to Parent's Knowledge, any union organizing activity, against Parent or any of its Subsidiaries. No event has occurred, and, to Parent's Knowledge, no condition or circumstance exists, that would reasonably be expected directly or indirectly to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

4.12. Registration Statement and Proxy Statement/Prospectus. None of the information supplied or to be supplied by Parent for inclusion or incorporation by reference in (a) the Registration Statement will, at the time the Registration Statement or any amendment or supplement thereto is declared effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading or (b) the Proxy Statement/Prospectus will, at the date it is first mailed to each of the Company's stockholders, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading. The Proxy Statement/Prospectus will comply as to form in all material respects with the requirements of the Exchange Act and the rules and regulations thereunder, except that no representation is made by Parent with respect to statements made or incorporated by reference therein based on information supplied by the Company for inclusion or incorporation by reference therein.

4.13. Transactions with Affiliates. Except as set forth in the Parent SEC Documents filed prior to the date of this Agreement, since the date of Parent's proxy statement filed in 2022 with the SEC, as of the date hereof, no event has occurred that would be required to be reported by Parent pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

4.14. Brokers and Finders. Except as set forth in Section 4.14 of the Parent Disclosure Schedule, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Parent or any of its Subsidiaries, including Merger Sub.

4.15. Opinion of Financial Advisor. As of the date of this Agreement, the Parent Board has received the opinion of Cantor Fitzgerald & Co. that, as of the date of such opinion and based upon and subject to the various qualifications, assumptions, limitations and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to Parent. Parent shall, promptly following the execution of this Agreement by all Parties, furnish a copy of each such written opinion to the Company solely for informational purposes (it being agreed that none of the Company, nor any of its Affiliates or Representatives, shall have the right to rely on such opinion).

4.16. Taxes. Except as set forth on Section 4.16 of the Parent Disclosure Schedule:

(a) Parent and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Entity in any jurisdiction where Parent or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that Parent or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income and other material Taxes due and owing by Parent or any of its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Parent and its Subsidiaries did not, as of the date of the Parent Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Parent Balance Sheet.

(c) All Taxes that Parent or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Entity or other Person or properly set aside in accounts for this purpose.

(d) There are no Liens for material Taxes (other than Taxes not yet due and payable) upon any of the assets of Parent or any of its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to Parent or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Entity in writing. There are no pending or ongoing, and, to Parent's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Parent or any of its Subsidiaries. Neither Parent nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Neither Parent nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither Parent nor any of its Subsidiaries is a party to any material Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Neither Parent nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) installment sale or open transaction disposition made on or prior to the Closing Date; (v) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; or (vi) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date. Parent has not made any election under Section 965(h) of the Code.

(i) Neither Parent nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Parent) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Parent nor any of its Subsidiaries has any liability for any material Taxes of any Person (other than Parent and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither Parent nor any of its Subsidiaries (i) is a "controlled foreign corporation" as defined in Section 957 of the Code; (ii) is a "passive foreign investment company" within the meaning of Section 1297 of the Code; or (iii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither Parent nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Neither Parent nor any of its Subsidiaries has taken or agreed to take any action or has Knowledge of the existence of any fact that could reasonably be expected to prevent or impede the Merger from qualifying for the Intended Tax Treatment.

(m) Neither Parent nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any pandemic response laws that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of Parent and its Affiliates (including the Company and its Subsidiaries) after the Closing Date.

For purposes of this Section 4.16, each reference to Parent or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Parent of any of its Subsidiaries.

4.17. Ownership and Operations of Merger Sub. Parent, directly or indirectly, owns beneficially all of the outstanding shares of common stock of Merger Sub. Merger Sub was formed solely for the purpose of engaging in the Merger, has engaged in no other business activities, and has incurred no liabilities or obligations other than as contemplated hereby or as otherwise required or incidental to negotiate, execute, deliver and effect the Contemplated Transactions. The authorized shares of common stock of Merger Sub consist of 1,000 shares, all of which are validly issued and outstanding. All of the issued and outstanding shares of Merger Sub are directly owned by Parent, free and clear of any Liens other than Liens imposed under any federal or state securities Laws.

4.18. Ownership of Company Common Stock. Since May 12, 2020, neither Parent nor any of its Subsidiaries has "owned" (as such term is defined in Section 203(c) of the DGCL), directly or indirectly, any shares of Company Common Stock or other securities convertible into, exchangeable into or exercisable for shares of Company Common Stock (other than pursuant to any employee benefit plan of Parent). There are no voting trusts or other agreements or understandings to which Parent or any its Subsidiaries is a party with respect to the voting of the capital stock or other equity interest of the Company or any of its Subsidiaries.

4.19. Regulatory Matters.

(a) Parent and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all respects with all applicable Laws, including the FDCA and any other similar Laws administered or promulgated by the FDA or other comparable Governmental Entity, except for any noncompliance, either individually or in the aggregate, which would not be material to Parent. To Parent's Knowledge, no investigation, inspection, claim, suit, proceeding, audit or other action by any Governmental Entity is pending or threatened against the Parent or any of its Subsidiaries.

(b) There is no agreement, judgment, injunction, order or decree binding upon Parent or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Parent or any of its Subsidiaries, any acquisition of material property by Parent or any of its Subsidiaries or the conduct of business by Parent or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on Parent's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions.

(c) Parent and its Subsidiaries have at all times since January 1, 2020 held and have operated in compliance with all Governmental Authorizations that are necessary for the conduct of business of Parent and its Subsidiaries as currently being conducted (the "**Parent Permits**"), except where such failures to hold or remain so in compliance with such Parent Permits would not, either individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect. All such Parent Permits are valid and are in full force and effect, and will continue to be so upon consummation of the Contemplated Transaction, except as would not, either individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect. No notice, filing, or other Consent is required as a result of the Contemplated Transactions under any material Parent Permit. Section 4.19(c) of the Parent Disclosure Schedule identifies each Parent Permit. Parent and its Subsidiaries hold all right, title and interest in and to all the Parent Permits free and clear of any Lien. All fees and charges with respect to such Parent Permits, as of the date hereof, have been paid in full and all filing, reporting and maintenance obligations have been completely and timely satisfied, except as would not, either individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect. Parent and each of its Subsidiaries are in material compliance with the terms of the Parent Permits. To Parent's Knowledge, no Legal Proceeding is pending or threatened, which seeks to revoke, limit, suspend, or materially modify any Parent Permit.

(d) To Parent's Knowledge, there are no proceedings pending or threatened with respect to an alleged material violation by Parent or any of its Subsidiaries of the FDCA or any other similar Law administered or promulgated by any comparable Governmental Entity. Neither Parent, any of its Subsidiaries nor to Parent's Knowledge, any Person providing services to Parent or any of its Subsidiaries with respect to Parent's products or product candidates (the "**Parent Products**") has received any written notice, including any warning letter, untitled letter FDA Form-483, written notice of other adverse finding, or notice of deficiency or violation, or similar written communication from the FDA or any other Governmental Entity alleging that Parent or its Subsidiaries, their respective operations, or the Parent Products are in material violation of any applicable Law or Parent Permits.

(e) As required under applicable Law or pursuant to a Governmental Authorization, Parent and its Subsidiaries have maintained, filed, or furnished to the applicable Governmental Entities or Person all filings, documents, claims, reports, notices, and other submissions (the "**Parent Reports**"), required to be maintained, filed, or furnished on a timely basis, and, at the time of maintenance, filing, or furnishing all such Parent Reports were complete and accurate when submitted, or were subsequently updated, changed, corrected, or modified, except where the failures to so maintain, file, furnish, update, change, correct or modify the same would not, either individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect.

(f) Neither Parent, its Subsidiaries, nor to Parent's Knowledge, any Person providing services to Parent or its Subsidiaries has made an untrue statement of a material fact or fraudulent statement to the FDA or a Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or a Governmental Entity, or made a statement, or failed to make a statement that, would reasonably be expected to provide a basis for the FDA to invoke the FDA Ethics Policy. Neither Parent, its Subsidiaries, nor to Parent's Knowledge, any Person providing services to Parent or its Subsidiaries has ever been investigated by the FDA or other Governmental Entity for data or healthcare program fraud. Neither Parent, its Subsidiaries, nor to Parent's Knowledge, any Person providing services to Parent or its Subsidiaries is the subject of any pending or, to Parent's Knowledge, threatened investigation pursuant to the FDA Ethics Policy, or resulting from any other untrue or false statement or omission.

(g) Neither Parent, its Subsidiaries, nor to Parent's Knowledge any Person providing services to Parent or its Subsidiaries, nor their respective officers, directors, partners, employees, or agents have been:

(i) debarred or suspended pursuant to 21 U.S.C. § 335a;

(ii) excluded under 42 U.S.C. § 1320a-7 or any similar law, rule or regulation of any Governmental Entity;

(iii) excluded, debarred, suspended or deemed ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration;

(iv) charged, named in a complaint, convicted, or otherwise found liable in any Legal Proceeding that falls within the ambit of 21 U.S.C. § 331, 21 U.S.C. § 333, 21 U.S.C. § 334, 21 U.S.C. § 335a, 21 U.S.C. § 335b, 42 U.S.C. § 1320a - 7, 31 U.S.C. §§ 3729 – 3733, 42 U.S.C. § 1320a-7a, or any other applicable Law;

(v) disqualified or deemed ineligible pursuant to 21 C.F.R. Parts 312, 511, or 812, or otherwise restricted, in whole or in part, or subject to an assurance; or

(vi) had a pending Legal Proceeding, or otherwise received any written notice from any Governmental Entity or any Person threatening, investigating, or pursuing (i)-(v) above.

(h) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Parent or any of its Subsidiaries, or in which Parent or any of its Subsidiaries or the Parent Products have participated, were and, if still pending, are being conducted in compliance in all material respects with all applicable Laws and regulations enforced by the FDA or any comparable Governmental Entity, including without limitation, 21 C.F.R. Parts 50, 54, 56, 58 and 312. To the Parent's Knowledge, there are no other studies, the results of which are inconsistent with, or otherwise call into question, the results of any such studies or tests conducted by or on behalf of, or sponsored by, Parent or any of its Subsidiaries, or in which Parent or any of its Subsidiaries or the Parent Products have participated. Parent has not received written notice of any complaints, information, or adverse drug experience reports related to a Parent Product that would reasonably be expected to have a Parent Material Adverse Effect.

(i) Neither Parent, its Subsidiaries, nor, to Parent's Knowledge, any Person providing services to Parent or its Subsidiaries has received any written notice, correspondence, or other written communications from the FDA, any other Governmental Entity, any IRB or other Person or board responsible for the oversight or conduct of any study conducted by or on behalf of, or sponsored by, Parent or any of its Subsidiaries, or in which Parent or any of the Parent Products are participating, requiring or threatening the termination, hold, material adverse modification or suspension of any clinical study that is being or is proposed to be conducted. All clinical studies conducted or sponsored by or on behalf of Parent or its Subsidiaries were and, if still pending, are being conducted in all material respects in accordance with all applicable Laws, the protocols, procedures and controls designed and approved for such studies, and in accordance with any requirement of an IRB or other Person or board responsible for review of such studies.

ARTICLE V
COVENANTS

5.1. Interim Operations.

(a) Conduct of Business by the Company. Except for (i) matters set forth in Section 5.1(a) of the Company Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect the health and safety of the Company's or any of its Subsidiaries' employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable Law, directive or guideline from any Governmental Entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by Parent (which consent shall not be unreasonably withheld, delayed or conditioned), from the date of this Agreement to the Effective Time, or, if earlier, the termination of this Agreement in accordance with its terms (such time, the "**Pre-Closing Period**"), the Company shall, and shall cause each of its Subsidiaries to, use commercially reasonable efforts to conduct its business in the Ordinary Course of Business. In addition, and without limiting the generality of the foregoing, except for matters set forth in the Company Disclosure Schedule or otherwise expressly permitted or expressly contemplated by this Agreement or required by applicable Law or with the prior written consent of Parent (which shall not be unreasonably withheld, conditioned or delayed), during the Pre-Closing Period, the Company shall not, and shall not permit any of its Subsidiaries to, do any of the following (provided that no such consent of Parent may be required to the extent the Company reasonably believes, based on its outside counsel's advice, that obtaining such consent may violate any Laws):

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of the Company or in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Company Stock Incentive Plan in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of the Company or any of its Subsidiaries (except for shares of Company Common Stock issued upon the valid exercise or conversion of outstanding Company Options or Company Warrants or settlement of Company RSUs); (B) any option, warrant or right to acquire any capital stock or any other security, other than stock options granted to employees and service providers in the Ordinary Course of Business which are included in the calculation of the Exchange Ratio; or (C) any instrument convertible into or exchangeable for any capital stock or other security of the Company or any of its Subsidiaries;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of the Company's or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of one hundred ten percent (110%) of the budgeted capital expenditure amounts set forth in the Company's operating budget delivered to Parent concurrently with the execution of this Agreement (the "**Company Budget**") or as provided in Section 5.1(a)(xiii);

(vi) other than as set forth on Section 5.1(a)(vi) of the Company Disclosure Schedule, required by applicable Law or the terms of any Company Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Company Benefit Plan, other than in the Ordinary Course of Business; (B) cause or permit any Company Benefit Plan to be amended in any material respect, other than in the Ordinary Course of Business; (C) increase the amount of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business or (D) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $150,000 per year (other than ordinary course replacement of departed employees or officers during the Pre-Closing Period);

(vii) recognize any labor union or labor organization, except as otherwise required by applicable Law or after prior written consent of Parent (which consent shall not be unreasonably withheld, delayed or conditioned);

(viii) enter into any material transaction other than in the Ordinary Course of Business;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Lien with respect to such assets or properties, except in the Ordinary Course of Business;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any material Company IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven months), or adopt or change any material accounting method in respect of Taxes;

(xii) other than amendments to Contracts related to the Company's desmoid programs to the extent necessary to comply with the Company Budget, enter into, materially amend or terminate any Company Material Contract;

(xiii) except as otherwise set forth in the Company Budget and for the incurrence or payment of any Transaction Expenses, other than in the Ordinary Course of Business, make any expenditures, incur any liabilities or discharge or satisfy any liabilities, in each case, in amounts that exceed the aggregate amount of the Company Budget by $150,000;

(xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xv) initiate or settle any Legal Proceeding;

(xvi) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or

(xvii) agree, resolve or commit to do any of the foregoing.

(b) Conduct of Business by Parent. Except (i) for matters set forth in Section 5.1(b) of the Parent Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect the health and safety of Parent's or any of its Subsidiaries' employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable Law, directive or guideline from any Governmental Entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by the Company (which consent shall not be unreasonably withheld, delayed or conditioned), during the Pre-Closing Period, Parent shall, and shall cause each of its Subsidiaries to, use commercially reasonable efforts to conduct its business in the Ordinary Course of Business. In addition, and without limiting the generality of the foregoing, except for matters set forth in the Parent Disclosure Schedule or otherwise expressly permitted or expressly contemplated by this Agreement or required by applicable Law or with the prior written consent of the Company (which shall not be unreasonably withheld, conditioned or delayed), during the Pre-Closing Period, Parent shall not, and shall not permit any of its Subsidiaries to, do any of the following (provided that no such consent of the Company may be required to the extent Parent reasonably believes, based on its outside counsel's advice, that obtaining such consent may violate any Laws):

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Parent or in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Parent Stock Plans in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Parent or Merger Sub (except for shares of Parent Common Stock issued upon the valid exercise or conversion of outstanding Parent Options or Parent Warrants); (B) any option, warrant or right to acquire any capital stock or any other security, other than stock options granted to employees and service providers in the Ordinary Course of Business which are included in the calculation of the Exchange Ratio; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Parent or Merger Sub;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of Parent's or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the Contemplated Transactions;

(iv) other than Merger Sub, form any Subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of one hundred ten percent (110%) of the budgeted capital expenditure amounts set forth in Parent's operating budget delivered to the Company concurrently with the execution of this Agreement (the "**Parent Budget**");

(vi) Other than as required by applicable Law or the terms of any Parent Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Parent Benefit Plan, other than in the Ordinary Course of Business; (B) cause or permit any Parent Benefit Plan to be amended in any material respect; (C) increase the amount of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees or (D) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $150,000 per year (other than ordinary course replacement of departed employees or officers during the Pre-Closing Period);

(vii) recognize any labor union or labor organization, except as otherwise required by applicable Law;

(viii) enter into any material transaction;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Lien with respect to such assets or properties;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any material Intellectual Property Rights that are owned or purported to be owned by Parent or its Subsidiaries, or exclusively licensed or purported to be exclusively licensed to Parent or its Subsidiaries;

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven months), or adopt or change any material accounting method in respect of Taxes;

(xii) enter into, materially amend or terminate any Parent Material Contract;

(xiii) except as set forth in the Parent Budget and for the incurrence or payment of any Transaction Expenses, make any expenditures, incur any liabilities or discharge or satisfy any liabilities, in each case, in amounts that exceed the aggregate amount of the Parent Budget by $150,000;

(xiv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xv) initiate or settle any Legal Proceeding;

(xvi) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or

(xvii) agree, resolve or commit to do any of the foregoing.

(c) Notice of Material Events. During the Pre-Closing Period, each Party shall promptly notify the other Party in writing of any event, condition, fact or circumstance that would reasonably be expected to make the timely satisfaction of any of the conditions set forth in Article VI impossible or unlikely or (in the case of the Company) that has had or could reasonably be expected to have or result in a Company Material Adverse Effect. Without limiting the generality of the foregoing, a Party shall promptly advise the other Party in writing of (i) any claim asserted or Legal Proceeding commenced, or, to the Party's knowledge, either: (A) with respect to a Governmental Entity, overtly threatened; or (B) with respect to any other Person, threatened in writing, in each case against, relating to, involving or otherwise affecting any of the Contemplated Transactions; (ii) any knowledge of any notice from any Person alleging that the consent of such Person is or may be required in connection with the Merger or any of the other Contemplated Transactions; and (iii) any other material Legal Proceeding or material claim threatened, commenced or asserted against or with respect to any Party or its respective Subsidiaries. No notification given pursuant to this Section 5.1(c) shall limit or otherwise affect any of the representations, warranties, covenants or obligations of such Party contained in this Agreement.

(d) All notices, requests, instructions, communications or other documents to be given in connection with any consultation or approval required pursuant to this Section 5.1 shall be in writing and shall be deemed given as provided for in Section 8.7, and, in each case, shall be addressed to such individuals as the Parties shall designate in writing from time to time.

5.2. Company Acquisition Proposals; Company Change in Recommendation.

(a) No Solicitation or Negotiation. During the Pre-Closing Period, except as expressly permitted by this Section 5.2, the Company shall not, and the Company shall cause its and its Subsidiaries' directors, officers and employees not to, and shall cause its and their respective investment bankers, attorneys, accountants and other advisors, agents or representatives (collectively, along with such directors, officers and employees, "**Representatives**") to not, directly or indirectly:

(i) solicit, initiate, induce, encourage or facilitate (including by way of granting a waiver under Section 203 of the DGCL), any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal;

(ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any proposal or offer the consummation of which would constitute a Company Acquisition Proposal;

(iii) provide any non-public information or data concerning the Company or any of its Subsidiaries to any Person in connection with any proposal the consummation of which would constitute a Company Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating a Company Acquisition Proposal;

(iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to a Company Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to a Company Acquisition Proposal;

(v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any Person (other than Parent and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or the Company's organizational or other governing documents; or

(vi) resolve, publicly propose or agree to do any of the foregoing.

The Company shall, and shall cause its Subsidiaries and Representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any Person conducted heretofore with respect to any Company Acquisition Proposal, or proposal that could reasonably be expected to lead to a Company Acquisition Proposal, and shall promptly terminate access by any such Person to any physical or electronic data rooms relating to any such Company Acquisition Proposal. As soon as reasonably practicable after the date of this Agreement, the Company shall deliver a written notice to each Person that entered into a confidentiality agreement in anticipation of potentially making a Company Acquisition Proposal within the last 12 months, to the effect that the Company is ending all discussions and negotiations with such Person with respect to any Company Acquisition Proposal, effective on the date hereof and requesting the prompt return or destruction of all confidential information previously furnished to such Person. The Company shall take all actions necessary to enforce its rights under the provisions of any "standstill" agreement between the Company and any Person (other than Parent), and shall not grant any waiver of, or agree to any amendment or modification to, any such agreement, to permit such Person to submit a Company Acquisition Proposal.

(b) Fiduciary Exception to No Solicitation Provision. Notwithstanding anything to the contrary in Section 5.2(a), prior to the time, but not after, the Company Stockholder Approval is obtained, the Company may, in response to an unsolicited, bona fide written Company Acquisition Proposal (which Company Acquisition Proposal was made after the date of this Agreement and has not been withdrawn) which did not result from a breach, in any respect, of this Section 5.2 and so long as it has provided prior written notice to Parent of the identity of such Person and its intention to engage or participate in any discussions or negotiations with any such Person, (i) provide access to non-public information regarding the Company or any of its Subsidiaries to the Person who made such Company Acquisition Proposal; *provided that* such information has previously been made available to Parent or is provided to Parent substantially concurrently with the making of such information available to such Person and that, prior to furnishing any such non-public information, the Company receives from the Person making such Company Acquisition Proposal an executed confidentiality agreement with terms at least as restrictive in all material respects on such Person as the Confidentiality Agreement's terms are on Parent (it being understood that such confidentiality agreement need not prohibit the making or amending of a Company Acquisition Proposal), and (ii) engage or participate in any discussions or negotiations with any such Person regarding such Company Acquisition Proposal if, and only if, prior to taking any action described in clause (i) or (ii) above, the Company Board determines in good faith after consultation with outside financial advisors and outside legal counsel that (x) such Company Acquisition Proposal either constitutes a Company Superior Proposal or would reasonably be expected to result in a Company Superior Proposal and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(c) Notice. The Company shall promptly (and, in any event, within 24 hours) notify Parent (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to a Company Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to a Company Acquisition Proposal are received by the Company, (ii) any non-public information is requested in connection with any Company Acquisition Proposal from the Company or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to a Company Acquisition Proposal are sought to be initiated or continued with the Company, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep Parent informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. The Company agrees that it and its Subsidiaries will not enter into any confidentiality agreement with any Person subsequent to the date of this Agreement which prohibits the Company from providing any information to Parent in accordance with this Section 5.2 or otherwise prohibits the Company from complying with its obligations under this Section 5.2. The Company further agrees that it will not provide information to any Person pursuant to any confidentiality agreement entered into prior to the date of this Agreement unless such Person agrees prior to receipt of such information to waive any provision that would prohibit the Company from providing any information to Parent in accordance with this Section 5.2 or otherwise prohibit the Company from complying with its obligations under this Section 5.2.

