UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to_____

Commission File Number 001-36138

AYALA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**02-0563870**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ	08852
(Address of principal executive offices)	**(Zip Code)**

(609) 452-9813
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

Securities registered pursuant to Section 12(g) of the Act.

Common Stock, par value $0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of June 30, 2023, the aggregate market value of the voting common equity held by non-affiliates was approximately $3.7 million based on the closing bid price of the registrant's common stock on the - OTCQX ® Best Market (for purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates). ☒

The registrant had 42,633,400 shares of common stock, par value $0.001 per share, outstanding as of April 8, 2024.

Documents Incorporated by Reference

Portions of the definitive proxy statement for the registrant's 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement") are incorporated by reference into Items 10, 11, 12, 13 and 14 in Part III of this Annual Report on Form 10-K. If the 2024 Proxy Statement is not filed by April 29, 2024 (the day that is 120 days after the last day of the registrant's 2023 fiscal year), an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

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INTRODUCTORY NOTE

Merger of Advaxis, Inc. with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Registrant entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among the Registrant, Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.), a Delaware corporation ("Old Ayala"), and Doe Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and a wholly-owned subsidiary of the Registrant. On January 19, 2023 (the "Closing Date"), pursuant to the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Registrant (the "Merger").

The Merger Agreement and additional information on the details of the Merger may be found in the Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") by the Registrant on October 19, 2022.

At the effective time of the Merger (the "Effective Time"), which occurred on January 19, 2023, (i) each share of the common stock, par value $0.01 per share, of Old Ayala (the "Old Ayala Common Stock") issued and outstanding immediately prior to the Merger was automatically converted into the right to receive 0.1874 shares (the "Exchange Ratio") of the common stock, par value $0.001 per share, of the Registrant (the "Common Stock"), (ii) each outstanding option to purchase shares of the Old Ayala Common Stock (each, an "Old Ayala Option") was substituted and converted automatically into an option (each, an "New Ayala Replacement Option") to purchase the number of shares of New Ayala Common Stock equal to the product obtained by multiplying (a) the number of shares of Old Ayala Common Stock subject to such Old 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 New Ayala Replacement Option to have an exercise price per share of Common Stock equal to (x) the per share exercise price for the shares of Old Ayala Common Stock subject to the corresponding Old 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 (iii) each restricted stock unit of Old Ayala (each, an "Old Ayala RSU") outstanding immediately prior to the effective time of the Merger, whether or not vested or issuable, was substituted and converted automatically into a restricted stock unit award of New Ayala with respect to a number of shares of Common Stock equal to the product obtained by multiplying (a) the total number of shares of Old Ayala Common Stock subject to such Old Ayala RSU 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.

The issuance of Common Stock in connection with the Merger Agreement was registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to The Registrant's registration statement on Form S-4 (Registration No. 333-268586) declared effective by the SEC on December 12, 2022 (the "Registration Statement"). The proxy statement/prospectus in the Registration Statement contains additional information about the Merger.

As a result of the consummation of the Merger, Old Ayala, the surviving entity in the Merger, became a wholly-owned subsidiary of the Registrant. For accounting purposes, the Merger was treated as a "reverse acquisition" and Old Ayala was considered the accounting acquirer. Accordingly, Old Ayala will be reflected as the predecessor and acquirer in the financial statements of the Registrant (the legal acquirer) for periods ending after December 31, 2022. The Registrant's historical financial condition and results of operations shown for comparative purposes in periodic filings for periods ending after December 31, 2022 reflect Old Ayala's historical results.

Merger with Biosight Ltd.

On July 26, 2023, the Registrant, Advaxis Israel Ltd., a company organized under the laws of the State of Israel and a wholly owned subsidiary of the Registrant ("ADXS Merger Sub") and Biosight, Ltd., a company organized under the laws of the State of Israel ("Biosight") entered into an Agreement and Plan of Merger and Reorganization (the "Biosight Merger Agreement"). On October 18, 2023 (the "Closing Date"), pursuant to the Merger Agreement, ADXS Merger Sub consummated the merger with and into Biosight, with Biosight continuing as the surviving company and a wholly-owned subsidiary of the Registrant (the "Biosight Merger").