(d) Definitions. For purposes of this Agreement:

"**Company Acquisition Proposal**" means any proposal (other than a proposal or offer by Parent or any of its Affiliates) for (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a Person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 20% of the outstanding shares of any class of voting securities of the Company; (ii) issuance or acquisition of securities representing more than 20% of the outstanding shares of any class of voting securities of the Company; (iii) any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of the Company and of the subsidiaries of the Company that constitute or account for (x) more than 20% of the consolidated net revenues of the Company, consolidated net income of the Company or consolidated book value of the Company; or (y) more than 20% of the fair market value of the consolidated assets of the Company; or (iv) any liquidation or dissolution of the Company.

"**Company Intervening Event**" means any event or development that has a material effect on the Company and its Subsidiaries taken as a whole, occurring or arising after the date of this Agreement that (i) was not known to, or reasonably foreseeable by, the Company Board prior to the execution of this Agreement, which event, occurrence, fact, condition, change, development or effect becomes known to, or reasonably foreseeable by, the Company Board prior to the receipt of the Company Stockholder Approval and (ii) does not relate to (A) a Company Acquisition Proposal or (B) (1) any changes in the market price or trading volume of the Company or Parent, (2) the Company or Parent meeting, failing to meet or exceeding published or unpublished revenue or earnings projections, in each case in and of itself, (3) any events or developments relating to Parent or any of the Parent Affiliates, (4) any event or development generally affecting the industries in which the Company or Parent operate or in the economy generally or other general business, financial or market conditions, (5) any change in any applicable Law, (6) any event, occurrence, result and/or development with respect to the product candidates AL101 or AL102 or (7) any event or development to the extent directly resulting from the announcement or pendency of, or any actions required to be taken by the Company or Parent (or refrained to be taken by the Company or Parent) pursuant to the Agreement or the consummation of the Contemplated Transactions.

"**Company Superior Proposal**" means any bona fide, binding, written Company Acquisition Proposal on terms which the Company Board determines in its good faith judgment, after consultation with outside financial advisors and outside counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the Person or group of Persons making the proposal, and, if consummated, would result in a transaction more favorable to the Company's stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the Contemplated Transactions pursuant to Section 5.2(f) of this Agreement and the time likely to be required to consummate such Company Acquisition Proposal); provided that for purposes of the definition of "Company Superior Proposal", the references to "20%" in the definition of Company Acquisition Proposal shall be deemed to be references to "50%."

(e) No Company Change in Recommendation or Company Alternative Acquisition Agreement. Except as provided in Section 5.2(f) and Section 5.2(g), the Company Board and each committee of the Company Board shall not (i) withhold, withdraw, qualify or modify (or publicly propose or resolve to withhold, withdraw, qualify or modify), in a manner adverse to Parent, the Company Board Recommendation or approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Company Acquisition Proposal or make or authorize the making of any public statement (oral or written) that has the substantive effect of such a withdrawal, qualification or modification, or remove the Company Board Recommendation from or fail to include the Company Board Recommendation in the Proxy Statement/Prospectus (each, a "**Company Change in Recommendation**") or (ii) cause or permit the Company or any of its Subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement referred to in Section 5.2(b) entered into in compliance with Section 5.2(a)) relating to or that could reasonably be expected to lead to any Company Acquisition Proposal or requiring the Company (or that would require or could reasonably be expected to require the Company) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by this Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the Contemplated Transactions (a "**Company Alternative Acquisition Agreement**").

(f) Fiduciary Exception to No Company Change in Recommendation Provision. Notwithstanding anything to the contrary set forth in Section 5.2(e), following receipt of an unsolicited, bona fide written Company Acquisition Proposal by the Company after the date of this Agreement that did not result from a breach of this Section 5.2 and with respect to which the Company has received a written, definitive form of Company Alternative Acquisition Agreement that has not been withdrawn, and the Company Board determining in good faith, after consultation with outside financial advisors and outside legal counsel, that such Company Acquisition Proposal constitutes a Company Superior Proposal, the Company Board may, at any time prior to the time the Company Stockholder Approval is obtained, make a Company Change in Recommendation and enter into a Company Alternative Acquisition Agreement with respect to such Company Superior Proposal, if all of the following conditions are met:

(i) the Company shall have complied in all material respects with the provisions of this Section 5.2 and shall have (A) provided to Parent four Business Days' prior written notice, which shall state expressly (1) that it has received a written Company Acquisition Proposal that constitutes a Company Superior Proposal, (2) the material terms and conditions of the Company Acquisition Proposal (including the consideration offered therein and the identity of the Person or group making the Company Acquisition Proposal), and shall have contemporaneously provided an unredacted copy of the Company Alternative Acquisition Agreement and all other written documents and a summary of the material terms of oral communications related to the Company Superior Proposal (it being understood and agreed that any amendment to the financial terms or any other material term or condition of such Company Superior Proposal shall require a new notice and an additional two Business Day period) and (3) that, subject to clause (ii) below, the Company Board has determined to effect a Company Change in Recommendation, and (B) prior to making such a Company Change in Recommendation, (x) engaged in good faith negotiations with Parent (to the extent Parent wishes to engage) during such notice period to consider adjustments to the terms and conditions of this Agreement which may be proposed in writing by Parent such that the Company Alternative Acquisition Agreement ceases to constitute a Company Superior Proposal, and (y) in determining whether to make a Company Change in Recommendation, the Company Board shall take into account any changes to the terms of this Agreement proposed in writing by Parent; and

(ii) the Company Board shall have determined, in good faith, after consultation with outside financial advisors and outside legal counsel, that, in light of such Company Superior Proposal and taking into account any revised terms proposed in writing by Parent, such Company Superior Proposal continues to constitute a Company Superior Proposal and, after consultation with outside legal counsel, that the failure to make such Company Change in Recommendation would be inconsistent with the directors' fiduciary duties under applicable Law.

(g) Company Change in Recommendation Due to Company Intervening Event. Notwithstanding anything to the contrary set forth in Section 5.2(e), upon the occurrence of any Company Intervening Event, the Company Board may, at any time prior to the time the Company Stockholder Approval is obtained, make a Company Change in Recommendation, if all of the following conditions are met:

(i) the Company shall have (A) provided to Parent four Business Days' prior written notice, which shall (1) set forth in reasonable detail information describing the Company Intervening Event and the rationale for the Company Change in Recommendation (it being understood and agreed that any amendment to the facts and circumstances relating to the Company Intervening Event shall require a new notice and an additional two Business Day period), and (2) state expressly that, subject to clause (ii) below, the Company Board has determined to effect a Company Change in Recommendation and (B) prior to making such a Company Change in Recommendation, engaged in good faith negotiations with Parent (to the extent Parent wishes to engage) during such four Business Day period to consider adjustments to the terms and conditions of this Agreement which may be proposed in writing by Parent in such a manner that the failure of the Company Board to make a Company Change in Recommendation in response to the Company Intervening Event in accordance with clause (ii) below would no longer be reasonably expected to be inconsistent with the directors' fiduciary duties under applicable Law; and

(ii) the Company Board shall have determined in good faith, after consultation with outside financial advisors and outside legal counsel, that in light of such Company Intervening Event and taking into account any revised terms proposed in writing by Parent, the failure to make a Company Change in Recommendation, would be inconsistent with the directors' fiduciary duties under applicable Law.

(h) Certain Permitted Disclosure. Nothing contained in this Section 5.2 shall be deemed to prohibit the Company from complying with its disclosure obligations under applicable U.S. federal or state Law with regard to a Company Acquisition Proposal; *provided* that any "stop look and listen" communication to its stockholders of the nature contemplated by Rule 14d-9 under the Exchange Act shall include an affirmative statement to the effect that the recommendation of the Company Board is affirmed or remains unchanged; *provided*, *further*, that this Section 5.2(h) shall not be deemed to permit the Company or the Company Board to effect a Company Change in Recommendation except in accordance with Sections 5.2(f) or 5.2(g). The Company shall not submit to the vote of its stockholders any Company Acquisition Proposal or Company Superior Proposal prior to the termination of this Agreement.

5.3. Parent Board Recommendation.

(a) No Solicitation or Negotiation. During the Pre-Closing Period, except as expressly permitted by this Section 5.3, Parent shall not, and Parent shall cause its and its Subsidiaries' directors, officers and employees not to, and shall cause its and their respective Representatives to not, directly or indirectly:

(i) solicit, initiate, induce, encourage or facilitate (including by way of granting a waiver under Section 203 of the DGCL), any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, a Parent Acquisition Proposal;

(ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any proposal or offer the consummation of which would constitute a Parent Acquisition Proposal;

(iii) provide any non-public information or data concerning Parent or any of its Subsidiaries to any Person in connection with any proposal the consummation of which would constitute a Parent Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating a Parent Acquisition Proposal;

(iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to a Parent Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to a Parent Acquisition Proposal;

(v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, a Parent Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any Person (other than the Company and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or the Parent's organizational or other governing documents; or

(vi) resolve, publicly propose or agree to do any of the foregoing.

Parent shall, and shall cause its Subsidiaries and Representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any Person conducted heretofore with respect to any Parent Acquisition Proposal, or proposal that could reasonably be expected to lead to a Parent Acquisition Proposal, and shall promptly terminate access by any such Person to any physical or electronic data rooms relating to any such Parent Acquisition Proposal. As soon as reasonably practicable after the date of this Agreement, Parent shall deliver a written notice to each Person that entered into a confidentiality agreement in anticipation of potentially making a Parent Acquisition Proposal within the last 12 months, to the effect that Parent is ending all discussions and negotiations with such Person with respect to any Parent Acquisition Proposal, effective on the date hereof and requesting the prompt return or destruction of all confidential information previously furnished to such Person. Parent shall take all actions necessary to enforce its rights under the provisions of any "standstill" agreement between Parent and any Person (other than the Company), and shall not grant any waiver of, or agree to any amendment or modification to, any such agreement, to permit such Person to submit a Parent Acquisition Proposal.

(b) Fiduciary Exception to No Solicitation Provision. Notwithstanding anything to the contrary in Section 5.3(a), prior to the time, but not after, the Company Stockholder Approval is obtained, Parent may, in response to an unsolicited, bona fide written Parent Acquisition Proposal (which Parent Acquisition Proposal was made after the date of this Agreement and has not been withdrawn) which did not result from a breach, in any respect, of this Section 5.3 and so long as it has provided prior written notice to the Company of the identity of such Person and its intention to engage or participate in any discussions or negotiations with any such Person, (i) provide access to non-public information regarding Parent or any of its Subsidiaries to the Person who made such Parent Acquisition Proposal; *provided that* such information has previously been made available to the Company or is provided to the Company substantially concurrently with the making of such information available to such Person and that, prior to furnishing any such non-public information, Parent receives from the Person making such Parent Acquisition Proposal an executed confidentiality agreement with terms at least as restrictive in all material respects on such Person as the Confidentiality Agreement's terms are on the Company (it being understood that such confidentiality agreement need not prohibit the making or amending of a Parent Acquisition Proposal), and (ii) engage or participate in any discussions or negotiations with any such Person regarding such Parent Acquisition Proposal if, and only if, prior to taking any action described in clause (i) or (ii) above, the Parent Board determines in good faith after consultation with outside financial advisors and outside legal counsel that (x) such Parent Acquisition Proposal either constitutes a Parent Superior Proposal or would reasonably be expected to result in a Parent Superior Proposal and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(c) Notice. Parent shall promptly (and, in any event, within 24 hours) notify the Company (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to a Parent Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to a Parent Acquisition Proposal are received by Parent, (ii) any non-public information is requested in connection with any Parent Acquisition Proposal from Parent or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to a Parent Acquisition Proposal are sought to be initiated or continued with Parent, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep the Company reasonably informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. Parent agrees that it and its Subsidiaries will not enter into any confidentiality agreement with any Person subsequent to the date of this Agreement which prohibits Parent from providing any information to the Company in accordance with this Section 5.3 or otherwise prohibits Parent from complying with its obligations under this Section 5.3. Parent further agrees that it will not provide information to any Person pursuant to any confidentiality agreement entered into prior to the date of this Agreement unless such Person agrees prior to receipt of such information to waive any provision that would prohibit Parent from providing any information to the Company in accordance with this Section 5.3 or otherwise prohibit Parent from complying with its obligations under this Section 5.3.

(d) Definitions. For purposes of this Agreement:

"**Parent Acquisition Proposal**" means any proposal (other than a proposal or offer by the Company or any of its Affiliates) for (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a Person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 20% of the outstanding shares of any class of voting securities of Parent; (ii) issuance or acquisition of securities representing more than 20% of the outstanding shares of any class of voting securities of Parent; (iii) any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of Parent and of the subsidiaries of Parent that constitute or account for (x) more than 20% of the consolidated net revenues of Parent, consolidated net income of Parent or consolidated book value of Parent; or (y) more than 20% of the fair market value of the consolidated assets of Parent; or (iv) any liquidation or dissolution of Parent.

"**Parent Superior Proposal**" means any bona fide, binding, written Parent Acquisition Proposal on terms which the Parent Board determines in its good faith judgment, after consultation with outside financial advisors and outside counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the Person or group of Persons making the proposal, and, if consummated, would result in a transaction more favorable to Parent's stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the Contemplated Transactions pursuant to Section 5.2(f) of this Agreement and the time likely to be required to consummate such Parent Acquisition Proposal); provided that for purposes of the definition of "Parent Superior Proposal", the references to "20%" in the definition of Parent Acquisition Proposal shall be deemed to be references to "50%."

(e) Parent Alternative Acquisition Agreement. Except as provided in Section 5.3(f), the Parent Board and each committee of the Parent Board shall not approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Parent Acquisition Proposal or cause or permit Parent or any of its Subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement referred to in Section 5.3(b) entered into in compliance with Section 5.3(b)) relating to or that could reasonably be expected to lead to any Parent Acquisition Proposal or requiring Parent (or that would require or could reasonably be expected to require Parent) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by this Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the Contemplated Transactions (a "**Parent Alternative Acquisition Agreement**").

(f) Fiduciary Exception to Parent Acquisition Proposal. Notwithstanding anything to the contrary set forth in Section 5.3(e), following receipt of an unsolicited, bona fide written Parent Acquisition Proposal by Parent after the date of this Agreement that did not result from a breach of this Section 5.3 and with respect to which Parent has received a written, definitive form of Parent Alternative Acquisition Agreement that has not been withdrawn, and the Parent Board determining in good faith, after consultation with outside financial advisors and outside legal counsel, that such Parent Acquisition Proposal constitutes a Parent Superior Proposal, the Parent Board may, at any time prior to the time the Company Stockholder Approval is obtained, enter into a Parent Alternative Acquisition Agreement with respect to such Parent Superior Proposal, if all of the following conditions are met:

(i) Parent shall have complied in all material respects with the provisions of this Section 5.3 and shall have (A) provided to the Company four Business Days' prior written notice, which shall state expressly (1) that it has received a written Parent Acquisition Proposal that constitutes a Parent Superior Proposal and (2) the material terms and conditions of the Parent Acquisition Proposal (including the consideration offered therein and the identity of the Person or group making the Parent Acquisition Proposal), and shall have contemporaneously provided an unredacted copy of the Parent Alternative Acquisition Agreement and all other written documents and a summary of the material terms of oral communications related to the Parent Superior Proposal (it being understood and agreed that any amendment to the financial terms or any other material term or condition of such Parent Superior Proposal shall require a new notice and an additional two Business Day period) and (B) (x) engaged in good faith negotiations with the Company (to the extent the Company wishes to engage) during such notice period to consider adjustments to the terms and conditions of this Agreement which may be proposed in writing by the Company such that the Parent Alternative Acquisition Agreement ceases to constitute a Parent Superior Proposal, and (y) the Parent Board shall take into account any changes to the terms of this Agreement proposed in writing by the Company; and

(ii) the Parent Board shall have determined, in good faith, after consultation with outside financial advisors and outside legal counsel, that, in light of such Parent Superior Proposal and taking into account any revised terms proposed in writing by the Company, such Parent Superior Proposal continues to constitute a Parent Superior Proposal.

(g) Certain Permitted Disclosure. Nothing contained in this Section 5.3 shall be deemed to prohibit Parent from complying with its disclosure obligations under applicable U.S. federal or state Law with regard to a Parent Acquisition Proposal.

5.4. Information Supplied.

(a) The Company and Parent shall jointly prepare and cause to be filed with the SEC a proxy statement (as amended or supplemented from time to time, the "**Proxy Statement/Prospectus**") with respect to the Company Stockholders Meeting. As promptly as practicable following the date of this Agreement, Parent shall prepare (with the Company's reasonable cooperation) and file with the SEC a registration statement on Form S-4 (as amended or supplemented from time to time, the "**Registration Statement**"), in which the Proxy Statement/Prospectus will be included as a prospectus, in connection with the registration under the Securities Act of the shares of Parent Common Stock to be issued in the Merger. Parent shall use its reasonable best efforts to have the Registration Statement declared effective under the Securities Act as promptly as practicable after such filing and to keep the Registration Statement effective as long as is necessary to consummate the Merger and the other Contemplated Transactions. Parent shall also take any action (other than qualifying to do business in any jurisdiction in which it is not now so qualified or filing a general consent to service of process) required to be taken under any applicable state securities or "blue sky" laws in connection with the issuance of shares of Parent Common Stock in the Merger. Each of the Company and Parent shall furnish all information concerning the Company and the holders of Shares and Parent and the holders of the capital stock of Parent, as applicable, as may be reasonably requested in connection with any such action. Each of the Company and Parent shall use reasonable best efforts to cause the Proxy Statement/Prospectus to be mailed to the Company's stockholders as promptly as practicable after the Registration Statement is declared effective under the Securities Act.

(b) No filing of, or amendment or supplement to, the Registration Statement will be made by Parent, and no filing of, or amendment or supplement to, the Proxy Statement/Prospectus will be made by the Company or Parent, in each case without providing the other Party a reasonable opportunity to review and comment thereon (other than, in each case, any filing, amendment or supplement in connection with a Company Change in Recommendation), and each Party shall consider in good faith all comments reasonably proposed by the other Party. Each of the Company and Parent shall promptly provide the other with copies of all such filings, amendments or supplements to the extent not publicly available. Each of the Company and Parent shall furnish all information concerning such Person and its Affiliates to the other and provide such other assistance as may be reasonably requested by such other Party to be included therein and shall otherwise reasonably assist and cooperate with the other in the preparation of the Registration Statement or Proxy Statement/Prospectus, as applicable, and the resolution of any comments to either received from the SEC. If at any time prior to the receipt of the Company Stockholder Approval, any information relating to the Company or Parent, or any of their respective Affiliates, directors or officers, should be discovered by the Company or Parent which is required to be set forth in an amendment or supplement to either the Registration Statement or the Proxy Statement/Prospectus, so that either such document would not include any misstatement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Party which discovers such information shall promptly notify the other Party and an appropriate amendment or supplement describing such information shall be promptly filed with the SEC and, to the extent required by applicable Law, disseminated to the stockholders of the Company or the stockholders of Parent, as applicable. The Parties shall notify each other promptly of the receipt of any comments from the SEC or the staff of the SEC and of any request by the SEC or the staff of the SEC for amendments or supplements to the Registration Statement or the Proxy Statement/Prospectus, or for additional information and shall supply each other with copies of (i) all correspondence between it or any of its Representatives, on the one hand, and the SEC or the staff of the SEC, on the other hand, with respect to the Registration Statement, Proxy Statement/Prospectus or the Merger and (ii) all orders of the SEC relating to the Registration Statement. No response to any comments from the SEC or the staff of the SEC relating to the Proxy Statement/Prospectus will be made by either Party without providing the other a reasonable opportunity to review and comment thereon unless pursuant to a telephone call initiated by the SEC, and each Party shall consider in good faith all comments reasonably proposed by the other Party. The Parties will cause the Registration Statement and Proxy Statement/Prospectus to comply as to form in all material respects with the applicable provisions of the Securities Act and the Exchange Act and the rules and regulations thereunder.

5.5. Special Stockholder Meetings.

(a) Company Stockholders Meeting. The Company will, as promptly as practicable in accordance with applicable Law and its certificate of incorporation and bylaws, establish a record date for, duly call and give notice of, and use its reasonable best efforts to convene a meeting of holders of Shares to consider and vote upon the adoption of this Agreement, which meeting shall in any event take place within 45 days after the declaration of the effectiveness of the Registration Statement (the "**Company Stockholders Meeting**"). The Company shall use its reasonable best efforts to hold the Company Stockholders Meeting as soon as practicable after the date on which the Registration Statement becomes effective. Subject to the provisions of Section 5.2, the Company Board shall include the Company Board Recommendation in the Proxy Statement/Prospectus and recommend at the Company Stockholders Meeting that the holders of Shares adopt this Agreement and shall use its reasonable best efforts to obtain and solicit such adoption. Notwithstanding the foregoing, (x) if on or before the date on which the Company Stockholders Meeting is scheduled, the Company reasonably believes that (i) it will not receive proxies representing the Company Stockholder Approval, whether or not a quorum is present or (ii) it will not have enough Shares represented to constitute a quorum necessary to conduct the business of the Company Stockholders Meeting, the Company may (and, if requested by Parent, the Company shall) postpone or adjourn, or make one or more successive postponements or adjournments of, the Company Stockholders Meeting and (y) the Company may postpone or adjourn the Company Stockholders Meeting to allow reasonable additional time for the filing or mailing of any supplemental or amended disclosure that the Company has determined, after consultation with outside legal counsel, is reasonably likely to be required under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by stockholders of the Company prior to the Company Stockholders Meeting, as long as the date of the Company Stockholders Meeting is not postponed or adjourned more than an aggregate of 15 calendar days in connection with any such postponements or adjournments pursuant to either or both of the preceding clauses (x) and (y).

(b) Parent Stockholders Meeting. Parent may, in accordance with applicable Law and its certificate of incorporation and bylaws, establish a record date for, duly call and give notice of, and convene and hold a meeting of holders of capital stock of Parent to consider and vote upon an amendment to Parent's certificate of incorporation and the Parent Stock Plans to implement a "reverse stock split" and amend the name of Parent to "Ayala Pharmaceuticals, Inc."

5.6. Regulatory Approvals and Related Matters.

(a) Each Party shall cooperate with each other Party and shall use reasonable best efforts to file, as soon as practicable after the date of this Agreement, all notices, reports and other documents required to be filed by such party with any Governmental Entity, with respect to the Merger and the Contemplated Transactions, and to submit promptly any information reasonably requested by any Governmental Entity. Each of the Company and Parent shall give the other Party prompt notice of the commencement or known threat of commencement of any Legal Proceeding by or before any Governmental Entity with respect to the Merger or any of the Contemplated Transactions, keep the other party reasonably informed as to the status of any such Legal Proceeding or threat, and in connection with any such Legal Proceeding, each of the Company or Parent will permit authorized representatives of the other party to be present at each meeting or conference relating to any such Legal Proceeding and to have access to and be consulted in connection with any document, opinion or proposal made or submitted to any Governmental Entity in connection with any such Legal Proceeding.

(b) Subject to the immediately following sentence, Parent and the Company shall use reasonable best efforts to take, or cause to be taken, all actions necessary to consummate the Merger and make effective the other Contemplated Transactions. Without limiting the generality of the foregoing, each Party to this Agreement: (i) shall make all filings (if any) and give all notices (if any) required to be made and given by such party in connection with the Merger and the other Contemplated Transactions; (ii) shall use reasonable best efforts to obtain each Consent (if any) required to be obtained (pursuant to any applicable Law or Contract, or otherwise) by such party in connection with the Merger or any of the other Contemplated Transactions; and (iii) shall use reasonable best efforts to lift any restraint, injunction or other legal bar to the Merger.

(c) The Company and Parent each shall, upon request by the other, promptly furnish the other with all information concerning itself, its Subsidiaries, directors, officers and shareholders and such other matters as may be reasonably necessary or advisable in connection with the Registration Statement, Proxy Statement/Prospectus and any other statement, filing, notice or application made by or on behalf of Parent, the Company or any of their respective Subsidiaries to any third party and/or any Governmental Entity in connection with the Contemplated Transactions.

(d) The Company and Parent each shall promptly furnish the other with copies of notices or other communications received by the Company or Parent, as the case may be, or any of their respective Subsidiaries from any third party and/or any Governmental Entity with respect to the Contemplated Transactions, other than immaterial communications.

5.7. Access; Consultation.

(a) Upon reasonable notice, and except as may otherwise be required by applicable Law, each of the Company and Parent shall, and shall cause each of its Subsidiaries to, afford the other Party's Representatives reasonable access (at the requesting Party's cost) under the supervision of appropriate personnel of the other Party, during normal business hours during the period prior to the Effective Time, to the other Party's, and each of its Subsidiaries' employees, properties, assets, books, records and contracts and, during such period, each of the Company and Parent shall, and shall cause each of its Subsidiaries to, furnish promptly to the other all information concerning its or any of its Subsidiaries' capital stock, business and personnel as may reasonably be requested by the other; provided that no investigation pursuant to this Section 5.7 shall affect or be deemed to modify any representation or warranty made by the Company or Parent; and provided, further that the foregoing shall require neither the Company nor Parent to permit any invasive sampling or testing or to disclose any information pursuant to this Section 5.7 to the extent that (i) in the reasonable good faith judgment of such Party, any applicable Law requires such Party or its Subsidiaries to restrict or prohibit access to any such properties or information, (ii) in the reasonable good faith judgment of such Party, the information is subject to confidentiality obligations to a third party or (iii) disclosure of any such information or document would result in the loss of attorney-client privilege; provided, further that with respect to clauses (i) through (iii) of this Section 5.7(a), Parent or the Company, as applicable, shall use its commercially reasonable efforts to (1) obtain the required consent of any such third party to provide such inspection or disclosure, (2) develop an alternative to providing such information so as to address such matters that is reasonably acceptable to Parent and the Company and (3) in the case of clauses (i) and (iii), implement appropriate and mutually agreeable measures to permit the disclosure of such information in a manner to remove the basis for the objection, including by arrangement of appropriate clean room procedures, redaction or entry into a customary joint defense agreement with respect to any information to be so provided, if the Parties determine that doing so would reasonably permit the disclosure of such information without violating applicable Law or jeopardizing such privilege. Any investigation pursuant to this Section 5.7 shall be conducted in such a manner as not to interfere unreasonably with the conduct of the business of the other Party. All requests for information made pursuant to this Section 5.7 shall be directed in writing to an executive officer of the Company or Parent, as applicable, or such Person as may be designated by any such executive officer.

5.8. Stock Exchange De-listing and De-registration. The Company shall take all actions necessary to permit the Shares and any other security issued by the Company or one of its Subsidiaries and listed on The Nasdaq Global Market to be de-listed and de-registered under the Exchange Act as soon as possible following the Effective Time.

5.9. Publicity. The initial press release with respect to the Merger and the other Contemplated Transactions shall be a joint press release and thereafter the Company and Parent shall consult with each other prior to issuing or making, and provide each other the reasonable opportunity to review and comment on, any press releases or other public announcements with respect to the Contemplated Transactions and any filings with any Governmental Entity (including any national securities exchange) with respect thereto, except (a) as may be required by applicable Law or by obligations pursuant to any listing agreement with or rules of any national securities exchange, (b) any consultation that would not be reasonably practicable as a result of requirements of applicable Law, (c) any press release or public statement that in the good faith judgment of the applicable Party is consistent with prior press releases issued or public statements made in compliance with this Section 5.9, (d) any internal announcements to employees regarding the Merger so long as such statements are consistent with previous press releases, public disclosures or public statements made jointly by the Parties (or individually, if approved by the other Party) or (e) with respect to any Company Change in Recommendation made in accordance with this Agreement or Parent's response thereto.

5.10. Expenses. Except as otherwise provided in Sections 7.5 and 7.6, whether or not the Merger is consummated, all costs and expenses incurred in connection with this Agreement and the Contemplated Transactions shall be paid by the Party incurring such expense.

5.11. Indemnification; Directors' and Officers' Insurance.

(a) All rights to indemnification by the Company existing in favor of those Persons who are directors and officers of the Company as of the date of this Agreement (the "**Indemnified Persons**") for their acts and omissions as directors and officers of the Company occurring prior to the Effective Time, as provided in the Company's Certificate of Incorporation or Bylaws (as in effect as of the date of this Agreement) and as provided in any indemnification agreements between the Company and said Indemnified Persons (as in effect as of the date of this Agreement), shall survive the Merger and be observed by the Surviving Company to the fullest extent permitted by Delaware law for a period of six years from the date on which the Merger becomes effective.

(b) Prior to the Effective Time, the Company shall purchase a six year "tail policy" for the existing policy of directors' and officers' liability insurance maintained by the Company as of the date of this Agreement in the form delivered or made available by the Company to Parent prior to the date of this Agreement at a premium not to exceed 300% of the annual premiums currently paid by the Company for such insurance. The costs of such tail policy will be split evenly between the Company and Parent, and the portion paid for by Parent will be treated as a Transaction Expense of Parent hereunder.

(c) In the event Parent or the Company or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, Parent shall ensure that the successors and assigns of Parent or the Surviving Company, as the case may be, or at Parent's option, Parent, shall assume the obligations set forth in this Section 5.11.

5.12. Takeover Statute. The Company and the Company Board and Parent and the Parent Board shall use their respective reasonable best efforts to (x) take all action reasonably appropriate to ensure that no state takeover statute or similar statute or regulation is or becomes applicable to this Agreement or the Contemplated Transactions and (y) if any state takeover statute or similar statute or regulation becomes applicable to this Agreement or the Contemplated Transactions, take all action reasonably appropriate to ensure that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement.

5.13. Control of the Company's or Parent's Operations. Nothing contained in this Agreement shall give Parent or the Company, directly or indirectly, rights to control or direct the operations of the other prior to the Effective Time. Prior to the Effective Time, each of Parent and the Company shall exercise, consistent with the terms and conditions of this Agreement, complete control and supervision of its operations. The Company and the Company Board and Parent and the Parent Board shall use their respective reasonable best efforts to (x) take all action reasonably appropriate to ensure that no state takeover statute or similar statute or regulation is or becomes applicable to this Agreement or the Contemplated Transactions and (y) if any state takeover statute or similar statute or regulation becomes applicable to this Agreement or the Contemplated Transactions, take all action reasonably appropriate to ensure that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement.

5.14. Directors and Officers. The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (a) the Parent Board is comprised of seven (7) members, with two (2) such members designated by Parent and five (5) such members designated by the Company, (b) the Persons listed in Exhibit C hereto under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in Exhibit C is unable or unwilling to serve as an officer of Parent, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. The Persons listed in Exhibit C under the heading "Board Designees – Parent" shall be Parent's designees pursuant to clause (a) of this Section 5.14 (which list may be changed by Parent at any time prior to the Closing by written notice to the Company to include different board designees who are reasonably acceptable to the Company) (the "**Parent Designees**"). The Persons listed in Exhibit C under the heading "Board Designees – Company" shall be the Company's designees pursuant to clause (a) of this Section 5.14 (which list may be changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent).

5.15. Section 16(b). The board of directors of each of the Company and Parent (or, in each case, a duly authorized committee thereof) shall, prior to the Effective Time, take all such actions within its control as may be necessary or appropriate to cause the Contemplated Transactions and any other dispositions of equity securities of the Company and acquisitions of equity securities of Parent (including derivative securities) in connection with the Contemplated Transactions by each individual who is a director or executive officer of the Company or is or may become a director or executive officer of Parent in connection with the Contemplated Transactions to be exempt under Rule 16b-3 promulgated under the Exchange Act.

5.16. Approval by Sole Stockholder of Merger Sub
. Immediately following the execution and delivery of this Agreement by the Parties, Parent, as sole stockholder of Merger Sub, shall adopt this Agreement and approve the Merger, in accordance with Delaware Law, by written consent.

5.17. Stockholder Litigation. Each Party shall notify the other Party, in writing and promptly after acquiring knowledge thereof, of any litigation related to this Agreement, the Merger or the other Contemplated Transactions that is brought against or, to the Knowledge of the Company or Parent, threatened against, either Party, either Party's Subsidiaries and/or any of their respective directors or officers and shall keep the other Party informed on a reasonably current basis with respect to the status thereof. Each Party shall provide the other Party (a) the opportunity to participate in the defense of any such Legal Proceedings and (b) the right to review and comment on all material filings or responses to be made by the Parties in connection with any such Legal Proceedings (and the Parties shall in good faith take such comments and other advice into consideration). The Parties agree to cooperate in the defense and settlement of any such litigation, and the Parties shall not settle any such litigation without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), including a majority of the Parent Designees for so long as any Parent Designees are still members of the Parent Board. Without limiting in any way the Parties' obligations under Section 5.6, each of the Company and Parent shall, and shall cause their respective Subsidiaries to, cooperate in the defense or settlement of any litigation contemplated by this Section 5.17.

5.18. Tax Treatment.

(a) Each of Parent and Merger Sub shall use its respective reasonable best efforts to, and cause each of their respective Subsidiaries to, cause the Merger to qualify for the Intended Tax Treatment. Neither Parent nor Merger Sub shall take any action (or fail to take any action, including failing to use its reasonable best efforts to proscribe any of its respective Subsidiaries from taking any action) that could reasonably be expected to prevent or impede such qualification.

(b) The Company shall use its reasonable best efforts to, and cause its Subsidiaries to cause the Merger to qualify for the Intended Tax Treatment. The Company shall not take any action (or fail to take any action, including failing to use its reasonable best efforts to proscribe any of its Subsidiaries from taking any action) that could reasonably be expected to prevent or impede such qualification.

(c) Unless otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code, (i) each of the Parties shall report the Merger for U.S. federal income tax purposes as a "reorganization" within the meaning of Section 368(a) of the Code in all Tax Returns, and (ii) none of the Parties shall take any Tax reporting position inconsistent with the characterization of the Contemplated Transactions as a "reorganization" under Section 368(a) of the Code. The Parties to this Agreement adopt this Agreement as a "plan of reorganization" within the meaning of Treasury Regulations Section 1.368-2(g).

ARTICLE VI
CONDITIONS

6.1. Conditions to Each Party's Obligation to Effect the Merger. The respective obligation of each Party to effect the Merger is subject to the satisfaction or waiver at or prior to the Closing of each of the following conditions:

(a) Stockholder Approvals. The Company Stockholder Approval shall have been obtained in accordance with applicable Law and the Company's Organizational Documents.

(b) Law; Judgment. No Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law or Judgment (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins or otherwise prohibits consummation of the Merger.

(c) Registration Statement. The Registration Statement shall have been declared effective by the SEC under the Securities Act and no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been initiated or threatened.

(d) Blue Sky. Any necessary state securities or "blue sky" filings or notices shall have been made and any required authorizations shall have been received for the issuance of shares of Parent Common Stock in the Merger, except for such authorizations the lack of receipt of which would not reasonably be expected to have a material adverse impact on any of the Parties or their respective Affiliates.

6.2. Conditions to Obligations of Parent and Merger Sub. The obligations of Parent and Merger Sub to effect the Merger are also subject to the satisfaction or waiver by Parent at or prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of the Company contained in this Agreement (except for the representations and warranties contained in Sections 3.1, 3.2(a), 3.3, 3.4, and 3.20) shall be true and correct (without giving effect to any limitation as to "materiality" or "Company Material Adverse Effect" set forth therein) at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to "materiality" or "Company Material Adverse Effect" set forth therein), individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect; the representations and warranties of the Company contained in Sections 3.1, 3.2(a), 3.4, and 3.20 shall be true and correct in all material respects at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date); and the representations and warranties of the Company contained in Section 3.3 shall be true and correct in all respects, except for *de minimis* inaccuracies at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

(b) Performance of Obligations of the Company. The Company shall have performed in all material respects all obligations required to be performed by it under this Agreement at or prior to the Closing.

(c) No Company Material Adverse Effect. After the date of this Agreement, there shall not have occurred any Effect that, individually or in the aggregate, has resulted in a Company Material Adverse Effect that is continuing.

(d) Company Certificate. Parent shall have received at the Closing a certificate signed on behalf of the Company by a senior executive officer of the Company to the effect that the conditions set forth in Sections 6.2(a), (b) and (c) have been satisfied.

6.3. Conditions to Obligation of the Company. The obligation of the Company to effect the Merger is also subject to the satisfaction or waiver by the Company at or prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of Parent contained in this Agreement (except for the representations and warranties contained in Sections 4.1, 4.2(a), 4.3, 4.4 and 4.14) shall be true and correct (without giving effect to any limitation as to "materiality" or "Parent Material Adverse Effect" set forth therein) at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to "materiality" or "Parent Material Adverse Effect" set forth therein), individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect; the representations and warranties of Parent contained in Sections 4.1, 4.2(a), 4.4 and 4.14 shall be true and correct in all material respects at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date); and the representations and warranties of parent contained in Section 4.3 shall be true and correct in all respects, except for *de minimis* inaccuracies at and as of the date of this Agreement and at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

(b) Performance of Obligations of Parent and Merger Sub. Each of Parent and Merger Sub shall have performed in all material respects all obligations required to be performed by it under this Agreement at or prior to the Closing.

(c) No Parent Material Adverse Effect. After the date of this Agreement, there shall not have occurred any Effect that, individually or in the aggregate, has resulted in a Parent Material Adverse Effect that is continuing.

(d) Parent Certificate. The Company shall have received at the Closing a certificate signed on behalf of Parent by a senior executive officer of Parent to the effect that the conditions set forth in Sections 6.3(a), (b) and (c) have been satisfied.

6.4. Frustration of Conditions. None of the Company, Parent or Merger Sub may rely, either as a basis for not consummating the Merger or the other transactions or terminating this Agreement and abandoning the Merger, on the failure of any condition set forth in Sections 6.1, 6.2 or 6.3, as the case may be, to be satisfied if such failure was caused by such Party's material breach of any provision of this Agreement.

ARTICLE VII
TERMINATION

7.1. Termination by Mutual Consent. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time, whether before or after the date of the Company Stockholder Approval referred to in Section 6.1(a), by mutual written consent of the Company and Parent.

7.2. Termination by Either Parent or the Company. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by either Parent or the Company if:

(a) the Merger shall not have been consummated by 11:59 p.m. (Eastern Standard time) on April 18, 2023, (the "**Termination Date**"), provided, however, that the right to terminate this Agreement under this Section 7.2(a) shall not be available to any party whose material breach of any provision of this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated by the Termination Date;

(b) the Company Stockholder Approval shall not have been obtained at a meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the adoption of this Agreement was taken; provided, however, that the right to terminate this Agreement under this Section 7.2(b) shall not be available to the Company if its material breach of any provision of this Agreement has been the cause of, or resulted in, the failure to obtain the Company Stockholder Approval; or

(c) any Law or Judgment permanently restraining, enjoining or otherwise prohibiting consummation of the Merger shall become final and non-appealable, whether before or after the date of the Company Stockholder Approval referred to in Section 6.1(a); *provided that* the right to terminate this Agreement under this Section 7.2(c) shall not be available to any Party if its material breach of any provision of this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated.

7.3. Termination by the Company. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by the Company if:

(a) at any time prior to the Company Stockholder Approval having been obtained, Parent shall have entered into a Parent Acquisition Proposal or Parent shall have materially breached or shall have failed to perform in any material respect its obligations set forth in Section 5.3;

(b) at any time prior to the Effective Time, whether before or after the Company Stockholder Approval referred to in Section 6.1(a) is obtained, if there has been a breach of any representation, warranty, covenant or agreement made by Parent or Merger Sub in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that any condition set forth in Sections 6.3(a) or 6.3(b) would not be satisfied and such breach or failure to be true is not curable or, if curable, is not cured prior to the earlier of (i) 30 days following notice to Parent from the Company of such breach or failure and (ii) the date that is three Business Days prior to the Termination Date; *provided* that the Company shall not have the right to terminate this Agreement pursuant to this Section 7.3(b) if the Company is then in material breach of any of its representations, warranties, covenants or agreements under this Agreement; or

(c) at any time prior to the Company Stockholder Approval having been obtained, (i) the Company Board authorizes the Company, to the extent permitted by and subject to complying with the terms of Section 5.2, to enter into a Company Acquisition Proposal constituting a Company Superior Proposal, (ii) concurrently with the termination of this Agreement, the Company enters into a Company Acquisition Proposal constituting a Company Superior Proposal, and (iii) prior to or concurrently with such termination, the Company pays to Parent in immediately available funds the Termination Fee pursuant to Section 7.5.

7.4. Termination by Parent. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by Parent if:

(a) at any time prior to the Company Stockholder Approval having been obtained, (i) the Company Board shall have made a Company Change in Recommendation, (ii) the Company shall have failed to include the Company Board Recommendation in the Proxy Statement/Prospectus, (iii) the Company shall have entered into a Company Acquisition Proposal or (iv) the Company shall have materially breached or shall have failed to perform in any material respect its obligations set forth in Section 5.2; provided that Parent's right to terminate this Agreement pursuant to this Section 7.4(a) shall expire upon receipt of the Company Stockholder Approval;

(b) at any time prior to the Effective Time, if there has been a breach of any representation, warranty, covenant or agreement made by the Company in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that any condition set forth in Sections 6.2(a) or 6.2(b) would not be satisfied and such breach or failure to be true is not curable or, if curable, is not cured prior to the earlier of (i) 30 days following notice to the Company from Parent of such breach or failure and (ii) the date that is three Business Days prior to the Termination Date; *provided that* Parent shall not have the right to terminate this Agreement pursuant to this Section 7.4(b) if Parent is then in material breach of any of its representations, warranties, covenants or agreements under this Agreement; or

(c) at any time prior to the Company Stockholder Approval having been obtained, (i) the Parent Board authorizes Parent, to the extent permitted by and subject to complying with the terms of Section 5.2, to enter into a Parent Acquisition Proposal constituting a Parent Superior Proposal, (ii) concurrently with the termination of this Agreement, Parent enters into a Parent Acquisition Proposal constituting a Parent Superior Proposal, and (iii) prior to or concurrently with such termination, Parent pays to the Company in immediately available funds the Termination Fee pursuant to Section 7.6.

7.5. Company Termination Fee. In the event that (x) (A) after the date of this Agreement, a Company Acquisition Proposal shall have been made to the Company and such Company Acquisition Proposal becomes publicly known prior to the Company Stockholders' Meeting and, in either case, such Company Acquisition Proposal shall not have been withdrawn at the time of the Company Stockholders Meeting, (B) this Agreement is terminated by the Company or Parent pursuant to Section 7.2(b), or by Parent pursuant to Section 7.4(b) and (C) within 12 months after such termination, the Company enters into a Company Alternative Acquisition Agreement with respect to a Company Acquisition Proposal or consummates a Company Acquisition Proposal (solely for purposes of this Section 7.5(x), the references to "20%" in the definition of Company Acquisition Proposal shall be deemed to be references to "50%"); or (y) if this Agreement is terminated by the Company pursuant to Section 7.3(c) or (z) this Agreement is terminated by Parent pursuant to Section 7.4(a); then the Company shall, within two Business Days after such termination in the case of clause (z) or concurrently with such termination in the case of clause (x) and clause (y), pay Parent the Termination Fee. In no event shall the Company be required to pay the Termination Fee on more than one occasion.

7.6. Parent Termination Fee. In the event that this Agreement is terminated (x) by Parent pursuant to Section 7.4(c) or (y) by the Company pursuant to Section 7.3(a), then Parent shall, within two Business Days after such termination in the case of clause (y) or concurrently with such termination in the case of clause (x), pay the Company the Termination Fee. In no event shall Parent be required to pay the Termination Fee on more than one occasion.

7.7. Effect of Termination and Abandonment. In the event of termination of this Agreement and the abandonment of the Merger pursuant to this Article VII, this Agreement (other than as set forth in this Section 7.7 and in Section 8.1) shall become void and of no effect with no liability on the part of any Party (or of any of its respective Representatives); provided that no such termination shall relieve any Party (1) from any liability for fraud or Willful Breach of this Agreement prior to such termination and (2) from any obligation to pay, if applicable, the Termination Fee pursuant to Sections 7.5 and 7.6, as applicable. For purposes of this Agreement, the term "**Willful Breach**" means a deliberate act or a deliberate failure to act, taken or not taken with the actual knowledge that such act or failure to act would, or would reasonably be expected to, result in or constitute a material breach of this Agreement, regardless of whether breaching was the object of the act or failure to act.

7.8. Remedies.

(a) Each Party acknowledges that the agreements contained in Sections 7.5 and 7.6 are an integral part of the Contemplated Transactions, and that, without these agreements, no Party would have entered into this Agreement; accordingly, if the Company fails to pay promptly the Termination Fee pursuant to Section 7.5 or Parent fails to pay promptly the Termination Fee pursuant to Section 7.6, and, in order to obtain such Termination Fee, the Party entitled to receive the Termination Fee (the "**Recipient**") commences a suit which results in a judgment against the Party obligated to pay the Termination Fee (the "**Payor**"), the Payor shall pay to the Recipient its costs and expenses (including attorneys' fees) in connection with such suit, together with interest on the Termination Fee at the prime rate in effect on the date the Termination Fee was required to be paid through the date of full payment thereof.

(b) The Parties agree that the monetary remedies set forth in this and the specific performance remedies set forth in Section 8.13 shall be the sole and exclusive remedies of (i) the Company and its Subsidiaries against Parent, Merger Sub and any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates for any loss suffered as a result of the failure of the Merger to be consummated except in the case of common law fraud or a Willful Breach of any covenant, agreement or obligation (in which case only Parent shall be liable for damages for such common law fraud or Willful Breach), and upon payment of such amount, none of Parent, Merger Sub or any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates shall have any further liability or obligation relating to or arising out of this Agreement or the Contemplated Transactions, except for the liability of Parent in the case of common law fraud or a Willful Breach of any covenant, agreement or obligation; and (ii) Parent and Merger Sub against the Company and its Subsidiaries and any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates for any loss suffered as a result of the failure of the Contemplated Transactions to be consummated except in the case of common law fraud or a Willful Breach of any covenant, agreement or obligation (in which case only the Company shall be liable for damages for such common law fraud or Willful Breach), and upon payment of such amount, none of the Company and its Subsidiaries or any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates shall have any further liability or obligation relating to or arising out of this Agreement or the Contemplated Transactions, except for the liability of the Company in the case of common law fraud or a Willful Breach of any covenant, agreement or obligation.