The Biosight Merger Agreement and additional information on the details of the Biosight Merger may be found in the Current Report on Form 8-K filed with the SEC by the Registrant on October 20, 2023.

The Biosight Merger Agreement provided, among other things, that on the terms and subject to the conditions set forth therein, each share of Biosight issued and outstanding immediately prior to the effective time of the Merger (excluding any shares held by any of Biosight's subsidiaries, the Registrant, ADXS Merger Sub or any of their respective subsidiaries, which will remain outstanding, and certain dormant shares under Israeli law, which will be cancelled, retired and cease to exist) was automatically deemed to have been transferred to the Registrant in exchange for the right to receive 1.82285 shares (the "Exchange Ratio") of Common Stock. The Exchange Ratio was subject to equitable adjustment pursuant to the terms of the Biosight Merger Agreement. Each outstanding option or other right to purchase ordinary or preferred shares of Biosight was cancelled as of the Effective Time and will have no further force or effect. In connection with the closing of the Biosight Merger, the Registrant issued approximately 5,913,480 shares of the Common Stock to former holders of Biosight shares.

The issuance of the shares of Common Stock in the Biosight Merger was made pursuant to exemptions from the registration requirements of the Securities Act pursuant to Regulations D and S thereunder.

Sale of Assets to Immunome, Inc.

On February 5, 2024, the Registrant and Immunome, Inc. ("Immunome"), entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") pursuant to which Immunome agreed to acquire certain of the Registrant's assets and liabilities related to its AL101 and AL102 programs (the "Asset Sale"), which constitute substantially all of the Registrant's assets.

On March 25, 2024, the Registrant and Immunome consummated the Asset Sale pursuant to the Asset Purchase Agreement. Immunome paid to the Registrant an aggregate purchase price of $20,000,000 in cash (of which $4,000,000 had been paid upon entering into the Asset Purchase Agreement), subject to certain adjustments and issued to the Registrant 2,175,489 shares (the "Shares") of Immunome's common stock, $0.0001 par value. The Asset Purchase Agreement further provides that Immunome may pay the Registrant up to $37,500,000 in cash due upon the achievement of certain development and commercial milestone events set forth in the Asset Purchase Agreement. At the March 25, 2023 closing, Immunome paid the remaining $16,000,000 of the cash consideration to the Company, at the Company's direction, to certain vendors of the Company.

The Asset Purchase Agreement contains customary representations, warranties, conditions and covenants, including covenants (i) concerning the conduct of business by the Registrant prior to the closing of the Asset Sale, (ii) prohibiting the Registrant and its representatives from soliciting, initiating or knowingly inducing, encouraging or facilitating any competing acquisition proposal, (iii) prohibiting the Registrant and its controlled affiliates from competing with Immunome for five years following the closing of the Asset Sale in certain fields, and (iv) restricting the Registrant's ability to make distributions to stockholders, dissolve or wind up its business or file for bankruptcy for six months following the closing of the Asset Sale.

The Asset Purchase Agreement and additional information on the details of the Asset Sale may be found in the Current Report on Form 8-K filed with the SEC by the Registrant on February 6, 2024.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2023 ("Form 10-K") includes statements that are, or may be deemed to be, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, our available cash, liquidity, prospects, growth and strategies, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, impacts of the ongoing conflicts in the Ukraine and the Middle East, inflation and the Federal Reserve's responses thereto, including increasing interest rates, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect our industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, they may not be predictive of results or developments in future periods.

Any forward-looking statements that we make in this Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate.

This Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

In this Form 10-K, unless otherwise stated or the context otherwise indicates, references to "New Ayala," "Advaxis," the "Company," "we," "us," "our" and similar references refer to Ayala Pharmaceuticals, Inc., a Delaware corporation, which prior to the change of its name effected on January 19, 2023 was known as Advaxis, Inc.

PART I

Item 1. Business.

Recent Developments

Recent Strategic Transactions

See "*Introductory Note*" beginning on page 3 of this Annual Report on Form 10-K.