ARTICLE VIII
MISCELLANEOUS AND GENERAL

8.1. Survival. This Article VIII and the agreements of the Company, Parent and Merger Sub Section 5.10, Section 5.11 and Section 5.18 shall survive the consummation of the Merger. This Article VIII (other than Section 8.2, Section 8.3 and Section 8.4) and the agreements of the Company, Parent and Merger Sub contained in, Section 5.7, Section 5.10, Section 7.5, Section 7.6, Section 7.7, Section 7.8 and the Confidentiality Agreement shall survive the termination of this Agreement. All other representations, warranties, covenants and agreements in this Agreement and in any certificate or other writing delivered pursuant hereto shall not survive the consummation of the Merger or the termination of this Agreement. This Section 8.1 shall not limit any covenant or agreement of the Parties which by its terms contemplates performance after the Effective Time.

8.2. Amendment. This Agreement may be amended with the approval of the Company, Merger Sub and Parent at any time (whether before or after obtaining the Company Stockholder Approval); provided, however, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent.

8.3. Assignability. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; provided, however, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

8.4. Waiver.

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

8.5. Entire Agreement; Counterparts; Exchanges by Electronic Transmission. This Agreement, the Company Disclosure Schedule, the Parent Disclosure Schedule and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; provided, however, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

8.6. Governing Law and Venue; Waiver of Jury Trial. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 8.6; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; and (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 8.7 of this Agreement. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY ACTION OR PROCEEDING WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION OR PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY OF THE AGREEMENTS DELIVERED IN CONNECTION HEREWITH, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF ANY ACTION OR PROCEEDING, SEEK TO ENFORCE EITHER OF SUCH WAIVERS, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS, (III) IT MAKES SUCH WAIVERS VOLUNTARILY AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.6.

8.7. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (if no automated notice of delivery failure is received by the sender) prior to 5:00 p.m. New York time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub

Advaxis, Inc.
212 Carnegie Center, Suite 206
Princeton New Jersey 08540
Attention: Kenneth A. Berlin and Igor Gitelman
Email: berlin@advaxis.com; gitelman@advaxis.com

with copies to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178
Attention: Robert W. Dickey
Email: robert.dickey@morganlewis.com

if to the Company

Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot, Israel 7670104
Attention: Roni Mamluk and Yossi Maimon
Email: roni.m@ayalapharma.com; yossi.m@ayalapharma.com

with copies to (which shall not constitute notice):

Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Attention: Peter N. Handrinos; Joshua M. Dubofsky
Email: Peter.Handrinos@lw.com; Josh.Dubofsky@lw.com

or to such other persons or addresses as may be designated in writing by the Party to receive such notice as provided above.

8.8. No Third Party Beneficiaries. This Agreement is not intended to, and does not, confer upon any Person other than Parties any rights or remedies hereunder, other than (a) the Indemnified Persons as provided in Section 5.11, (b) the right of the Company's stockholders to receive the Merger Consideration after the Closing and (c) the right of the holders of awards under the Company Stock Incentive Plan and holders of Company Warrants to receive such consideration as provided for in Section 2.3 after the Closing.

8.9. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

8.10. No Other Representations and Warranties.

(a) Except for the representations and warranties of the Company contained in Article III, Parent and Merger Sub acknowledge that neither the Company nor any of its Subsidiaries is making and has not made, and no other Person is making or has made on behalf of the Company or any of its Subsidiaries, any express or implied representation or warranty in connection with this Agreement or the Contemplated Transactions. Neither Parent nor Merger Sub is relying and neither Parent nor Merger Sub has relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in Article III, including the Company Disclosure Schedule. Such representations and warranties by the Company constitute the sole and exclusive representations and warranties of the Company and its Subsidiaries in connection with the Contemplated Transactions and each of Parent and Merger Sub understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by the Company and its Subsidiaries.

(b) Except for the representations and warranties Parent and Merger Sub contained in Article IV, the Company acknowledges that neither Parent nor Merger Sub is making or has made, and no other Person is making or has made on behalf of the Parent or Merger Sub, any express or implied representation or warranty in connection with this Agreement or the Contemplated Transactions. The Company is not relying and it has not relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in Article IV, including the Parent Disclosure Schedule. Such representations and warranties by Parent and Merger Sub constitute the sole and exclusive representations and warranties of Parent and Merger Sub in connection with the Contemplated Transactions and the Company understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by Parent.

8.11. Construction

(a) References to “cash,” “dollars” or “$” are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(e) Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively. Any capitalized terms used in any Exhibits or Schedules but not otherwise defined therein have the meanings ascribed to such terms as in this Agreement.

(f) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(g) The bold-faced headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(h) The Parties agree that each of the Company Disclosure Schedule and the Parent Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Company Disclosure Schedule or the Parent Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is readily apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

(i) Each of "delivered" or "made available" means, with respect to any documentation, that prior to 11:59 p.m. (New York time) on the date that is one calendar day prior to the date of this Agreement (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party or (ii) such material is disclosed in the Company SEC Documents or the Parent SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC's Electronic Data Gathering Analysis and Retrieval system.

(j) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in New York, New York are authorized or obligated by Law to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

8.12. Certain Definitions: For the purposes of this Agreement:

(a) An "**Affiliate**" of any Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person. For purposes of this definition, "control," when used with respect to any specified Person, means the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities or by Contract or otherwise, and the terms "controlling" and "controlled by" have correlative meanings to the foregoing.

(b) "**Anti-Bribery Laws**" means the FCPA, as amended, any rules or regulations thereunder, or any other applicable United States or foreign anti-corruption or anti-bribery laws or regulations.

(c) "**Business Day**" means any day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or obligated by Law to be closed.

(d) "**Company Affiliate**" means any Person under common control with any of the Company or any of its Subsidiaries within the meaning of Section 414(b), Section 414(c), Section 414(m) or Section 414(o) of the Code, and the regulations issued thereunder.

(e) "**Company Associate**" means any current or former officer, employee, independent contractor, consultant or director, of or to the Company or any of its Subsidiaries or any controlled Company Affiliate.

(f) "**Company Benefit Plan**" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment (other than at-will employment offer letters on the Company's standard form that may be terminated without notice and with no penalty to the Company or any of its Subsidiaries and other than individual Company Options, Company restricted stock or other compensatory equity award agreements made pursuant to the Company's standard forms, in which case only representative standard forms of such agreements shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, maintained, contributed to, or required to be contributed to, by the Company, any of its Subsidiaries or Company ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of the Company or any of its Subsidiaries or under which the Company or any of its Subsidiaries has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Section 414 of the Code with any other person).

(g) "**Company Capital Stock**" means Company Common Stock, together with Company Preferred Stock.

(h) "**Company Closing Price**" means the volume weighted average closing trading price of a share of Company Common Stock for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

(i) "**Company Contract**" means any Contract: (a) to which the Company or any of its Subsidiaries is a party; (b) by which the Company or any of its Subsidiaries or any Company IP or any other asset of the Company or its Subsidiaries is or may become bound or under which the Company or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which the Company or any of its Subsidiaries has or may acquire any right or interest.

(j) "**Company ERISA Affiliate**" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with the Company or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

(k) "**Company IP**" means Company Owned IP and Company Licensed IP.

(l) "**Company Licensed IP**" means all Intellectual Property Rights that are exclusively licensed to the Company or any of its Subsidiaries and cover the products of the Company.

(m) "**Company Material Adverse Effect**" means any Effect that, individually or in the aggregate with all other Effects, (1) materially adversely affects or would reasonably be expected to materially adversely affect the business, financial condition or results of operations of the Company and its Subsidiaries, taken as a whole, or (2) would reasonably be expected to prevent or materially impair or delay the consummation of the Contemplated Transactions by the Company, excluding, in the case of Clause (1) any Effect to the extent that, either alone or in combination, it results from or arises out of (i) general business or economic conditions generally affecting the industry in which the Company and its Subsidiaries operate, (ii) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters and health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof), (iii) changes in financial, banking or securities markets, (iv) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (v) any change in the stock price or trading volume of Company Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Company Common Stock may be taken into account in determining whether a Company Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (vi) the failure of the Company to meet internal or analysts' expectations or projections or the results of operations of the Company (it being understood, however, that any Effect causing or contributing to the failure of the Company to meet internal or analysts' expectations or projections or the results of operations of the Company may be taken into account in determining whether a Company Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition) or (vii) the announcement of this Agreement or the pendency of the Contemplated Transactions; except, in each case, with respect to clauses (i) through (iv), to the extent disproportionately affecting the Company and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which the Company and its Subsidiaries operate.

(n) "**Company Option**" means any option to purchase Shares (whether granted under the Company Stock Incentive Plan, assumed by the Company in connection with any merger, acquisition or similar transaction or otherwise issued or granted).

(o) "**Company Owned IP**" means all Intellectual Property Rights that are owned by the Company or any of its Subsidiaries that cover the products of the Company.

(p) "**Company RSU**" means any Company restricted stock unit that is subject to vesting conditioned upon satisfaction of a service condition (whether granted under the Company Stock Incentive Plan, assumed by the Company in connection with any merger, acquisition or similar transaction or otherwise issued or granted).

(q) "**Company Stock Incentive Plan**" means the Company's 2017 Stock Incentive Plan, as amended.

(r) "**Confidentiality Agreement**" means the confidentiality agreement entered into between Company and Parent on July 19, 2022.

(s) "**Consent**" means consent, approval, ratification, permission, authorization, clearance, waiver, permit or order.

(t) "**Contemplated Transactions**" means the Merger and the other transactions and actions contemplated by this Agreement.

(u) "**Contract**" means any written, oral or other agreement, contract, subcontract, lease, understanding, arrangement, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment or undertaking of any nature.

(v) "**Effect**" means any fact, circumstance, effect, change, event or development.

(w) "**Environmental Laws**" means any Law concerning or relating to pollution or protection of the environment or natural resources, or protection of human health and safety as related to exposure to any harmful or deleterious substances.

(x) "**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended.

(y) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

(z) "**Exchange Ratio**" means 0.1874 as of the date of this Agreement, subject to Section 2.1(c) and subject to adjustment at Closing to reflect the following ratio (rounded to four decimal places): the quotient obtained by dividing (a) (i) the Company Valuation divided by (ii) the Company Outstanding Shares by (b) (i) the Parent Valuation divided by (ii) the Parent Outstanding Shares, in which:

- "**Company Outstanding Shares**" means the total number of shares of Company Capital Stock outstanding immediately prior to the Effective Time expressed on an as-exercised basis and using the treasury stock method, but assuming, without limitation or duplication the issuance of shares of Company Capital Stock in respect of all outstanding Company Options, Company RSUs, Company Warrants and other outstanding options, restricted stock awards, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time (assuming cashless exercise using the Company Closing Price), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Company Capital Stock reserved for issuance other than with respect to outstanding Company Warrants or Company Options under the Company Stock Incentive Plan as of immediately prior to the Effective Time). No out-of-the-money Company Options or Company Warrants shall be included in the total number of shares of Company Common Stock outstanding for purposes of determining the Company Outstanding Shares.

- "**Company Valuation**" means $14,859,960.

- "**Parent Outstanding Shares**" means, subject to Section 2.1(c) and the immediately following sentence, the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time expressed on an as-exercised basis and using the treasury stock method, but assuming, without limitation or duplication, the issuance of shares of Parent Common Stock in respect of all Parent Options, Parent Warrants and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time (assuming cashless exercise using the Parent Closing Price), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger, (but excluding any shares of Parent Common Stock reserved for issuance other than with respect to outstanding Parent Options and Parent Warrants as of immediately prior to the Effective Time and as set forth above). No out-of-the-money Parent Options or Parent Warrants shall be included in the total number of shares of Parent Common Stock outstanding for purposes of determining the Parent Outstanding Shares.

- "**Parent Valuation**" means $8,915,976.

(aa) "**FCPA**" means the Foreign Corrupt Practices Act of 1977, as amended.

(bb) "**FDA**" means the U.S. Food and Drug Administration or any successor Governmental Entity thereto.

(cc) "**FDCA**" means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the regulations promulgated thereunder.

(dd) "**GAAP**" means United States generally accepted accounting principles.

(ee) "**Governmental Authorization**" means any: (a) permit, license, certificate, franchise, permission, variance, exception, exemption, approval, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Entity or pursuant to any Law; or (b) right under any Contract with any Governmental Entity.

(ff) "**Governmental Entity**" means any (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (d) self-regulatory organization (including The Nasdaq Global Select Market).

(gg) "**Hazardous Materials**" means any substance, material or waste that is listed, defined or otherwise characterized as "hazardous", "toxic", "radioactive" or a "pollutant", or "contaminant" or terms of similar meaning or effect under any Environmental Law, including petroleum or its by-products, asbestos and polychlorinated biphenyls.

(hh) "**Indebtedness**" means, with respect to any Person, without duplication, (i) all obligations of such Person for borrowed money, or with respect to deposits or advances of any kind to such Person, including related prepayment fees, final fees or other similar fees, (ii) all obligations of such Person evidenced by bonds, debentures, notes or similar instruments, (iii) all capitalized lease obligations of such Person or obligations of such Person to pay the deferred and unpaid purchase price of property and equipment, (iv) all obligations of such Person pursuant to securitization or factoring programs or arrangements, (v) all guarantees and arrangements having the economic effect of a guarantee of such Person of any debt of any other Person (other than any guarantee by a Party with respect to debt of such Party or any wholly owned Subsidiary of such Party), (vi) net cash payment obligations of such Person under swaps, options, derivatives and other hedging agreements or arrangements that will be payable upon termination thereof (assuming they were terminated on the date of determination) or (vii) letters of credit, bank guarantees, and other similar contractual obligations entered into by or on behalf of such Person.

(ii) "**Intellectual Property Rights**" means all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (b) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any goodwill associated therewith; (c) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (d) patents and industrial property rights; (e) other proprietary rights in intellectual property of every kind and nature; (f) rights of privacy and publicity; and (g) all registrations, renewals, extensions, statutory invention registrations, provisionals, utility applications, continuations, continuations-in-part, divisionals, or reissues of, and applications for, any of the rights referred to in clauses "(a)" through "(f)" above (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples, studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution, registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing.

(jj) "**Judgment**" means any judgment, order, injunction, ruling, writ award or decree of any Governmental Entity.

(kk) The "**Knowledge**" of any Person means, in the case of Parent, the actual knowledge after reasonable inquiry of any of the Persons set forth on Section 8.12(kk) of the Parent Disclosure Schedule and, in the case of the Company, the actual knowledge after reasonable inquiry of any of the Persons set forth on Section 8.12(kk) of the Company Disclosure Schedule.

(ll) "**Law**" means any federal, state, local, foreign or transnational law, statute, regulation, ordinance, common law, ruling, writ, award or decree of any Governmental Entity.

(mm) "**Legal Proceeding**" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Entity or any arbitrator or arbitration panel.

(nn) "**Liens**" means pledges, liens, claims, charges, mortgages, deeds of trust, rights of first offer or first refusal, options, encumbrances and security interests of any kind or nature whatsoever (collectively, with covenants, conditions, restrictions, easements, encroachments, any conditional sale or title retention agreements or other third party rights or title defect of any kind or nature whatsoever).

(oo) "**Nasdaq**" means the National Association of Securities Dealers Automatic Quotation System.

(pp) "**Ordinary Course of Business**" means, in the case of each of the Company and Parent, such actions taken in the ordinary course of its and its Subsidiaries' normal operations and consistent with its and its Subsidiaries' past practices and the Ordinary Course of Business of Parent shall also include actions required to effect the winding down of Parent's prior research and development activities (including the termination of ongoing contractual obligations relating to Parent's current products or product candidates).

(qq) "**Organizational Documents**" means, with respect to any Person (other than an individual), (a) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, regulations and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

(rr) "**Parent Affiliate**" means any Person under common control with the Parent within the meaning of Section 414(b), Section 414(c), Section 414(m) or Section 414(o) of the Code, and the regulations issued thereunder.

(ss) "**Parent Associate**" means any current or former officer, employee, independent contractor, consultant or director, of or to the Parent or any of its Subsidiaries or any controlled Parent Affiliate.

(tt) "**Parent Benefit Plan**" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment (other than at-will employment offer letters on Parent's standard form that may be terminated without notice and with no penalty to Parent or any of its Subsidiaries and other than individual Parent Options or other compensatory equity award agreements made pursuant to Parent's standard forms, in which case only representative standard forms of such agreements shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, maintained, contributed to, or required to be contributed to, by Parent, any of its Subsidiaries or Parent ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of Parent or any of its Subsidiaries or under which Parent or any of its Subsidiaries has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Section 414 of the Code with any other person).

(uu) "**Parent Closing Price**" means the volume weighted average closing trading price of a share of Parent Common Stock for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

(vv) "**Parent Contract**" means any Contract: (a) to which Parent or any of its Subsidiaries is a party; (b) by which Parent or any of its Subsidiaries or any intellectual property owned or licensed by Parent or any other asset of Parent or its Subsidiaries is or may become bound or under which Parent or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which Parent or any of its Subsidiaries has or may acquire any right or interest.

(ww) "**Parent ERISA Affiliate**" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Parent or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

(xx) "**Parent Material Adverse Effect**" means any Effect that, individually or in the aggregate with all other Effects, (1) materially adversely affects or would reasonably be expected to materially adversely affect the business, financial condition or results of operations of Parent and its Subsidiaries, taken as a whole, or (2) would reasonably be expected to prevent or materially impair or delay the consummation of the Contemplated Transactions by Parent, excluding, in the case of Clause (1), any Effect to the extent that, either alone or in combination, it results from or arises out of (i) general business or economic conditions generally affecting the industry in which Parent and its Subsidiaries operate, (ii) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters and health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof), (iii) changes in financial, banking or securities markets, (iv) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (v) any change in the stock price or trading volume of Parent Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Parent Common Stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (vi) the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent (it being understood, however, that any Effect causing or contributing to the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), or (vii) the announcement of this Agreement or the pendency of the Contemplated Transactions; except, in each case, with respect to clauses (i) through (iv), to the extent disproportionately affecting Parent and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Parent and its Subsidiaries operate.

(yy) "**Parent Option**" means any option to purchase Parent Common Stock (whether granted under any Parent Stock Plan, assumed by the Parent in connection with any merger, acquisition or similar transaction or otherwise issued or granted).

(zz) "**Parent Stock Plans**" means Parent's Amended and Restated 2009 Stock Option Plan, 2011 Omnibus Incentive Plan and 2015 Incentive Plan, each as amended from time to time.

(aaa) "**Parent Warrants**" means the warrants to purchase capital stock of Parent listed on Section 4.3(a) of the Parent Disclosure Schedule.

(bbb) "**Permitted Liens**" means any (1) Lien (i) for Taxes or governmental assessments, charges or claims of payment (A) not yet due and payable or (B) being contested in good faith in appropriate proceedings, (ii) which is a carriers', warehousemen's, mechanics', materialmen's, repairmen's, or other similar lien arising in the ordinary course of business, (iii) with respect to zoning, planning, and other limitations and restrictions, including all rights of any Governmental Entity (but not violations thereof), (iv) in the case of any Contract, Liens that are restrictions against the transfer or assignment thereof that are included in the terms of such Contract or any license of Intellectual Property Rights, (v) with respect to this Agreement and Liens created by the execution and delivery of this Agreement, (vi) which is disclosed on the most recent consolidated balance sheet of the Company or Parent, as applicable, or notes thereto which has been previously provided to Parent or the Company, as applicable, or (vii) for which adequate reserves have been established and (2) non-exclusive licenses of Intellectual Property Rights in the ordinary course of business consistent with past practice.

(ccc) "**Person**" means any natural person, firm, corporation, partnership, company, limited liability company, trust, joint venture, association, Governmental Entity or other entity.

(ddd) "**Reference Date**" means October 14, 2022.

(eee) "**Registered IP**" means all Intellectual Property Rights that cover the products of the Company that are pending, granted, or registered with, by or under the authority of any Governmental Entity, including all patents, patent applications, registered copyrights, registered mask works and registered trademarks and all applications for any of the foregoing.

(fff) "**SEC**" means the Securities and Exchange Commission.

(ggg) "**Securities Act**" means the Securities Act of 1933, as amended.

(hhh) "**Subsidiary**" of any Person means another Person, an amount of the voting securities, other voting ownership or voting partnership interests of which is sufficient to elect at least a majority of its Board of Directors or other governing Person or body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned directly or indirectly by such first Person.

(iii) "**Tax Return**" means all Tax returns, declarations, statements, reports, claims for refund, schedules, forms and information returns, any amended Tax return and any other document filed or required to be filed with a taxing authority relating to Taxes.

(jjj) "**Taxes**" means all federal, state, local and foreign income, profits, franchise, gross receipts, environmental, customs duty, capital stock, severance, stamp, payroll, sales, employment, Medicare, unemployment, disability, use, property, withholding, excise, production, value added, occupancy and other taxes, duties or assessments in the nature of a tax, together with all interest, penalties and additions imposed with respect to such amounts and any interest in respect of such penalties and additions.

(kkk) "**Termination Fee**" means $600,000.

(lll) "**Transaction Expenses**" means with respect to each Party, all fees and expenses incurred by such party at or prior to the Effective Time in connection with this Agreement and the Contemplated Transactions, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such party; (b) fees paid to the SEC in connection with filing the Registration Statement, the Proxy Statement/Prospectus, and any amendments and supplements thereto, with the SEC; (c) any fees and expenses in connection with the printing, mailing and distribution of the Registration Statement, including any amendments and supplements thereto; and (d) any fees associated with delisting or de-registering the Shares and any other security issued by the Company or one of its Subsidiaries from The Nasdaq Global Market under the Exchange Act.

8.13. Specific Performance. The Parties acknowledge and agree that irreparable damage would occur and that the Parties would not have any adequate remedy at law if any provision of this Agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each Party hereby waives any requirement for the security or posting of any bond in connection with such remedy), this being in addition to any other remedy to which they are entitled at Law or in equity. The Parties further agree not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable Law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that the Company or Parent otherwise have an adequate remedy at law. The Parties acknowledge that the agreements contained in this Section 8.13 are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the Parties would not enter into this Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, this Agreement has been duly executed and delivered by the duly authorized officers of the Parties hereto as of the date first written above.

AYALA PHARMACEUTICALS, INC.

By: */s/ Roni Mamluk*
Name: Roni Mamluk
Title: President and Chief Executive Officer

ADVAXIS, INC.

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer

DOE MERGER SUB, INC.

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President

EXHIBIT A

Form of Certificate of Merger

CERTIFICATE OF MERGER

OF

DOE MERGER SUB, INC.

WITH AND INTO

AYALA PHARMACEUTICALS, INC.

[●], 2022

Pursuant to Section 251 of the Delaware General Corporation Law (the "DGCL"), the undersigned corporation hereby certifies as follows:

1. The name and state of incorporation of each constituent corporation is Ayala Pharmaceuticals, Inc., a Delaware corporation, (the "Corporation"), and Doe Merger Sub, Inc., a Delaware corporation ("Merger Sub" and together with the Corporation, the "Constituent Corporations").

2. An Agreement and Plan of Merger, dated as of [●], 2022 (the "Merger Agreement"), by and among Advaxis, Inc., a Delaware corporation, Merger Sub and the Corporation, pursuant to which Merger Sub will merge with and into the Corporation, with the Corporation as the surviving corporation (the "Merger"), has been approved, executed and acknowledged by each of the Constituent Corporations in accordance with the requirements of Section 251 of the DGCL and adopted by the stockholders of each of the Constituent Corporations in accordance with Section 211 and 228 of the DGCL.

3. The name of the surviving corporation (the "Surviving Corporation") of the Merger shall be "Ayala Pharmaceuticals, Inc."

4. The Certificate of Incorporation of the Surviving Corporation shall be amended and restated in its entirety to read as set forth in Exhibit A attached hereto upon the effective time of the Merger and, as so amended and restated, shall be the certificate of incorporation of the Surviving Corporation until thereafter changed or amended as provided therein or by applicable legal requirements.

5. The Merger is to become effective immediately upon the filing of this Certificate of Merger with the Secretary of State of the State of Delaware.

6. The executed Merger Agreement is on file at an office of the Surviving Corporation, the address of which is Oppenheimer 4, Rehovot, Israel 7670104.

7. A copy of the Merger Agreement will be furnished by the Surviving Corporation on request, without cost, to any stockholder of either Constituent Corporation.

[*Remainder of page left intentionally left blank. Signature page follows.*]

IN WITNESS WHEREOF, this certificate has been executed by a duly authorized officer of the Surviving Corporation as of the date first written above.

AYALA PHARMACEUTICALS, INC.

By:
Name:
Title:

[Signature page to Certificate of Merger]

AMENDED & RESTATED CERTIFICATE OF INCORPORATION
OF
AYALA PHARMACEUTICALS, INC.

ARTICLE I

The name of this corporation is Ayala Pharmaceuticals, Inc. (the "Company").

ARTICLE II

The address of the Company's registered office in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which the Company may be organized under the General Corporation Law of Delaware (the "DGCL").

ARTICLE IV

The total number of shares of capital stock which the Company is authorized to issue is 1,000 shares, all of which are to be designated "Common Stock" with a par value of $0.01 per share.

ARTICLE V

To the fullest extent permitted by law, a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL or any other law of the State of Delaware is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the DGCL or such other law of the State of Delaware as so amended.

Any amendment, alteration, change, modification, repeal or rescission of the foregoing provisions of this Article VI by the stockholders of the Company shall not adversely affect any right or protection of a director of the Company existing at the time of, or increase the liability of any director of the Company with respect to any acts or omissions of a director of the Company occurring prior to, such amendment, alteration, change, modification, repeal or rescission.

ARTICLE VI

Except as otherwise provided for in Article V and Article XI, the Company reserves the right at any time, and from time to time, to amend, alter, change, modify, repeal or rescind any provision contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this Article VI.

ARTICLE VII

Election of directors need not be by written ballot unless the Bylaws of the Company shall so provide.

ARTICLE VIII

The number of directors which shall constitute the whole Board of Directors of the Company shall be determined in the manner set forth in the Bylaws of the Company.

ARTICLE IX

Meetings of stockholders of the Company may be held within or outside of the State of Delaware, as the Bylaws of the Company may provide. The books and records of the Company may be kept, subject to any provision contained in the statutes, within or outside of the State of Delaware at such place or places as may be designated from time to time by the Board of Directors of the Company or in the Bylaws of the Company.

ARTICLE X

Except as otherwise provided in this Certificate of Incorporation or in the Bylaws of the Company, in furtherance and not in limitation of the powers conferred by law, the Board of Directors of the Company is expressly authorized to make, adopt, amend, alter, change, modify, repeal or rescind any or all of the Bylaws of the Company.

ARTICLE XI

To the fullest extent permitted by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers, and agents of the Company (and any other persons to which DGCL permits the Company to provide indemnification) through Bylaw provisions, agreements with such directors, officers, agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the DGCL.

Any amendment, alteration, change, modification, repeal or rescission of the foregoing provisions of this Article XII by the stockholders of the Company shall not adversely affect any right or protection of a director, officer, agent or other person of the Company existing at the time of, or increase the liability of any such director, officer, agent or other person of the Company with respect to any acts or omissions of such director, officer, agent or other person of the Company occurring prior to such amendment, alteration, change, modification, repeal or rescission.

EXHIBIT B

Form of Certificate of Incorporation

AMENDED & RESTATED CERTIFICATE OF INCORPORATION
OF
AYALA PHARMACEUTICALS, INC.

ARTICLE I

The name of this corporation is Ayala Pharmaceuticals, Inc. (the "Company").

ARTICLE II

The address of the Company's registered office in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which the Company may be organized under the General Corporation Law of Delaware (the "DGCL").

ARTICLE IV

The total number of shares of capital stock which the Company is authorized to issue is 1,000 shares, all of which are to be designated "Common Stock" with a par value of $0.01 per share.

ARTICLE V

To the fullest extent permitted by law, a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL or any other law of the State of Delaware is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the DGCL or such other law of the State of Delaware as so amended.

Any amendment, alteration, change, modification, repeal or rescission of the foregoing provisions of this Article VI by the stockholders of the Company shall not adversely affect any right or protection of a director of the Company existing at the time of, or increase the liability of any director of the Company with respect to any acts or omissions of a director of the Company occurring prior to, such amendment, alteration, change, modification, repeal or rescission.

ARTICLE VI

Except as otherwise provided for in Article V and Article XI, the Company reserves the right at any time, and from time to time, to amend, alter, change, modify, repeal or rescind any provision contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this Article VI.

ARTICLE VII

Election of directors need not be by written ballot unless the Bylaws of the Company shall so provide.

ARTICLE VIII

The number of directors which shall constitute the whole Board of Directors of the Company shall be determined in the manner set forth in the Bylaws of the Company.

ARTICLE IX

Meetings of stockholders of the Company may be held within or outside of the State of Delaware, as the Bylaws of the Company may provide. The books and records of the Company may be kept, subject to any provision contained in the statutes, within or outside of the State of Delaware at such place or places as may be designated from time to time by the Board of Directors of the Company or in the Bylaws of the Company.

ARTICLE X

Except as otherwise provided in this Certificate of Incorporation or in the Bylaws of the Company, in furtherance and not in limitation of the powers conferred by law, the Board of Directors of the Company is expressly authorized to make, adopt, amend, alter, change, modify, repeal or rescind any or all of the Bylaws of the Company.

ARTICLE XI

To the fullest extent permitted by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers, and agents of the Company (and any other persons to which DGCL permits the Company to provide indemnification) through Bylaw provisions, agreements with such directors, officers, agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the DGCL.

Any amendment, alteration, change, modification, repeal or rescission of the foregoing provisions of this Article XII by the stockholders of the Company shall not adversely affect any right or protection of a director, officer, agent or other person of the Company existing at the time of, or increase the liability of any such director, officer, agent or other person of the Company with respect to any acts or omissions of such director, officer, agent or other person of the Company occurring prior to such amendment, alteration, change, modification, repeal or rescission.

EXHIBIT C

Directors and Officers

I. Directors and Officers - Parent

A. Board Designees – Company:

1. Dr. David Sidransky
2. Dr. Vered Bisker-Leib
3. Dr. Robert Spiegel
4. Murray A. Goldberg
5. Kenneth A. Berlin

B. Board Designees – Parent:

1. Roni A. Appel
2. Samir N. Khleif

C. Officers:

1. Kenneth A. Berlin, President and Chief Executive Officer
2. Dr. Andres A. Gutierrez: Chief Medical Officer
3. Igor Gitelman: Chief Financial Officer

II. Directors and Officers – Surviving Company

A. Directors:

1. Kenneth A. Berlin

B. Officers:

1. Kenneth A. Berlin, President and Chief Executive Officer
2. Dr. Andres A. Gutierrez: Chief Medical Officer
3. Igor Gitelman: Chief Financial Officer

[Exhibit C to Agreement and Plan of Merger]

Torreya Capital LLC
555 Madison Avenue, Suite 1201
New York, NY 10022
(212) 257-5801
www.torreya.com

CONFIDENTIAL DRAFT

The Board of Directors
Ayala Pharmaceuticals
Oppenheimer 4, Rehovot
7670104 Israel

Dear Board of Directors:

You have asked Torreya Capital LLC ("Torreya") to render a written opinion (the "Opinion") to the Board of Directors of Ayala Pharmaceuticals. ("Ayala") as to the fairness, from a financial point of view, to the holders of Ayala common stock of the Exchange Ratio (as defined herein) provided for in the contemplated transaction described below (the "Proposed Transaction").

Description of the Proposed Transaction

It is Torreya's understanding that Ayala is considering entering into an Agreement and Plan of Merger (the "Agreement") between Ayala and Advaxis Inc. ("Advaxis"), a public limited company incorporated under the laws of Delaware, pursuant to which, among other things, Ayala will merge with and into Advaxis and each outstanding share of the common stock of Ayala will be converted into the right to receive 0.1874 (the "Exchange Ratio") of Advaxis common stock. The terms and conditions of the Merger are more fully set forth in the Agreement.

Scope of Analysis

In connection with this opinion, we have reviewed, among other things:

(a) Reviewed Ayala-Advaxis Merger Agreement dated [October 16, 2022];
(b) Reviewed and analyzed certain financial and other information with respect to Ayala and Advaxis which was publicly available
(c) Reviewed diligence findings provided by advisors (Latham and Watkins LLP and EY) instructed by Ayala
(d) Reviewed and analyzed certain information, including financial forecasts relating to the business, earnings, cash flow, assets, liabilities and prospects of Ayala and Advaxis, on a stand-alone basis, that were publicly available, as well as those that were provided to Torreya by Ayala
(e) Held discussions with the senior management team of Ayala and Advaxis with respect to the matters described in the preceding three bullets, as well as the respective business
(f) Also compared the proposed financial terms of the Agreement with other financial studies and analyses and took into account such other information as we deemed appropriate in evaluating the Merger Consideration.

Assumptions, Qualifications and Limiting Conditions

In rendering our Opinion, we assumed and relied upon, without independent verification or investigation, the accuracy and completeness of all of the financial and other data and information provided to or discussed with us by Ayala and its employees, representatives and affiliates or otherwise reviewed by us.

We are not expressing any opinion as to the underlying valuation, future performance, or long-term viability of Ayala. We were not requested to, and we did not, participate in the negotiation or structuring of the Agreement. We express no view as to, and our Opinion does not address, any terms or other aspects or implications of the Agreement (other than the Merger Consideration to the extent expressly specified herein) or any aspect or implication of any other agreement, arrangement or understanding entered into in connection with the Agreement or otherwise, including, without limitation, the form or the structure of Merger Agreement, or the fairness of the amount or nature of the compensation resulting from the Agreement to any individual officers, directors or employees of Ayala, or class of such persons, relative to the Agreement. In addition, we express no view as to, and our Opinion does not address, the underlying business decision of Ayala to proceed with or effect the Agreement nor does our Opinion address the relative merits of the Agreement as compared to any alternative business strategies that might exist for Ayala or the effect of any other transaction in which Ayala might engage. Our Opinion is necessarily based on the information available to us and general economic, financial and stock market conditions and circumstances as they exist and can be evaluated by us on the date hereof. Although subsequent developments may affect this Opinion, we do not have any obligation to update, revise or reaffirm this Opinion.

Disclosure

We have been engaged by Ayala in connection with the Transaction. We will receive a fee for our services in connection with the Transaction, a portion of which is payable upon the rendering of this opinion and a substantial portion of which is contingent upon the consummation of the Merger. In addition, the Company has agreed to reimburse certain of our expenses arising and indemnify us against certain liabilities that may arise out of our engagement, including liabilities under the federal securities laws.

The issuance of this Opinion was approved by an authorized committee of Torreya. As part of our investment banking business, we are regularly engaged in valuations of businesses and securities in connection with acquisitions and mergers, underwritings, private placements and valuations for other purposes.

Conclusion

Based upon and subject to the foregoing, we are of the opinion that, as of the date hereof, the Merger Consideration is fair, from a financial point of view, to the holders of Ayala Common Stock. This Opinion is for the use of the Board of Directors of Ayala (in its capacity as such) in its evaluation of the Agreement and does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to any matters relating to the Agreement.

Sincerely,

DocuSigned by:

471C17D9A26A401...

Tom Babich
Partner and CEO
Torreya Capital LLC

Cantor Fitzgerald & CO.
110 East 59th Street
New York, New York 10022
Tel 212.938.5000
www.cantorfitzgerald.com

October 18, 2022

The Board of Directors
Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey

Ladies and Gentlemen:

We understand that Advaxis, Inc. ("Advaxis"), Doe Merger Sub, Inc., a wholly owned subsidiary of Advaxis ("Merger Sub"), and Ayala Pharmaceuticals, Inc. ("Ayala") intend to enter into an Agreement and Plan of Merger (the "Agreement"), pursuant to which Merger Sub will merge with and into Ayala (the "Merger"), and each issued and outstanding share of common stock, par value $0.01 per share, of Ayala ("Ayala Common Stock"), other than shares held by Ayala in its treasury, will be converted into the right to receive 0.1874 (the "Exchange Ratio") shares of common stock, par value $0.001 per share, of Advaxis ("Advaxis Common Stock"). The Exchange Ratio is subject to adjustment as set forth in the Agreement and as to which we express no opinion. The terms and conditions of the Merger are set forth in more detail in the Agreement.

You have asked us to render our opinion as to whether the Exchange Ratio is fair, from a financial point of view, to Advaxis.

In the course of performing our reviews and analyses for rendering this opinion, we have:

- reviewed a draft of the Agreement, dated October 18, 2022;
- reviewed certain publicly available business and financial information relating to Advaxis and Ayala;
- reviewed certain operating and financial information relating to Advaxis's business and prospects, including projections for Advaxis through December 31, 2023, all as prepared and approved for our use by Advaxis's management;
- reviewed certain operating and financial information relating to Ayala's business and prospects, including projections for Ayala for the 11 years ended December 31, 2033, all as prepared by Ayala's management and adjusted and approved for our use by Advaxis's management;
- met with certain members of Advaxis's senior management to discuss Advaxis's and Ayala's respective businesses, operations, historical and projected financial results and future prospects;

- reviewed the historical prices and trading volumes of the Advaxis Common Stock and Ayala Common Stock;
- reviewed and performed analyses based on certain publicly available financial information with respect to companies in the biopharmaceutical industry that we deemed to be relevant;
- performed discounted cash flow analyses based on the projections for Advaxis and Ayala furnished to us by Advaxis;
- reviewed the pro forma financial results, financial condition and capitalization of Advaxis giving effect to the Merger; and
- conducted such other studies, analyses, inquiries and investigations as we deemed appropriate.

We have relied upon and assumed, without independent verification, the accuracy and completeness of the financial and other information provided to or discussed with us by Advaxis and Ayala or obtained by us from public sources, including, without limitation, the projections referred to above. With respect to the projections, we have relied on representations that they have been reasonably prepared on bases reflecting the best currently available estimates and judgments of the senior management of Advaxis and Ayala, as the case may be, as to the expected future performance of Advaxis and Ayala. We have not assumed any responsibility for the independent verification of, and have not independently verified, any such information, including, without limitation, the projections; we express no view or opinion as to such projections or the assumptions upon which they are based; and we have further relied upon the assurances of the senior management of Advaxis and Ayala, as the case may be, that they are unaware of any facts that would make the information or projections incomplete or misleading. We have assumed that the executed Agreement will not differ in any material respect from the draft reviewed by us.

In arriving at our opinion, we have not performed or obtained any independent appraisal of the assets or liabilities (contingent or otherwise) of Advaxis and Ayala, nor have we been furnished with any such appraisals. During the course of our engagement, we were directed by the Board of Directors to solicit indications of interest from various third parties regarding a transaction with Advaxis, and we have considered the results of such solicitation in rendering our opinion. We have assumed that the Merger will qualify as a tax-free “reorganization” within the meaning of Section 368(a) of the Internal Revenue Code. We have assumed that the Merger will be consummated in a timely manner and in accordance with the terms of the Agreement without any limitations, restrictions, conditions, amendments or modifications, regulatory or otherwise, that would be material in any respect to our analysis or our opinion. We are not legal, regulatory, tax or accounting experts and have relied on the assessments made by Advaxis, Ayala and their respective advisors with respect to such issues. Our opinion does not address any legal, tax, regulatory or accounting matters.

We do not express any opinion as to the price or range of prices at which the Advaxis Common Stock may trade subsequent to the announcement or consummation of the Merger.

We have acted as a financial advisor to Advaxis in connection with the Merger and will receive a customary fee for such services, a substantial portion of which is contingent on successful consummation of the Merger. A portion of our compensation is payable upon delivery of this letter and may be credited against the fee payable upon consummation of the Merger. In addition, Advaxis has agreed to reimburse us for certain expenses and to indemnify us against certain liabilities arising out of our engagement. Advaxis has also given us the exclusive right to provide certain investment banking and other services to Advaxis for a period of 12 months following this engagement, on customary terms and conditions.

During the two year period prior to the date hereof, Cantor Fitzgerald & Co. ("CF&CO") has not been engaged by Advaxis to provide financial advisory or other services on matters unrelated to the Merger, and we have not received any compensation from Advaxis during such period. CF&CO may seek to provide Advaxis, Ayala or their respective affiliates with certain investment banking and other services unrelated to the Merger in the future.

Consistent with applicable legal and regulatory requirements, CF&CO has adopted certain policies and procedures to establish and maintain the independence of CF&CO's research departments and personnel. As a result, CF&CO's research analysts may hold views, make statements or investment recommendations and/or publish research reports with respect to Advaxis, Ayala, the Merger and other participants in the Merger that differ from the views of CF&CO's investment banking personnel.

In the ordinary course of business, CF&CO and its affiliates may actively trade (for their own accounts and for the accounts of their customers) certain equity and debt securities, bank debt and/or other financial instruments issued by Advaxis and/or Ayala and their respective affiliates, as well as derivatives thereof, and, accordingly, may at any time hold long or short positions in such securities, bank debt, financial instruments and derivatives.

It is understood that this letter is intended solely for the benefit and use of the Board of Directors of Advaxis (in its capacity as such) in connection with its consideration of the Merger. As you are aware, David Sidransky is the Chair of the Board of Directors of both Advaxis and Ayala. You have informed us, and we have assumed for purposes of our opinion, that he recused himself from any board deliberations or meetings regarding, and has not otherwise been involved in your consideration of, the Merger. This letter and our opinion are not to be used for any other purpose, or be reproduced, disseminated, quoted from or referred to at any time, in whole or in part, without our prior written consent; *provided, however,* that this letter may be included in its entirety in any SEC filing that is required to be distributed to the holders of Advaxis Common Stock in connection with the Merger. This letter and our opinion do not constitute a recommendation to the Board of Directors of Advaxis in connection with the Merger, nor do this letter and our opinion constitute a recommendation to how any holders of Advaxis Common Stock or Ayala Common Stock should vote or act with respect to the Merger or any related matters. Our opinion does not address Advaxis's underlying business decision to pursue the Merger, the relative merits of the Merger as compared to any alternative business or financial strategies that might exist for Advaxis, or the effects of any other transaction in which Advaxis might engage. In addition, this opinion does not constitute a solvency opinion or a fair value opinion, and we have not evaluated the solvency or fair value of Advaxis under any federal or state laws relating to bankruptcy, insolvency or similar matters. Furthermore, we do not express any view or opinion as to the fairness, financial or otherwise, of the amount or nature of any compensation payable to or to be received by any of Advaxis's officers, directors or employees, or any class of such persons, in connection with the Merger relative to the Exchange Ratio. We express no view as to any other aspect or implication of the Merger or any other agreement, arrangement or understanding entered into in connection with the Merger or otherwise.

Our opinion has been authorized for issuance by the Fairness Opinion and Valuation Committee of CF&CO. Our opinion is subject to the assumptions, limitations, qualifications and other conditions contained herein and is necessarily based on economic, market and other conditions, and the information made available to us, as of the date hereof. We assume no responsibility for updating or revising our opinion based on circumstances or events occurring after the date hereof.

Based on and subject to the foregoing, it is our opinion that, as of the date hereof, the Exchange Ratio is fair, from a financial point of view, to Advaxis.

Very truly yours,

CANTOR FITZGERALD & CO.

By: /s/ Sage Kelly
Managing Director

Annex D

Execution Version

VOTING AND SUPPORT AGREEMENT

THIS VOTING AND SUPPORT AGREEMENT (this "**Agreement**") is made and entered into as of October 18, 2022, by and among Advaxis, Inc., a Delaware corporation ("**Parent**"); and Israel Biotech Fund I, L.P., a Cayman Islands Exempted Limited Partnership ("**Stockholder**").

WHEREAS, concurrently with the execution and delivery of this Agreement, Parent, Doe Merger Sub, Inc., a Delaware corporation and a wholly owned Subsidiary of Parent ("**Merger Sub**"), and Ayala Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), are entering into an Agreement and Plan of Merger, dated as of the date hereof (the "**Merger Agreement**"), providing, among other things, for the merger of Merger Sub with and into the Company, with the Company being the surviving corporation (the "**Merger**"); and

WHEREAS, as a condition of and inducement to Parent's willingness to enter into the Merger Agreement, Parent and Merger Sub have required that Stockholder enter into this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth in this Agreement and in the Merger Agreement, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Certain Definitions. For the purposes of this Agreement, capitalized terms used but not otherwise defined in this Agreement have the meanings ascribed to them in the Merger Agreement, and other capitalized terms used herein have the respective meanings ascribed to them in this Section 1.

"**Additional Owned Shares**" means all shares of Company Common Stock and any other equity securities of the Company which are beneficially owned by Stockholder and are acquired after the date hereof and prior to the Expiration Date.

"**Affiliate**" has the meaning set forth in the Merger Agreement; *provided, however*, that the Company shall not be deemed to be an Affiliate of Stockholder.

"**beneficial ownership**" (and related terms such as "beneficially owned" or "beneficial owner") has the meaning set forth in Rule 13d-3 under the Exchange Act, and a Person's beneficial ownership of securities shall be calculated in accordance with the provisions of such rule (in each case, irrespective of whether or not such rule is actually applicable in such circumstance).

"**Covered Shares**" means the Owned Shares and Additional Owned Shares.