The Company has incurred recurring losses since inception as a research and development organization. For the year ended December 31, 2023, the Company used approximately $29.5 million of cash in operations and incurred a net loss of $48.1 million. As of December 31, 2023, the Company had $4.9 million in cash and cash equivalents, $25.0 million in current liabilities and an accumulated deficit of $197.2 million.

Upon closing of the Asset Sale, on March 25, 2024, the Company received $13.0 million in cash, and Immunome paid $3.0 million of the Company's liabilities directly to vendors of the Company. In addition, under the Asset Sale Agreement the Company received 2,175,489 shares of Immunome's common stock (the "Immunome Shares"). The Asset Sale Agreement prohibits the Company from selling more than 50% of the Immunome Shares in the first six months following the closing of the Asset Sale. In addition, on March 1, 2024, the Company issued additional convertible notes and warrants in exchange for $2.0 million in funding from the Convertible Notes investors. As of the date of this filing, the cash proceeds received from the Asset Sale and the convertible notes sold on March 1, 2024 were not sufficient to pay the Company's existing liabilities. Therefore, the Company has limited available cash resources and requires additional financing, through the sale of a portion of the Immunome Shares or otherwise, in order to continue to fund its current operations beyond May 2024.

Raising additional funds or the satisfactory sale of a portion of the Immunome Shares prior to the end of May 2024 is essential to provide sufficient cash flow to meet future liabilities and other obligations, such as tax payments arising from the Asset Sale. Furthermore, even if the Company is successful in selling a portion of the Immunome Shares or raising additional funds through other means, the Company cannot give any assurance that it will, in the future, be able to achieve a level of profitability from the sale of its products to sustain its operations.

If the Company is unable to obtain funding, or able to receive sufficient funds from the sale of a portion of the Immunome Shares, the Company would be forced to delay, reduce, or eliminate its research and development programs, 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.

As part of a cost reduction plan, during the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. During the first quarter of 2024, the Company gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company. The Company expects to be able to meet its financial obligations to its employees.

The Company can give no assurances that it will be successful in raising funds through the sale of a portion of the Immunome Shares or any other alternative. Any inability to so obtain additional financing or funding will likely cause the Company to cease business operations. 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, 2023, 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.

Overview

Following the completion of the Asset Sale on March 25, 2024, the Company is a clinical-stage oncology company whose primary clinical assets currently include aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). BST-236 is a novel prodrug of cytarabine, enabling delivery of high cytarabine doses with reduced systemic toxicity, creating a potential new backbone for AML combination regimens. We believe that our novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from solid and hematological cancers. We also continue to conduct certain operations relating to former Advaxis' operations as clinical-stage biotechnology company focused on the development and commercialization of proprietary Listeria monocytogenes ("Lm")-based antigen delivery products. These efforts are primarily focused on the development of ADXS-504, an Lm-based therapy for early-stage prostate cancer.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. Our net losses were approximately $48.1 million and $38.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $197.2 million.

Following closing of the sale of AL102 and AL101 to Immunome, we anticipate that our expenses will decrease as we:

- Continue to conduct certain operations related to advancing the development of BST-236
- Satisfy certain debts and obligations remaining from our operations prior to the consummation of the Asset Sale

We do not expect to generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. Additionally, we currently use contract research organizations, or CROs, to carry out our clinical development activities. Furthermore, we incur additional costs associated with operating as a public company.

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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 New Ayala, 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 New Ayala, the stockholders of New Ayala and us. As a result of the Share Exchange, New Ayala 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 New Ayala. 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. Shares of New Ayala's common stock are currently quoted on the OTCQX under the symbol "ADXS."

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.ayalapharma.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 numerous patents and applications, which are owned, licensed from, or co-owned with University of Pennsylvania, or Penn, National Institute of Health, or NIH, and/or Augusta University. 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. Issued patents which are directed to AXAL, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2024 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 2024 and 2031. Issued patents directed to our Lm-based immunotherapy platform outside of the United States, will expire between 2024 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 2024 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 2024 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.