"**Expiration Date**" has the meaning set forth in Section 6.

"**knowledge of Stockholder**" means, for any Stockholder that is an individual, the actual knowledge of such Stockholder and, for any Stockholder that is not an individual, the actual knowledge of any officer of Stockholder.

"**Liens**" has the meaning set forth in Section 5(a).

"**Owned Shares**" means all shares of Company Common Stock and any other equity securities of the Company which are beneficially owned by Stockholder as of the date hereof, as set forth on Schedule I.

"**Permitted Transfer**" has the meaning set forth in Section 3(a).

"**Representatives**" means, with respect to a Person, all of the officers, directors, employees, consultants, legal representatives, agents, advisors, auditors, investment bankers, and other advisors, agents or representatives of such Person.

"**Transfer**" means, with respect to a security, the transfer, pledge, hypothecation, encumbrance, assignment or other disposition (whether by sale, merger, consolidation, liquidation, dissolution, dividend, distribution or otherwise, and including the creation of any Liens) of such security or the beneficial ownership thereof, the offer to make such a transfer or other disposition, and each option, agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. As a verb, "**Transfer**" has a correlative meaning.

2. Agreement to Vote. Prior to the Expiration Date, at the Company Stockholders Meeting, however called, or at any adjournment or postponement thereof, or in any other circumstance in which the vote, consent or other approval of the stockholders of the Company is sought, Stockholder irrevocably and unconditionally agrees that it shall, and shall cause any other holder of record of Stockholder's Covered Shares to, (a) appear at each such meeting or otherwise cause all Covered Shares to be counted as present thereat for purposes of calculating a quorum and (b) vote (or cause to be voted), or execute and deliver a written consent (or cause a written consent to be executed and delivered) covering, all Covered Shares:

(i) in favor of the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement, and the execution and delivery by the Company of the Merger Agreement and the approval of the terms thereof and each of the other actions contemplated by the Merger Agreement and this Agreement;

(ii) in favor of any adjournment or postponement recommended by the Company with respect to the Company Stockholders Meeting to the extent permitted or required pursuant to Section 5.5(a) of the Merger Agreement;

(iii) against any Company Acquisition Proposal, except as expressly permitted by Section 5.2 of the Merger Agreement;

(iv) against any merger agreement or merger (other than the Merger Agreement and the Merger), consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by the Company, in each case except as expressly permitted by Section 5.2 of the Merger Agreement; and

(v) against any proposal, action or agreement that would reasonably be expected to (A) materially delay or postpone, prevent or otherwise impair the Merger or the other transactions contemplated by the Merger Agreement, (B) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of the Company under the Merger Agreement, (C) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of Stockholder under this Agreement, (D) result in any of the conditions set forth in Section 6 of the Merger Agreement not being fulfilled or (E) except as expressly contemplated by the Merger Agreement, change in any manner the dividend policy or capitalization of, including the voting rights of any class of capital stock of, the Company. Stockholder shall not commit or agree to take any action inconsistent with the foregoing.

3. No Disposition or Solicitation.

(a) No Disposition or Adverse Act. Stockholder hereby covenants and agrees that, except as contemplated by this Agreement and the Merger Agreement, prior to the Expiration Date, Stockholder shall not (i) offer to Transfer, Transfer or consent to any Transfer of any or all of the Covered Shares or any interest therein without the prior written consent of Parent, (ii) enter into any contract, option or other agreement or understanding with respect to any Transfer of any or all Covered Shares or any interest therein, (iii) grant any proxy, power-of-attorney or other authorization or consent in or with respect to any or all of the Covered Shares (other than a proxy card or broker instructions directing that the Covered Shares be voted in accordance with Section 2), (iv) deposit any or all of the Covered Shares into a voting trust or enter into a voting agreement or arrangement with respect to any or all of the Covered Shares or (v) take any other action that would make any representation or warranty of Stockholder contained herein untrue or incorrect or in any way restrict, limit or interfere with the performance of Stockholder's obligations hereunder or the transactions contemplated hereby or by the Merger Agreement. Notwithstanding the foregoing, a Stockholder may Transfer Covered Shares (i) to effect a "cashless exercise" to pay the exercise price of Company Options or to satisfy such Stockholder's Tax withholding obligations in connection with such exercise, as permitted pursuant to the terms of any of the Company Equity Awards, (ii) to effect a "net settlement" of Company RSUs to satisfy such Stockholder's Tax withholding obligations upon the settlement of a Company RSU, as permitted pursuant to the terms of any of the Company Equity Awards, (iii), in the case of a Stockholder that is not an individual, to an Affiliate of such Stockholder and (iv), in the case of a Stockholder that is an individual, (A) to any member of such Stockholder's immediate family, (B) to a trust for the sole benefit of such Stockholder or any member of such Stockholder's immediate family (i.e., spouse, lineal descendant or antecedent, brother or sister, adopted child or grandchild or the spouse of any child, adopted child, grandchild or adopted grandchild), (C) upon the death of such Stockholder, and (D) by will, divorce decree, intestacy or other similar law; *provided* that any such Transfer referenced in clauses (iii) - (iv) shall be permitted only if the applicable transferee agrees in writing to be bound by the terms of this Agreement (a "**Permitted Transfer**"). Any attempted Transfer of Covered Shares or any interest therein in violation of this Section 3(a) shall be null and void *ab initio*.

(b) Non-Solicitation. Prior to the Expiration Date, Stockholder hereby agrees that Stockholder shall not, and shall use its reasonable best efforts to cause its controlled Affiliates and Representatives not to, directly or indirectly:

(i) solicit, initiate, induce, encourage or facilitate, any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal;

(ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any proposal or offer the consummation of which would constitute a Company Acquisition Proposal;

(iii) provide any non-public information or data concerning the Company or any of its Subsidiaries to any Person in connection with any proposal the consummation of which would constitute a Company Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating a Company Acquisition Proposal;

(iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to a Company Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to a Company Acquisition Proposal;

(v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any Person (other than Parent and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or the Company's organizational or other governing documents;

(vi) take any action that could reasonably be expected to lead to a Company Acquisition Proposal except as expressly permitted by Section 5.2 of the Merger Agreement; or

(vii) resolve, publicly propose or agree to do any of the foregoing.

(c) Notification. Prior to the Company Stockholder Meeting, Stockholder shall promptly (and, in any event, within 24 hours) notify Parent (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to a Company Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to a Company Acquisition Proposal are received by Stockholder, (ii) any non-public information is requested in connection with any Company Acquisition Proposal from the Company or (iii) any discussions or negotiation with respect to or that could reasonably be expected to lead to a Company Acquisition Proposal are sought to be initiated or continued with the Company, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep Parent informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. Promptly following the execution and delivery of this Agreement, Stockholder shall and shall use its reasonable best efforts to cause its Representatives to, immediately cease and cause to be terminated any existing solicitation of, or discussions or negotiations with, any Person (other than Parent and its Representatives) relating to any Company Acquisition Proposal made prior to the date hereof and any access any such Persons may have to any physical or electronic data room or any confidential or proprietary information relating to any potential Company Acquisition Proposal.

4. Additional Agreements.

(a) Certain Events. In the event of any stock split, stock dividend, merger, reorganization, recapitalization or other change in the capital structure of the Company affecting the Covered Shares or the acquisition of Additional Owned Shares or other securities or rights of the Company by Stockholder, (i) the type and number of Covered Shares shall be adjusted appropriately, and (ii) this Agreement and the obligations hereunder shall automatically attach to any Additional Owned Shares or other securities or rights of the Company issued to or acquired by Stockholder. In the event of a Company Change in Recommendation, to the extent the Covered Shares (together will all shares of Company Common Stock subject to voting agreements entered into on the date hereof by and between Company stockholders and Parent) exceed 30% of the Company Outstanding Shares, then the number of shares of Company Common Stock subject to such voting agreements shall only be 30% of the Company Outstanding Shares in the aggregate, and the number of shares of Company Common Stock of each such Company stockholder subject to each such voting agreement shall be reduced proportionately based upon the number of shares of Company Common Stock subject thereto.

(b) Stop Transfer. In furtherance of this Agreement, Stockholder hereby authorizes and instructs the Company (including through the Company's transfer agent) to enter a stop transfer order with respect to all of the Covered Shares, including authorizing the Company to, as promptly as practicable after the date of this Agreement, make a notation on its records and give instructions to the transfer agent for the Covered Shares not to permit, during the term of this Agreement, the Transfer of the Covered Shares unless such Transfer is a Permitted Transfer, *provided* that promptly following the earlier of (x) the Expiration Date and (y) obtaining the Company Stockholder Approval, any such stop transfer instructions imposed pursuant to this Section 4(b) shall be lifted.

(c) Waiver of Appraisal and Dissenters' Rights and Actions. Stockholder hereby (i) waives and agrees not to exercise any rights of appraisal or rights to dissent from the Merger that Stockholder may have and (ii) agrees not to commence or participate in, assist or knowingly encourage, and to take all actions necessary to opt out of, any class in any class action with respect to, any action or claim, derivative or otherwise, against Parent, Merger Sub, the Company or any of their respective Subsidiaries or Affiliates and each of their successors and assigns relating to the negotiation, execution or delivery of this Agreement or the Merger Agreement or the consummation of the Merger, including any claim (A) challenging the validity of, or seeking to enjoin the operation of, any provision of this Agreement (including any claim seeking to enjoin or delay the closing of the Merger) or (B) alleging a breach of any fiduciary duty of the Company Board in connection with the Merger Agreement or the transactions contemplated thereby; *provided* that nothing in this Section 4(c) shall restrict or prohibit Stockholder from asserting (x) its right to receive the Merger Consideration in accordance with the Merger Agreement and the DGCL or (y) counterclaims or defenses in any proceeding brought or claims asserted against it by Parent, Merger Sub, the Company or any of their respective Subsidiaries or Affiliates and each of their successors and assigns relating to this Agreement or the Merger Agreement, or from enforcing its rights under this Agreement.

(d) Communications. Stockholder shall not, and shall use reasonable best efforts to cause its Representatives not to, make any press release, public announcement or other communication with respect to the business or affairs of any of the Company, Parent or Merger Sub, including this Agreement and the Merger Agreement and the transactions contemplated hereby and thereby, without the prior written consent of Parent. Stockholder hereby (i) consents to and authorizes the publication and disclosure by Parent of Stockholder's identity and holding of Covered Shares, and the nature of Stockholder's commitments, arrangements and understandings under this Agreement in any press release or any other disclosure document in connection with the Merger or any other transactions contemplated by the Merger Agreement and (ii) agrees as promptly as practicable to notify Parent of any required corrections with respect to any written information supplied by Stockholder specifically for use in any such disclosure document.

(e) Additional Owned Shares. Stockholder hereby agrees to notify Parent promptly in writing of the number and description of any Additional Owned Shares.

5. Representations and Warranties of Stockholder. Stockholder hereby represents and warrants to Parent as follows:

(a) Title. Stockholder is the sole record and beneficial owner of the Covered Shares. The Owned Shares constitute all of the capital stock and any other equity securities of the Company owned of record or beneficially by Stockholder on the date hereof, and Stockholder is not the beneficial owner of, and does not have any right to acquire (whether currently, upon lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing) any shares of Company Common Stock or any other equity securities of the Company or any securities convertible into or exchangeable or exercisable for shares of Company Common Stock or such other equity securities, in each case other than the Owned Shares and any Additional Owned Shares. Dr. David Sidranksy, Chairman of the Board of Directors of the Company and managing partner of Stockholder, is not the beneficial owner of, and does not have any right to acquire (whether currently, upon lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing), directly or indirectly, (i) 5% or greater shares of Company Common Stock or any other equity securities of the Company or any securities convertible into or exchangeable or exercisable for shares of Company Common Stock or such other equity securities, or (ii) 5% or more of the Merger Consideration. Stockholder (or its nominee or custodian for the benefit of Stockholder) has sole voting power, sole power of disposition and sole power to issue instructions with respect to the matters set forth in Sections 3 and 4 hereof and all other matters set forth in this Agreement, in each case with respect to all of the Covered Shares with no limitations, qualifications or restrictions on such rights, subject to applicable securities laws and the terms of this Agreement. Except as permitted by this Agreement, the Owned Shares and the certificates representing such Owned Shares, if any, are now, and at all times prior to the Expiration Date will be, held by Stockholder, or by a nominee or custodian for the benefit of Stockholder, free and clear of any and all liens, pledges, claims, options, proxies, voting trusts or agreements, security interests, understandings or arrangements or any other encumbrances whatsoever on title, transfer or exercise of any rights of a stockholder in respect of the Owned Shares (other than as created by this Agreement) (collectively, "**Liens**").

(b) Organization and Qualification. If Stockholder is not an individual, Stockholder is a legal entity duly organized, validly existing and, to the extent such concept is applicable, in good standing under the laws of the jurisdiction of its organization.

(c) Authority. Stockholder has all necessary individual or entity power and authority and legal capacity to, and has taken all action necessary in order to, execute, deliver and perform all of Stockholder's obligations under this Agreement, and consummate the transactions contemplated hereby, and no other proceedings or actions on the part of Stockholder are necessary to authorize the execution, delivery or performance of this Agreement or the consummation of the transactions contemplated hereby.

(d) Due Execution and Delivery. This Agreement has been duly and validly executed and delivered by Stockholder and, assuming due authorization, execution and delivery hereof by Parent, constitutes a legal, valid and binding agreement of Stockholder, enforceable against Stockholder in accordance with its terms, subject to the Bankruptcy and Equity Exception. If Stockholder is an individual and is married, and any of the Covered Shares constitute community property or spousal approval is otherwise necessary for this Agreement to be legal, binding and enforceable, this Agreement has been duly authorized, executed and delivered by, and constitutes the legal, valid and binding obligation of, Stockholder's spouse, enforceable against Stockholder's spouse in accordance with its terms.

(e) No Filings; No Conflict or Default. Except for any required filings under the any competition, antitrust and investment laws or regulations of foreign jurisdictions and the Exchange Act, no filing with, and no permit, authorization, consent or approval of, any Governmental Entity or any other Person is necessary for the execution and delivery of this Agreement by Stockholder, the consummation by Stockholder of the transactions contemplated hereby and the compliance by Stockholder with the provisions hereof. None of the execution and delivery of this Agreement by Stockholder, the consummation by Stockholder of the transactions contemplated hereby or compliance by Stockholder with any of the provisions hereof will (i) result in a violation or breach of, or constitute (with or without notice or lapse of time or both) a default (or give rise to any third party right of termination, cancellation, modification or acceleration) under, any of the terms, conditions or provisions of any note, bond, mortgage, indenture, lease, license, permit, contract, commitment, arrangement, understanding, agreement or other instrument or obligation of any kind, including any voting agreement, proxy arrangement, pledge agreement, shareholders agreement or voting trust, to which Stockholder is a party or by which Stockholder or any of Stockholder's properties or assets may be bound, (ii) violate any judgment, order, writ, injunction, decree or award of any court, administrative agency or other Governmental Entity that is applicable to Stockholder or any of Stockholder's properties or assets, (iii) constitute a violation by Stockholder of any law or regulation of any jurisdiction, (iv) render Section 203 of the DGCL, or any other state takeover statute or similar statute or regulation, applicable to the Merger or any other transaction involving Parent, or (v) if Stockholder is not an individual, contravene or conflict with Stockholder's governing or organizational documents, in each case, except, in the case of clauses (i) through (iv), for any conflict, breach, default or violation described above which would not materially impair the ability of Stockholder to perform its obligations hereunder or consummate the transactions contemplated hereby.

(f) No Litigation. There is no suit, claim, action, investigation or proceeding pending or, to the knowledge of Stockholder, threatened against Stockholder at law or in equity before or by any Governmental Entity that questions the beneficial or record ownership of Stockholder's Covered Shares, the validity of this Agreement or the performance by Stockholder of its obligations under this Agreement or that would reasonably be expected to materially impair the ability of Stockholder to perform its obligations hereunder or to consummate the transactions contemplated hereby.

(g) No Fees. No broker, finder or investment banker is entitled to any brokerage, finder's or other similar fee or commission in connection with the transactions contemplated hereby based upon arrangements made by or on behalf of Stockholder.

(h) Receipt; Reliance. Stockholder has received and reviewed a copy of the Merger Agreement. Stockholder understands and acknowledges that Parent and Merger Sub are entering into the Merger Agreement in reliance upon Stockholder's execution, delivery and performance of this Agreement and the representations, warranties, covenants and other agreements of Stockholder contained herein.

6. Termination. This Agreement and all rights and obligations of the parties hereunder shall commence on the date hereof and shall terminate upon the earliest of (such time, the "**Expiration Date**") (a) the mutual agreement of Parent and Stockholder, (b) the Company Stockholders Meeting at which a vote upon the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement is taken and (c) the termination of the Merger Agreement in accordance with its terms; *provided* that (i) nothing herein shall relieve any party hereto from liability for any breach of this Agreement and (ii) this Section 6 and Section 8 shall survive any termination of this Agreement.

7. No Limitation. Nothing in this Agreement shall be construed to prohibit Stockholder or any of Stockholder's Representatives who is an officer or member of the Company Board from taking any action (or failing to take any action) solely in his or her capacity as an officer or member of the Company Board (or any committee thereof) or from taking any action with respect to any Company Acquisition Proposal as an officer or member of the Company Board (or any committee thereof).

8. Miscellaneous.

(a) Entire Agreement. This Agreement (together with Schedule I) constitutes the entire agreement and supersedes all prior and contemporaneous agreements and understandings, both written and oral, among or between any of the parties hereto with respect to the subject matter hereof.

(b) Reasonable Efforts. At the other party's reasonable request and without further consideration, each party hereto shall execute and deliver such additional documents and take all such further lawful action as may be reasonably required or necessary to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated hereby. Without limiting the foregoing, Stockholder shall execute and deliver to Parent and any of its designees any proxies, including with respect to Additional Owned Shares, reasonably requested by Parent in furtherance of this Agreement.

(c) No Assignment. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the parties hereto and their respective successors and permitted assigns; *provided*, however, that, except in connection with a Permitted Transfer, neither this Agreement nor any of a party's rights or obligations hereunder may be assigned or delegated by such party without the prior written consent of the other party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such party without the other party's prior written consent shall be void and of no effect.

(d) Binding Successors. Without limiting any other rights Parent may have hereunder in respect of any Transfer of the Covered Shares, Stockholder agrees that this Agreement and the obligations hereunder shall attach to the Covered Shares beneficially owned by Stockholder and shall be binding upon any Person to which legal or beneficial ownership of such Covered Shares shall pass, whether by operation of law or otherwise, including, without limitation, Stockholder's heirs, guardians, administrators, Representatives, successors or permitted assigns.

(e) Amendments. This Agreement may be amended at any time prior to the Effective Time (whether before or after receipt of the Company Stockholder Approval) by an instrument in writing signed on behalf of each of the parties hereto.

(f) Notice. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (if no automated notice of delivery failure is received by the sender) prior to 5:00 p.m. New York time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub

Advaxis, Inc.
212 Carnegie Center, Suite 206
Princeton, New Jersey 08540
Attention: Kenneth A. Berlin and Igor Gitelman
Email: berlin@advaxis.com; gitelman@advaxis.com

with copies to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178
Attention: Robert W. Dickey
Email: robert.dickey@morganlewis.com

if to the Stockholder

Israel Biotech Fund I, L.P.
75 Fort Street, Clifton House
PO Box, 1350
KYI-1108, Grand Cayman
Attention: Sarit Steinberg
Email: sarit@ibf.fund

with copies to (which shall not constitute notice):

Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Attention: Peter N. Handrinos; Joshua M. Dubofsky
Email: Peter.Handrinos@lw.com; Josh.Dubofsky@lw.com

(g) Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties hereto agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.

(h) Remedies. All rights, powers and remedies provided under this Agreement or otherwise available in respect hereof at law or in equity shall be cumulative and not alternative, and the exercise of any such right, power or remedy by any party hereto shall not preclude the simultaneous or later exercise of any other such right, power or remedy by such party.

(i) No Waiver. Except as otherwise provided in this Agreement, any failure of any of the parties to comply with any obligation, covenant, agreement or condition herein may be waived by the party or parties entitled to the benefits thereof only by a written instrument signed by the party granting such waiver. Any such waiver shall not be applicable or have any effect except in the specific instance in which it is given. No failure on the part of any party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy. No single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(j) No Third Party Beneficiaries. This Agreement shall be binding upon and inure solely to the benefit of each party hereto, and nothing in this Agreement, express or implied, is intended to confer upon any other Person any rights or remedies of any nature whatsoever under or by reason of this Agreement.

(k) Applicable Law; Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the parties hereto arising out of or relating to this Agreement, each of the parties hereto: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 8(k); (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any party hereto; and (e) agrees that service of process upon such party in any such action or proceeding shall be effective if notice is given in accordance with Section 8(f) of this Agreement. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT ANY ACTION OR PROCEEDING WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION OR PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY OF THE AGREEMENTS DELIVERED IN CONNECTION HEREWITH, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF ANY ACTION OR PROCEEDING, SEEK TO ENFORCE EITHER OF SUCH WAIVERS, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS, (III) IT MAKES SUCH WAIVERS VOLUNTARILY AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8(k).

(l) Specific Performance. Each of the parties hereto acknowledges and agrees that irreparable damage would occur and that the parties hereto would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. It is accordingly agreed that, in addition to any other remedy that a party hereto may have under law or in equity, in the event of any breach or threatened breach by Parent or Stockholder of any covenant or obligation of such party contained in this Agreement, the other party shall be entitled to obtain an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each party hereto hereby waives any requirement for the security or posting of any bond in connection with such remedy). The parties hereto further agree not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable Law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that Stockholder or Parent otherwise have an adequate remedy at law. The parties hereto acknowledge that the agreements contained in this Section 8(l) are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the parties hereto would not enter into this Agreement.

(m) Interpretation. The terms of Section 8.11 of the Merger Agreement apply to this Agreement *mutatis mutandis*.

(n) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all parties hereto by electronic transmission in .PDF format shall be sufficient to bind the parties hereto to the terms and conditions of this Agreement.

(o) Expenses. Except as otherwise provided herein, each party hereto shall pay such party's own expenses incurred in connection with this Agreement.

(p) No Ownership Interest. Nothing contained in this Agreement shall be deemed, upon execution, to vest in Parent any direct or indirect ownership or incidence of ownership of or with respect to any Covered Shares. All rights, ownership and economic benefits of and relating to the Covered Shares shall remain vested in and belong to Stockholder, and Parent shall have no authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of the Company or exercise any power or authority to direct Stockholder in the voting of any of the Covered Shares, except as otherwise provided herein.

(q) Capacity as Stockholder. Notwithstanding anything herein to the contrary, Stockholder signs this Agreement solely in Stockholder's capacity as a stockholder of the Company, and not in any other capacity, and this Agreement shall not limit or otherwise affect the actions (or failure to take any actions) of any Affiliate, employee or designee of Stockholder or any of its Affiliates in his or her capacity, if applicable, as an officer or director of the Company or any other Person.

[Signature page follows]

IN WITNESS WHEREOF, Parent and Stockholder have caused this Agreement to be duly executed as of the date first written above.

ADVAXIS, INC.

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer

ISRAEL BIOTECH FUND I, L.P.
By its general partner:
Israel Biotech Fund GP Partners, L.P.
By its general partner:
I.B.F. Management, Ltd.

By: */s/ Yuval Cabilly*
Name: Yuval Cabilly
Title: CEO

SCHEDULE I

Name and Contact Information for Stockholder	Number of Shares of Company Common Stock Beneficially Owned
Israel Biotech Fund I, L.P. 75 Fort Street, Clifton House PO Box, 1350 KYI-1108, Grand Cayman	3,315,119

Annex E

Execution Version

VOTING AND SUPPORT AGREEMENT

THIS VOTING AND SUPPORT AGREEMENT (this "**Agreement**") is made and entered into as of October 18, 2022, by and among Advaxis, Inc., a Delaware corporation ("**Parent**"); and aMoon Growth Fund Limited Partnership, a Cayman Islands Exempted Limited Partnership ("**Stockholder**").

WHEREAS, concurrently with the execution and delivery of this Agreement, Parent, Doe Merger Sub, Inc., a Delaware corporation and a wholly owned Subsidiary of Parent ("**Merger Sub**"), and Ayala Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), are entering into an Agreement and Plan of Merger, dated as of the date hereof (the "**Merger Agreement**"), providing, among other things, for the merger of Merger Sub with and into the Company, with the Company being the surviving corporation (the "**Merger**"); and

WHEREAS, as a condition of and inducement to Parent's willingness to enter into the Merger Agreement, Parent and Merger Sub have required that Stockholder enter into this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth in this Agreement and in the Merger Agreement, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Certain Definitions. For the purposes of this Agreement, capitalized terms used but not otherwise defined in this Agreement have the meanings ascribed to them in the Merger Agreement, and other capitalized terms used herein have the respective meanings ascribed to them in this Section 1.

"**Additional Owned Shares**" means all shares of Company Common Stock and any other equity securities of the Company which are beneficially owned by Stockholder and are acquired after the date hereof and prior to the Expiration Date.

"**Affiliate**" has the meaning set forth in the Merger Agreement; *provided, however*, that the Company shall not be deemed to be an Affiliate of Stockholder.

"**beneficial ownership**" (and related terms such as "beneficially owned" or "beneficial owner") has the meaning set forth in Rule 13d-3 under the Exchange Act, and a Person's beneficial ownership of securities shall be calculated in accordance with the provisions of such rule (in each case, irrespective of whether or not such rule is actually applicable in such circumstance).

"**Covered Shares**" means the Owned Shares and Additional Owned Shares.

"**Expiration Date**" has the meaning set forth in Section 6.

"**knowledge of Stockholder**" means, for any Stockholder that is an individual, the actual knowledge of such Stockholder and, for any Stockholder that is not an individual, the actual knowledge of any officer of Stockholder.

"**Liens**" has the meaning set forth in Section 5(a).

"**Owned Shares**" means all shares of Company Common Stock and any other equity securities of the Company which are beneficially owned by Stockholder as of the date hereof, as set forth on Schedule I.

"**Permitted Transfer**" has the meaning set forth in Section 3(a).

"**Representatives**" means, with respect to a Person, all of the officers, directors, employees, consultants, legal representatives, agents, advisors, auditors, investment bankers, and other advisors, agents or representatives of such Person.

"**Transfer**" means, with respect to a security, the transfer, pledge, hypothecation, encumbrance, assignment or other disposition (whether by sale, merger, consolidation, liquidation, dissolution, dividend, distribution or otherwise, and including the creation of any Liens) of such security or the beneficial ownership thereof, the offer to make such a transfer or other disposition, and each option, agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. As a verb, "**Transfer**" has a correlative meaning.

2. Agreement to Vote. Prior to the Expiration Date, at the Company Stockholders Meeting, however called, or at any adjournment or postponement thereof, or in any other circumstance in which the vote, consent or other approval of the stockholders of the Company is sought, Stockholder irrevocably and unconditionally agrees that it shall, and shall cause any other holder of record of Stockholder's Covered Shares to, (a) appear at each such meeting or otherwise cause all Covered Shares to be counted as present thereat for purposes of calculating a quorum and (b) vote (or cause to be voted), or execute and deliver a written consent (or cause a written consent to be executed and delivered) covering, all Covered Shares:

(i) in favor of the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement, and the execution and delivery by the Company of the Merger Agreement and the approval of the terms thereof and each of the other actions contemplated by the Merger Agreement and this Agreement;

(ii) in favor of any adjournment or postponement recommended by the Company with respect to the Company Stockholders Meeting to the extent permitted or required pursuant to Section 5.5(a) of the Merger Agreement;

(iii) against any Company Acquisition Proposal, except as expressly permitted by Section 5.2 of the Merger Agreement;

(iv) against any merger agreement or merger (other than the Merger Agreement and the Merger), consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by the Company, in each case except as expressly permitted by Section 5.2 of the Merger Agreement; and

(v) against any proposal, action or agreement that would reasonably be expected to (A) materially delay or postpone, prevent or otherwise impair the Merger or the other transactions contemplated by the Merger Agreement, (B) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of the Company under the Merger Agreement, (C) result in a breach in any respect of any covenant, representation, warranty or any other obligation or agreement of Stockholder under this Agreement, (D) result in any of the conditions set forth in Section 6 of the Merger Agreement not being fulfilled or (E) except as expressly contemplated by the Merger Agreement, change in any manner the dividend policy or capitalization of, including the voting rights of any class of capital stock of, the Company. Stockholder shall not commit or agree to take any action inconsistent with the foregoing.

3. No Disposition or Solicitation.

(a) No Disposition or Adverse Act. Stockholder hereby covenants and agrees that, except as contemplated by this Agreement and the Merger Agreement, prior to the Expiration Date, Stockholder shall not (i) offer to Transfer, Transfer or consent to any Transfer of any or all of the Covered Shares or any interest therein without the prior written consent of Parent, (ii) enter into any contract, option or other agreement or understanding with respect to any Transfer of any or all Covered Shares or any interest therein, (iii) grant any proxy, power-of-attorney or other authorization or consent in or with respect to any or all of the Covered Shares (other than a proxy card or broker instructions directing that the Covered Shares be voted in accordance with Section 2), (iv) deposit any or all of the Covered Shares into a voting trust or enter into a voting agreement or arrangement with respect to any or all of the Covered Shares or (v) take any other action that would make any representation or warranty of Stockholder contained herein untrue or incorrect or in any way restrict, limit or interfere with the performance of Stockholder's obligations hereunder or the transactions contemplated hereby or by the Merger Agreement. Notwithstanding the foregoing, a Stockholder may Transfer Covered Shares (i) to effect a "cashless exercise" to pay the exercise price of Company Options or to satisfy such Stockholder's Tax withholding obligations in connection with such exercise, as permitted pursuant to the terms of any of the Company Equity Awards, (ii) to effect a "net settlement" of Company RSUs to satisfy such Stockholder's Tax withholding obligations upon the settlement of a Company RSU, as permitted pursuant to the terms of any of the Company Equity Awards, (iii), in the case of a Stockholder that is not an individual, to an Affiliate of such Stockholder and (iv), in the case of a Stockholder that is an individual, (A) to any member of such Stockholder's immediate family, (B) to a trust for the sole benefit of such Stockholder or any member of such Stockholder's immediate family (i.e., spouse, lineal descendant or antecedent, brother or sister, adopted child or grandchild or the spouse of any child, adopted child, grandchild or adopted grandchild), (C) upon the death of such Stockholder, and (D) by will, divorce decree, intestacy or other similar law; *provided* that any such Transfer referenced in clauses (iii) - (iv) shall be permitted only if the applicable transferee agrees in writing to be bound by the terms of this Agreement (a "**Permitted Transfer**"). Any attempted Transfer of Covered Shares or any interest therein in violation of this Section 3(a) shall be null and void *ab initio*.

(b) Non-Solicitation. Prior to the Expiration Date, Stockholder hereby agrees that Stockholder shall not, and shall use its reasonable best efforts to cause its controlled Affiliates and Representatives not to, directly or indirectly:

(i) solicit, initiate, induce, encourage or facilitate, any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal;

(ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any proposal or offer the consummation of which would constitute a Company Acquisition Proposal;

(iii) provide any non-public information or data concerning the Company or any of its Subsidiaries to any Person in connection with any proposal the consummation of which would constitute a Company Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating a Company Acquisition Proposal;

(iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to a Company Acquisition Proposal or any proposal or offer that could reasonably be expected to lead to a Company Acquisition Proposal;

(v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, a Company Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL); take any action or exempt any Person (other than Parent and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or the Company's organizational or other governing documents;

(vi) take any action that could reasonably be expected to lead to a Company Acquisition Proposal except as expressly permitted by Section 5.2 of the Merger Agreement; or

(vii) resolve, publicly propose or agree to do any of the foregoing.

(c) Notification. Prior to the Company Stockholders Meeting, Stockholder shall promptly (and, in any event, within 24 hours) notify Parent (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to a Company Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to a Company Acquisition Proposal are received by Stockholder, (ii) any non-public information is requested in connection with any Company Acquisition Proposal from the Company or (iii) any discussions or negotiation with respect to or that could reasonably be expected to lead to a Company Acquisition Proposal are sought to be initiated or continued with the Company, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep Parent informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. Promptly following the execution and delivery of this Agreement, Stockholder shall and shall use its reasonable best efforts to cause its Representatives to, immediately cease and cause to be terminated any existing solicitation of, or discussions or negotiations with, any Person (other than Parent and its Representatives) relating to any Company Acquisition Proposal made prior to the date hereof and any access any such Persons may have to any physical or electronic data room or any confidential or proprietary information relating to any potential Company Acquisition Proposal.

4. Additional Agreements.

(a) Certain Events. In the event of any stock split, stock dividend, merger, reorganization, recapitalization or other change in the capital structure of the Company affecting the Covered Shares or the acquisition of Additional Owned Shares or other securities or rights of the Company by Stockholder, (i) the type and number of Covered Shares shall be adjusted appropriately, and (ii) this Agreement and the obligations hereunder shall automatically attach to any Additional Owned Shares or other securities or rights of the Company issued to or acquired by Stockholder. In the event of a Company Change in Recommendation, to the extent the Covered Shares (together will all shares of Company Common Stock subject to voting agreements entered into on the date hereof by and between Company stockholders and Parent) exceed 30% of the Company Outstanding Shares, then the number of shares of Company Common Stock subject to such voting agreements shall only be 30% of the Company Outstanding Shares in the aggregate, and the number of shares of Company Common Stock of each such Company stockholder subject to each such voting agreement shall be reduced proportionately based upon the number of shares of Company Common Stock subject thereto.

(b) Stop Transfer. In furtherance of this Agreement, Stockholder hereby authorizes and instructs the Company (including through the Company's transfer agent) to enter a stop transfer order with respect to all of the Covered Shares, including authorizing the Company to, as promptly as practicable after the date of this Agreement, make a notation on its records and give instructions to the transfer agent for the Covered Shares not to permit, during the term of this Agreement, the Transfer of the Covered Shares unless such Transfer is a Permitted Transfer, *provided* that promptly following the earlier of (x) the Expiration Date and (y) obtaining the Company Stockholder Approval, any such stop transfer instructions imposed pursuant to this Section 4(b) shall be lifted.

(c) Waiver of Appraisal and Dissenters' Rights and Actions. Stockholder hereby (i) waives and agrees not to exercise any rights of appraisal or rights to dissent from the Merger that Stockholder may have and (ii) agrees not to commence or participate in, assist or knowingly encourage, and to take all actions necessary to opt out of, any class in any class action with respect to, any action or claim, derivative or otherwise, against Parent, Merger Sub, the Company or any of their respective Subsidiaries or Affiliates and each of their successors and assigns relating to the negotiation, execution or delivery of this Agreement or the Merger Agreement or the consummation of the Merger, including any claim (A) challenging the validity of, or seeking to enjoin the operation of, any provision of this Agreement (including any claim seeking to enjoin or delay the closing of the Merger) or (B) alleging a breach of any fiduciary duty of the Company Board in connection with the Merger Agreement or the transactions contemplated thereby; *provided* that nothing in this Section 4(c) shall restrict or prohibit Stockholder from asserting (x) its right to receive the Merger Consideration in accordance with the Merger Agreement and the DGCL or (y) counterclaims or defenses in any proceeding brought or claims asserted against it by Parent, Merger Sub, the Company or any of their respective Subsidiaries or Affiliates and each of their successors and assigns relating to this Agreement or the Merger Agreement, or from enforcing its rights under this Agreement.

(d) Communications. Stockholder shall not, and shall use reasonable best efforts to cause its Representatives not to, make any press release, public announcement or other communication with respect to the business or affairs of any of the Company, Parent or Merger Sub, including this Agreement and the Merger Agreement and the transactions contemplated hereby and thereby, without the prior written consent of Parent. Stockholder hereby (i) consents to and authorizes the publication and disclosure by Parent of Stockholder's identity and holding of Covered Shares, and the nature of Stockholder's commitments, arrangements and understandings under this Agreement in any press release or any other disclosure document in connection with the Merger or any other transactions contemplated by the Merger Agreement and (ii) agrees as promptly as practicable to notify Parent of any required corrections with respect to any written information supplied by Stockholder specifically for use in any such disclosure document.

(e) Additional Owned Shares. Stockholder hereby agrees to notify Parent promptly in writing of the number and description of any Additional Owned Shares.

5. Representations and Warranties of Stockholder. Stockholder hereby represents and warrants to Parent as follows:

(a) Title. Stockholder is the sole record and beneficial owner of the Covered Shares. The Owned Shares constitute all of the capital stock and any other equity securities of the Company owned of record or beneficially by Stockholder on the date hereof, and Stockholder is not the beneficial owner of, and does not have any right to acquire (whether currently, upon lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing) any shares of Company Common Stock or any other equity securities of the Company or any securities convertible into or exchangeable or exercisable for shares of Company Common Stock or such other equity securities, in each case other than the Owned Shares and any Additional Owned Shares. Stockholder (or its nominee or custodian for the benefit of Stockholder) has sole voting power, sole power of disposition and sole power to issue instructions with respect to the matters set forth in Sections 3 and 4 hereof and all other matters set forth in this Agreement, in each case with respect to all of the Covered Shares with no limitations, qualifications or restrictions on such rights, subject to applicable securities laws and the terms of this Agreement. Except as permitted by this Agreement, the Owned Shares and the certificates representing such Owned Shares, if any, are now, and at all times prior to the Expiration Date will be, held by Stockholder, or by a nominee or custodian for the benefit of Stockholder, free and clear of any and all liens, pledges, claims, options, proxies, voting trusts or agreements, security interests, understandings or arrangements or any other encumbrances whatsoever on title, transfer or exercise of any rights of a stockholder in respect of the Owned Shares (other than as created by this Agreement) (collectively, "**Liens**").

(b) Organization and Qualification. If Stockholder is not an individual, Stockholder is a legal entity duly organized, validly existing and, to the extent such concept is applicable, in good standing under the laws of the jurisdiction of its organization.

(c) Authority. Stockholder has all necessary individual or entity power and authority and legal capacity to, and has taken all action necessary in order to, execute, deliver and perform all of Stockholder's obligations under this Agreement, and consummate the transactions contemplated hereby, and no other proceedings or actions on the part of Stockholder are necessary to authorize the execution, delivery or performance of this Agreement or the consummation of the transactions contemplated hereby.

(d) Due Execution and Delivery. This Agreement has been duly and validly executed and delivered by Stockholder and, assuming due authorization, execution and delivery hereof by Parent, constitutes a legal, valid and binding agreement of Stockholder, enforceable against Stockholder in accordance with its terms, subject to the Bankruptcy and Equity Exception. If Stockholder is an individual and is married, and any of the Covered Shares constitute community property or spousal approval is otherwise necessary for this Agreement to be legal, binding and enforceable, this Agreement has been duly authorized, executed and delivered by, and constitutes the legal, valid and binding obligation of, Stockholder's spouse, enforceable against Stockholder's spouse in accordance with its terms.

(e) No Filings; No Conflict or Default. Except for any required filings under the any competition, antitrust and investment laws or regulations of foreign jurisdictions and the Exchange Act, no filing with, and no permit, authorization, consent or approval of, any Governmental Entity or any other Person is necessary for the execution and delivery of this Agreement by Stockholder, the consummation by Stockholder of the transactions contemplated hereby and the compliance by Stockholder with the provisions hereof. None of the execution and delivery of this Agreement by Stockholder, the consummation by Stockholder of the transactions contemplated hereby or compliance by Stockholder with any of the provisions hereof will (i) result in a violation or breach of, or constitute (with or without notice or lapse of time or both) a default (or give rise to any third party right of termination, cancellation, modification or acceleration) under, any of the terms, conditions or provisions of any note, bond, mortgage, indenture, lease, license, permit, contract, commitment, arrangement, understanding, agreement or other instrument or obligation of any kind, including any voting agreement, proxy arrangement, pledge agreement, shareholders agreement or voting trust, to which Stockholder is a party or by which Stockholder or any of Stockholder's properties or assets may be bound, (ii) violate any judgment, order, writ, injunction, decree or award of any court, administrative agency or other Governmental Entity that is applicable to Stockholder or any of Stockholder's properties or assets, (iii) constitute a violation by Stockholder of any law or regulation of any jurisdiction, (iv) render Section 203 of the DGCL, or any other state takeover statute or similar statute or regulation, applicable to the Merger or any other transaction involving Parent, or (v) if Stockholder is not an individual, contravene or conflict with Stockholder's governing or organizational documents, in each case, except, in the case of clauses (i) through (iv), for any conflict, breach, default or violation described above which would not materially impair the ability of Stockholder to perform its obligations hereunder or consummate the transactions contemplated hereby.

(f) No Litigation. There is no suit, claim, action, investigation or proceeding pending or, to the knowledge of Stockholder, threatened against Stockholder at law or in equity before or by any Governmental Entity that questions the beneficial or record ownership of Stockholder's Covered Shares, the validity of this Agreement or the performance by Stockholder of its obligations under this Agreement or that would reasonably be expected to materially impair the ability of Stockholder to perform its obligations hereunder or to consummate the transactions contemplated hereby.

(g) No Fees. No broker, finder or investment banker is entitled to any brokerage, finder's or other similar fee or commission in connection with the transactions contemplated hereby based upon arrangements made by or on behalf of Stockholder.

(h) Receipt; Reliance. Stockholder has received and reviewed a copy of the Merger Agreement. Stockholder understands and acknowledges that Parent and Merger Sub are entering into the Merger Agreement in reliance upon Stockholder's execution, delivery and performance of this Agreement and the representations, warranties, covenants and other agreements of Stockholder contained herein.

6. Termination. This Agreement and all rights and obligations of the parties hereunder shall commence on the date hereof and shall terminate upon the earliest of (such time, the "**Expiration Date**") (a) the mutual agreement of Parent and Stockholder, (b) the Company Stockholders Meeting at which a vote upon the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement is taken and (c) the termination of the Merger Agreement in accordance with its terms; *provided* that (i) nothing herein shall relieve any party hereto from liability for any breach of this Agreement and (ii) this Section 6 and Section 8 shall survive any termination of this Agreement.

7. No Limitation. Nothing in this Agreement shall be construed to prohibit Stockholder or any of Stockholder's Representatives who is an officer or member of the Company Board from taking any action (or failing to take any action) solely in his or her capacity as an officer or member of the Company Board (or any committee thereof) or from taking any action with respect to any Company Acquisition Proposal as an officer or member of the Company Board (or any committee thereof).

8. Miscellaneous.

(a) Entire Agreement. This Agreement (together with Schedule I) constitutes the entire agreement and supersedes all prior and contemporaneous agreements and understandings, both written and oral, among or between any of the parties hereto with respect to the subject matter hereof.

(b) Reasonable Efforts. At the other party's reasonable request and without further consideration, each party hereto shall execute and deliver such additional documents and take all such further lawful action as may be reasonably required or necessary to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated hereby. Without limiting the foregoing, Stockholder shall execute and deliver to Parent and any of its designees any proxies, including with respect to Additional Owned Shares, reasonably requested by Parent in furtherance of this Agreement.

(c) No Assignment. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the parties hereto and their respective successors and permitted assigns; *provided*, however, that, except in connection with a Permitted Transfer, neither this Agreement nor any of a party's rights or obligations hereunder may be assigned or delegated by such party without the prior written consent of the other party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such party without the other party's prior written consent shall be void and of no effect.

(d) Binding Successors. Without limiting any other rights Parent may have hereunder in respect of any Transfer of the Covered Shares, Stockholder agrees that this Agreement and the obligations hereunder shall attach to the Covered Shares beneficially owned by Stockholder and shall be binding upon any Person to which legal or beneficial ownership of such Covered Shares shall pass, whether by operation of law or otherwise, including, without limitation, Stockholder's heirs, guardians, administrators, Representatives, successors or permitted assigns.

(e) Amendments. This Agreement may be amended at any time prior to the Effective Time (whether before or after receipt of the Company Stockholder Approval) by an instrument in writing signed on behalf of each of the parties hereto.

(f) Notice. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (if no automated notice of delivery failure is received by the sender) prior to 5:00 p.m. New York time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub

Advaxis, Inc.
212 Carnegie Center, Suite 206
Princeton, New Jersey 08540
Attention: Kenneth A. Berlin and Igor Gitelman
Email: berlin@advaxis.com; gitelman@advaxis.com

with copies to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178
Attention: Robert W. Dickey
Email: robert.dickey@morganlewis.com

if to the Stockholder

aMoon Growth Fund Limited Partnership
34 Yerushalaim Rd
Beit Gamla, 6th Floor
Attention: Noam Waldoks
Email: noam@aMoon.fund

with copies to (which shall not constitute notice):

Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Attention: Peter N. Handrinos; Joshua M. Dubofsky
Email: Peter.Handrinos@lw.com; Josh.Dubofsky@lw.com

(g) Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties hereto agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.

(h) Remedies. All rights, powers and remedies provided under this Agreement or otherwise available in respect hereof at law or in equity shall be cumulative and not alternative, and the exercise of any such right, power or remedy by any party hereto shall not preclude the simultaneous or later exercise of any other such right, power or remedy by such party.

(i) No Waiver. Except as otherwise provided in this Agreement, any failure of any of the parties to comply with any obligation, covenant, agreement or condition herein may be waived by the party or parties entitled to the benefits thereof only by a written instrument signed by the party granting such waiver. Any such waiver shall not be applicable or have any effect except in the specific instance in which it is given. No failure on the part of any party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy. No single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(j) No Third Party Beneficiaries. This Agreement shall be binding upon and inure solely to the benefit of each party hereto, and nothing in this Agreement, express or implied, is intended to confer upon any other Person any rights or remedies of any nature whatsoever under or by reason of this Agreement.

(k) Applicable Law; Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the parties hereto arising out of or relating to this Agreement, each of the parties hereto: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 8(k); (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any party hereto; and (e) agrees that service of process upon such party in any such action or proceeding shall be effective if notice is given in accordance with Section 8(f) of this Agreement. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT ANY ACTION OR PROCEEDING WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION OR PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY OF THE AGREEMENTS DELIVERED IN CONNECTION HEREWITH, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF ANY ACTION OR PROCEEDING, SEEK TO ENFORCE EITHER OF SUCH WAIVERS, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS, (III) IT MAKES SUCH WAIVERS VOLUNTARILY AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8(k).

(l) Specific Performance. Each of the parties hereto acknowledges and agrees that irreparable damage would occur and that the parties hereto would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. It is accordingly agreed that, in addition to any other remedy that a party hereto may have under law or in equity, in the event of any breach or threatened breach by Parent or Stockholder of any covenant or obligation of such party contained in this Agreement, the other party shall be entitled to obtain an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each party hereto hereby waives any requirement for the security or posting of any bond in connection with such remedy). The parties hereto further agree not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable Law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that Stockholder or Parent otherwise have an adequate remedy at law. The parties hereto acknowledge that the agreements contained in this Section 8(l) are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the parties hereto would not enter into this Agreement.

(m) Interpretation. The terms of Section 8.11 of the Merger Agreement apply to this Agreement *mutatis mutandis*.

(n) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all parties hereto by electronic transmission in .PDF format shall be sufficient to bind the parties hereto to the terms and conditions of this Agreement.

(o) Expenses. Except as otherwise provided herein, each party hereto shall pay such party's own expenses incurred in connection with this Agreement.

(p) No Ownership Interest. Nothing contained in this Agreement shall be deemed, upon execution, to vest in Parent any direct or indirect ownership or incidence of ownership of or with respect to any Covered Shares. All rights, ownership and economic benefits of and relating to the Covered Shares shall remain vested in and belong to Stockholder, and Parent shall have no authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of the Company or exercise any power or authority to direct Stockholder in the voting of any of the Covered Shares, except as otherwise provided herein.

(q) Capacity as Stockholder. Notwithstanding anything herein to the contrary, Stockholder signs this Agreement solely in Stockholder's capacity as a stockholder of the Company, and not in any other capacity, and this Agreement shall not limit or otherwise affect the actions (or failure to take any actions) of any Affiliate, employee or designee of Stockholder or any of its Affiliates in his or her capacity, if applicable, as an officer or director of the Company or any other Person.

[Signature page follows]

IN WITNESS WHEREOF, Parent and Stockholder have caused this Agreement to be duly executed as of the date first written above.

ADVAXIS, INC.

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer

AMOON GROWTH FUND LIMITED PARTNERSHIP
BY: AMOON GROWTH FUND G.P. LIMITED PARTNERSHIP, ITS GENERAL PARTNER

BY: AMOON GENERAL PARTNER, LTD., ITS GENERAL PARTNER

By: */s/ Dr. Yair C. Schindel*
Name: Dr. Yair C. Schindel
Title: Director and Managing Partner

By: */s/ Todd Sone*
Name: Todd Sone
Title: General Partner

SCHEDULE I

Name and Contact Information for Stockholder	Number of Shares of Company Common Stock Beneficially Owned
aMoon Growth Fund Limited Partnership 34 Yerushalaim Rd Beit Gamla, 6th Floor Ra'anana, 4350110, Israel	2,991,473

GENERAL CORPORATION LAW OF THE STATE OF DELAWARE

§262. APPRAISAL RIGHTS.

(a) Any stockholder of a corporation of this State who holds shares of stock on the date of the making of a demand pursuant to subsection (d) of this section with respect to such shares, who continuously holds such shares through the effective date of the merger, consolidation, or conversion, who has otherwise complied with subsection (d) of this section and who has neither voted in favor of the merger, consolidation or conversion nor consented thereto in writing pursuant to § 228 of this title shall be entitled to an appraisal by the Court of Chancery of the fair value of the stockholder's shares of stock under the circumstances described in subsections (b) and (c) of this section. As used in this section, the word "stockholder" means a holder of record of stock in a corporation; the words "stock" and "share" mean and include what is ordinarily meant by those words; the words "depository receipt" mean a receipt or other instrument issued by a depository representing an interest in 1 or more shares, or fractions thereof, solely of stock of a corporation, which stock is deposited with the depository; the words "beneficial owner" mean a person who is the beneficial owner of shares of stock held either in voting trust or by a nominee on behalf of such person; and the word "person" means any individual, corporation, partnership, unincorporated association or other entity.

(b) Appraisal rights shall be available for the shares of any class or series of stock of a constituent or converting corporation in a merger, consolidation or conversion to be effected pursuant to § 251 (other than a merger effected pursuant to § 251(g) of this title), § 252, § 254, § 255, § 256, § 257, § 258, § 263, § 264 or § 266 of this title (other than, in each case and solely with respect to a domesticated corporation, a merger, consolidation or conversion authorized pursuant to and in accordance with the provisions of § 388 of this title):

(1) Provided, however, that no appraisal rights under this section shall be available for the shares of any class or series of stock, which stock, or depository receipts in respect thereof, at the record date fixed to determine the stockholders entitled to receive notice of the meeting of stockholders, or at the record date fixed to determine the stockholders entitled to consent pursuant to § 228 of this title, to act upon the agreement of merger or consolidation or the resolution providing for conversion (or, in the case of a merger pursuant to § 251(h) of this title, as of immediately prior to the execution of the agreement of merger), were either: (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders; and further provided that no appraisal rights shall be available for any shares of stock of the constituent corporation surviving a merger if the merger did not require for its approval the vote of the stockholders of the surviving corporation as provided in § 251(f) of this title.

(2) Notwithstanding paragraph (b)(1) of this section, appraisal rights under this section shall be available for the shares of any class or series of stock of a constituent or converting corporation if the holders thereof are required by the terms of an agreement of merger or consolidation, or by the terms of a resolution providing for conversion, pursuant to § 251, § 252, § 254, § 255, § 256, § 257, § 258, § 263, § 264 or § 266 of this title to accept for such stock anything except:

a. Shares of stock of the corporation surviving or resulting from such merger or consolidation, or of the converted entity if such entity is a corporation as a result of the conversion, or depository receipts in respect thereof;

b. Shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger, consolidation or conversion will be either listed on a national securities exchange or held of record by more than 2,000 holders;

c. Cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a. and b. of this section; or

d. Any combination of the shares of stock, depository receipts and cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a., b. and c. of this section.

(3) In the event all of the stock of a subsidiary Delaware corporation party to a merger effected under § 253 or § 267 of this title is not owned by the parent immediately prior to the merger, appraisal rights shall be available for the shares of the subsidiary Delaware corporation.

(4) [Repealed.]

(c) Any corporation may provide in its certificate of incorporation that appraisal rights under this section shall be available for the shares of any class or series of its stock as a result of an amendment to its certificate of incorporation, any merger or consolidation in which the corporation is a constituent corporation, the sale of all or substantially all of the assets of the corporation or a conversion effected pursuant to § 266 of this title. If the certificate of incorporation contains such a provision, the provisions of this section, including those set forth in subsections (d), (e), and (g) of this section, shall apply as nearly as is practicable.

(d) Appraisal rights shall be perfected as follows:

(1) If a proposed merger, consolidation or conversion for which appraisal rights are provided under this section is to be submitted for approval at a meeting of stockholders, the corporation, not less than 20 days prior to the meeting, shall notify each of its stockholders who was such on the record date for notice of such meeting (or such members who received notice in accordance with § 255(c) of this title) with respect to shares for which appraisal rights are available pursuant to subsection (b) or (c) of this section that appraisal rights are available for any or all of the shares of the constituent corporations or the converting corporation, and shall include in such notice either a copy of this section (and, if 1 of the constituent corporations or the converting corporation is a nonstock corporation, a copy of § 114 of this title) or information directing the stockholders to a publicly available electronic resource at which this section (and, § 114 of this title, if applicable) may be accessed without subscription or cost. Each stockholder electing to demand the appraisal of such stockholder's shares shall deliver to the corporation, before the taking of the vote on the merger, consolidation or conversion, a written demand for appraisal of such stockholder's shares; provided that a demand may be delivered to the corporation by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such stockholder's shares. A proxy or vote against the merger, consolidation or conversion shall not constitute such a demand. A stockholder electing to take such action must do so by a separate written demand as herein provided. Within 10 days after the effective date of such merger, consolidation or conversion, the surviving, resulting or converted entity shall notify each stockholder of each constituent or converting corporation who has complied with this subsection and has not voted in favor of or consented to the merger, consolidation or conversion, and any beneficial owner who has demanded appraisal under paragraph (d)(3) of this section, of the date that the merger, consolidation or conversion has become effective; or

(2) If the merger, consolidation or conversion was approved pursuant to § 228, § 251(h), § 253, or § 267 of this title, then either a constituent or converting corporation before the effective date of the merger, consolidation or conversion, or the surviving, resulting or converted entity within 10 days after such effective date, shall notify each stockholder of any class or series of stock of such constituent or converting corporation who is entitled to appraisal rights of the approval of the merger, consolidation or conversion and that appraisal rights are available for any or all shares of such class or series of stock of such constituent or converting corporation, and shall include in such notice either a copy of this section (and, if 1 of the constituent corporations or the converting corporation is a nonstock corporation, a copy of § 114 of this title) or information directing the stockholders to a publicly available electronic resource at which this section (and § 114 of this title, if applicable) may be accessed without subscription or cost. Such notice may, and, if given on or after the effective date of the merger, consolidation or conversion, shall, also notify such stockholders of the effective date of the merger, consolidation or conversion. Any stockholder entitled to appraisal rights may, within 20 days after the date of giving such notice or, in the case of a merger approved pursuant to § 251(h) of this title, within the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days after the date of giving such notice, demand in writing from the surviving or resulting entity the appraisal of such holder's shares; provided that a demand may be delivered to such entity by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs such entity of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such holder's shares. If such notice did not notify stockholders of the effective date of the merger, consolidation or conversion, either (i) each such constituent corporation or the converting corporation shall send a second notice before the effective date of the merger, consolidation or conversion notifying each of the holders of any class or series of stock of such constituent or converting corporation that are entitled to appraisal rights of the effective date of the merger, consolidation or conversion or (ii) the surviving, resulting or converted entity shall send such a second notice to all such holders on or within 10 days after such effective date; provided, however, that if such second notice is sent more than 20 days following the sending of the first notice or, in the case of a merger approved pursuant to § 251(h) of this title, later than the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days following the sending of the first notice, such second notice need only be sent to each stockholder who is entitled to appraisal rights and who has demanded appraisal of such holder's shares in accordance with this subsection and any beneficial owner who has demanded appraisal under paragraph (d)(3) of this section. An affidavit of the secretary or assistant secretary or of the transfer agent of the corporation or entity that is required to give either notice that such notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of determining the stockholders entitled to receive either notice, each constituent corporation or the converting corporation may fix, in advance, a record date that shall be not more than 10 days prior to the date the notice is given, provided, that if the notice is given on or after the effective date of the merger, consolidation or conversion, the record date shall be such effective date. If no record date is fixed and the notice is given prior to the effective date, the record date shall be the close of business on the day next preceding the day on which the notice is given.

(3) Notwithstanding subsection (a) of this section (but subject to this paragraph (d)(3)), a beneficial owner may, in such person's name, demand in writing an appraisal of such beneficial owner's shares in accordance with either paragraph (d)(1) or (2) of this section, as applicable; provided that (i) such beneficial owner continuously owns such shares through the effective date of the merger, consolidation or conversion and otherwise satisfies the requirements applicable to a stockholder under the first sentence of subsection (a) of this section and (ii) the demand made by such beneficial owner reasonably identifies the holder of record of the shares for which the demand is made, is accompanied by documentary evidence of such beneficial owner's beneficial ownership of stock and a statement that such documentary evidence is a true and correct copy of what it purports to be, and provides an address at which such beneficial owner consents to receive notices given by the surviving, resulting or converted entity hereunder and to be set forth on the verified list required by subsection (f) of this section.

(e) Within 120 days after the effective date of the merger, consolidation or conversion, the surviving, resulting or converted entity, or any person who has complied with subsections (a) and (d) of this section hereof and who is otherwise entitled to appraisal rights, may commence an appraisal proceeding by filing a petition in the Court of Chancery demanding a determination of the value of the stock of all such stockholders. Notwithstanding the foregoing, at any time within 60 days after the effective date of the merger, consolidation or conversion, any person entitled to appraisal rights who has not commenced an appraisal proceeding or joined that proceeding as a named party shall have the right to withdraw such person's demand for appraisal and to accept the terms offered upon the merger, consolidation or conversion. Within 120 days after the effective date of the merger, consolidation or conversion, any person who has complied with the requirements of subsections (a) and (d) of this section hereof, upon request given in writing (or by electronic transmission directed to an information processing system (if any) expressly designated for that purpose in the notice of appraisal), shall be entitled to receive from the surviving, resulting or converted entity a statement setting forth the aggregate number of shares not voted in favor of the merger, consolidation or conversion (or, in the case of a merger approved pursuant to § 251(h) of this title, the aggregate number of shares (other than any excluded stock (as defined in § 251(h)(6)d. of this title)) that were the subject of, and were not tendered into, and accepted for purchase or exchange in, the offer referred to in § 251(h)(2) of this title)), and, in either case, with respect to which demands for appraisal have been received and the aggregate number of stockholders or beneficial owners holding or owning such shares (provided that, where a beneficial owner makes a demand pursuant to paragraph (d)(3) of this section, the record holder of such shares shall not be considered a separate stockholder holding such shares for purposes of such aggregate number). Such statement shall be given to the person within 10 days after such person's request for such a statement is received by the surviving, resulting or converted entity or within 10 days after expiration of the period for delivery of demands for appraisal under subsection (d) of this section hereof, whichever is later.

(f) Upon the filing of any such petition by any person other than the surviving, resulting or converted entity, service of a copy thereof shall be made upon such entity, which shall within 20 days after such service file in the office of the Register in Chancery in which the petition was filed a duly verified list containing the names and addresses of all persons who have demanded appraisal for their shares and with whom agreements as to the value of their shares have not been reached by such entity. If the petition shall be filed by the surviving, resulting or converted entity, the petition shall be accompanied by such a duly verified list. The Register in Chancery, if so ordered by the Court, shall give notice of the time and place fixed for the hearing of such petition by registered or certified mail to the surviving, resulting or converted entity and to the persons shown on the list at the addresses therein stated. The forms of the notices by mail and by publication shall be approved by the Court, and the costs thereof shall be borne by the surviving, resulting or converted entity.

(g) At the hearing on such petition, the Court shall determine the persons who have complied with this section and who have become entitled to appraisal rights. The Court may require the persons who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any person fails to comply with such direction, the Court may dismiss the proceedings as to such person. If immediately before the merger, consolidation or conversion the shares of the class or series of stock of the constituent or converting corporation as to which appraisal rights are available were listed on a national securities exchange, the Court shall dismiss the proceedings as to all holders of such shares who are otherwise entitled to appraisal rights unless (1) the total number of shares entitled to appraisal exceeds 1% of the outstanding shares of the class or series eligible for appraisal, (2) the value of the consideration provided in the merger, consolidation or conversion for such total number of shares exceeds $1 million, or (3) the merger was approved pursuant to § 253 or § 267 of this title.

(h) After the Court determines the persons entitled to an appraisal, the appraisal proceeding shall be conducted in accordance with the rules of the Court of Chancery, including any rules specifically governing appraisal proceedings. Through such proceeding the Court shall determine the fair value of the shares exclusive of any element of value arising from the accomplishment or expectation of the merger, consolidation or conversion, together with interest, if any, to be paid upon the amount determined to be the fair value. In determining such fair value, the Court shall take into account all relevant factors. Unless the Court in its discretion determines otherwise for good cause shown, and except as provided in this subsection, interest from the effective date of the merger, consolidation or conversion through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5% over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective date of the merger, consolidation or conversion and the date of payment of the judgment. At any time before the entry of judgment in the proceedings, the surviving, resulting or converted entity may pay to each person entitled to appraisal an amount in cash, in which case interest shall accrue thereafter as provided herein only upon the sum of (1) the difference, if any, between the amount so paid and the fair value of the shares as determined by the Court, and (2) interest theretofore accrued, unless paid at that time. Upon application by the surviving, resulting or converted entity or by any person entitled to participate in the appraisal proceeding, the Court may, in its discretion, proceed to trial upon the appraisal prior to the final determination of the persons entitled to an appraisal. Any person whose name appears on the list filed by the surviving, resulting or converted entity pursuant to subsection (f) of this section may participate fully in all proceedings until it is finally determined that such person is not entitled to appraisal rights under this section.

(i) The Court shall direct the payment of the fair value of the shares, together with interest, if any, by the surviving, resulting or converted entity to the persons entitled thereto. Payment shall be so made to each such person upon such terms and conditions as the Court may order. The Court's decree may be enforced as other decrees in the Court of Chancery may be enforced, whether such surviving, resulting or converted entity be an entity of this State or of any state.

(j) The costs of the proceeding may be determined by the Court and taxed upon the parties as the Court deems equitable in the circumstances. Upon application of a person whose name appears on the list filed by the surviving, resulting or converted entity pursuant to subsection (f) of this section who participated in the proceeding and incurred expenses in connection therewith, the Court may order all or a portion of such expenses, including, without limitation, reasonable attorney's fees and the fees and expenses of experts, to be charged pro rata against the value of all the shares entitled to an appraisal not dismissed pursuant to subsection (k) of this section or subject to such an award pursuant to a reservation of jurisdiction under subsection (k) of this section.

(k) From and after the effective date of the merger, consolidation or conversion, no person who has demanded appraisal rights with respect to some or all of such person's shares as provided in subsection (d) of this section shall be entitled to vote such shares for any purpose or to receive payment of dividends or other distributions on such shares (except dividends or other distributions payable to stockholders of record at a date which is prior to the effective date of the merger, consolidation or conversion); provided, however, that if no petition for an appraisal is filed within the time provided in subsection (e) of this section, or if a person who has made a demand for an appraisal in accordance with this section shall deliver to the surviving, resulting or converted entity a written withdrawal of such person's demand for an appraisal in respect of some or all of such person's shares in accordance with subsection (e) of this section, then the right of such person to an appraisal of the shares subject to the withdrawal shall cease. Notwithstanding the foregoing, no appraisal proceeding in the Court of Chancery shall be dismissed as to any person without the approval of the Court, and such approval may be conditioned upon such terms as the Court deems just, including without limitation, a reservation of jurisdiction for any application to the Court made under subsection (j) of this section; provided, however that this provision shall not affect the right of any person who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such person's demand for appraisal and to accept the terms offered upon the merger, consolidation or conversion within 60 days after the effective date of the merger, consolidation or conversion, as set forth in subsection (e) of this section.

(l) The shares or other equity interests of the surviving, resulting or converted entity to which the shares of stock subject to appraisal under this section would have otherwise converted but for an appraisal demand made in accordance with this section shall have the status of authorized but not outstanding shares of stock or other equity interests of the surviving, resulting or converted entity, unless and until the person that has demanded appraisal is no longer entitled to appraisal pursuant to this section.

SCAN TO
VIEW MATERIALS & VOTE

AYALA PHARMACEUTICALS, INC.
OPPENHEIMER 4
REHOVOT, 7670104 ISRAEL

VOTE BY INTERNET
Before The Meeting - Go to **www.proxyvote.com or scan the QR Barcode above**

Use the Internet to transmit your voting instructions and for electronic delivery of information up until 11:59 p.m. Eastern Time on January 12, 2023. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

During The Meeting - Go to **www.virtualshareholdermeeting.com/AYLA2023SM**

You may attend the meeting via the Internet and vote during the meeting. We recommend, however, that you vote before the meeting even if you plan to participate in the meeting, since you can change your vote during the meeting by voting when the polls are open. Have the information that is printed in the box marked by the arrow available and follow the instructions.

VOTE BY PHONE - 1-800-690-6903
Use any touch-tone telephone to transmit your voting instructions up until 11:59 p.m. Eastern Time on January 12, 2023. Have your proxy card in hand when you call and then follow the instructions.

VOTE BY MAIL
Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS:

D92693-S57706 — KEEP THIS PORTION FOR YOUR RECORDS

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED. — DETACH AND RETURN THIS PORTION ONLY

AYALA PHARMACEUTICALS, INC.

The Board of Directors recommends you vote FOR the following proposals:	**For**	**Against**	**Abstain**
1. To adopt the Agreement and Plan of Merger (the "Merger Agreement"), dated October 18, 2022, by and among Ayala Pharmaceuticals, Inc. ("Ayala"), Advaxis, Inc. ("Advaxis") and Doe Merger Sub, Inc. ("Merger Sub"), pursuant to which, among other things, Merger Sub will merge with and into Ayala, with Ayala surviving as a wholly owned subsidiary of Advaxis; and	☐	☐	☐
2. To approve the adjournment of the special meeting of Ayala stockholders from time to time, if necessary or appropriate, to solicit additional affirmative votes in favor of the Merger Agreement if there are insufficient votes at the time of such adjournment to approve the Merger Agreement.	☐	☐	☐

NOTE: Such other business as may properly come before the meeting or any continuation, postponement, or adjournment thereof.

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name by authorized officer.

Signature [PLEASE SIGN WITHIN BOX] Date

Signature (Joint Owners) Date

Important Notice Regarding the Availability of Proxy Materials for the Special Meeting:
The Notice and Proxy Statement is available at www.proxyvote.com.

D92694-S57706

AYALA PHARMACEUTICALS, INC.
Special Meeting of Stockholders
January 13, 2023 10:00 AM Eastern Time
This proxy is solicited by the Board of Directors

The undersigned stockholder(s) hereby appoint(s) Roni Mamluk, Ph.D. and Yossi Maimon, or either of them, as proxies, each with the power to appoint her or his substitute, and hereby authorize(s) them to represent and to vote, as designated on the reverse side of this proxy card, all of the shares of common stock of AYALA PHARMACEUTICALS, INC. that the stockholder(s) is/are entitled to vote at the Special Meeting of Stockholders to be held at 10:00 AM, Eastern Time on January 13, 2023, virtually at www.virtualshareholdermeeting.com/AYLA2023SM, and any continuation, postponement, or adjournment thereof.

Such proxies are authorized to vote in their discretion (x) on any matter that the Board of Directors did not know would be presented at the Special Meeting of Stockholders by a reasonable time before the proxy solicitation was made, and (y) on such other business as may properly be brought before the meeting or any continuation, postponement, or adjournment thereof.

This proxy, when properly executed, will be voted in the manner directed herein. If no such direction is made, this proxy will be voted in accordance with the Board of Directors' recommendations.

Continued and to be signed on reverse side