BST-236

Our commercial success depends, in part, on our ability to obtain and maintain proprietary protection for our product candidate, BST-236, as well any future product candidates, novel discoveries, product development technologies and know-how. We own all of our intellectual property relating to BST-236 and have a patent portfolio that includes several patent families that cover composition, methods and use. We protect these intellectual property rights, which are critical to the development, formulation and marketing of our product candidate, by filing patents or patent applications with the U.S. Patent & Trademark Office and the comparable patent offices of Israel, Europe and other countries. In addition, we rely on know-how, continuing technological innovation, orphan drug exclusivity and potential in-licensing opportunities to develop and maintain our proprietary position. As of April 4, 2024, we have filed patent applications relating to BST-236 in multiple jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, Israel, Russia, Korea, Hong Kong and the United States, as well as under the Patent Cooperation Treaty. We have been issued five patents in United States, two in Europe two in each of Australia, Israel, Canada, Japan and Russia and one in each India and Macau. Issued patents and currently pending patent applications are summarized below:

- *BIOST/002 patent family*. We have two issued US patents (US 8,993,278, US 7,989,188) and one European patent (validated in France, United Kingdom and Germany) to cover BST-236, composition and use.

- *BIOST/004*. We have one granted patent in the US, two granted Australia, One granted in each of Russia, Canada, China, Monaco, Israel and India and one under examination in each of US, EP, Brazil,, Japan (two applications)to cover BST-236 pharmaceutically acceptable salts and use.

- *BIOST/005 patent family*. We have one granted patent and one allowed patent in US, one granted in each of Australia, Russia, Israel, Japan, Canada and one European patent (validated in Germany, France and United Kingdom), and one under examination in each of , Brazil, China, Japan and Israel to cover use.

- *BIOST/007*. We have one granted patent in Israel and one granted patent in Japan, and one under examination in each of US, Europe, Brazil, Japan, Canada, China, Korea and Hong Kong, to cover combination therapy.

- *BIOST/008*. We have patents under examination in US, Europe, Israel, Brazil, Canada, China, Hong Kong, Japan and Korea to cover use.

- *BIOST/009*. We have patents under examination in US, Europe, Israel, Brazil, Canada, China, Hong Kong, Japan and Korea to cover formulation.

- *BIOST/010*. We have patents under examination in US, Europe, Israel, Australia, Brazil, Canada, China, Hong Kong, India, Japan and Korea to cover polymorph.

- *BIOST/011*. We have one patent under the PCT to cover Dimers.

- *BIOST/012*. We have one patent under the PCT to cover Crystalline forms.

- *BIOST/013*. We have one patent under the PCT to cover Intermediates.

  BIOST/011. We have one patent under the PCT to cover Impurities.

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 investigational new drug application, or IND, which must become effective before human clinical trials may begin;

● approval by an independent institutional review board, or 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, we 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, pharmacokinetics, pharmacology, and pharmacodynamics 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 Risk Evaluation and Mitigation Strategy, or 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.

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.

In the EU, orphan drug designation provides up to 10 years of market exclusivity in Europe, in addition to the 7-year exclusivity in the U.S. as a result of the FDA's orphan drug designation in 2019. EMA designation will also provide us with other benefits and incentives such as clinical protocol assistance, access to a centralized marketing authorization procedure that is valid in all European Union ("EU") member states and reduced regulatory fees.

The Company has an ODD BST-236 (. As well as EMA ODD for BST-236.

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 the 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 the 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, the 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 the 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 the FDA.

Under the provisions of the FDA Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request the 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 the 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 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, former 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, former 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 has 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 New Ayala's 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.

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 our 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.

New Ayala 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.

The pharmaceutical industry is characterized by rapid evolution of technologies and intense competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize 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 our ability to effectively compete with other therapies include the efficacy, safety, method of administration, cost, level of promotional activity and intellectual property protection of our products. Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products.

With respect to MM, we are 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.

With respect to BST-236, our competitors include companies such as, but not limited to, AbbVie, Aprea, Astellas, BMS, Gilead, Jazz Pharmaceuticals, Novartis and Pfizer.

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 us 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, our programs.

The availability of reimbursement from government and private payors will also significantly impact the pricing and competitiveness of our products. Our competitors may obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approvals for our product candidates, if any, which could result in our competitors establishing a strong market position before we are able to commercialize our product candidates.

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 December 31, 2023, we had 21 employees, 20 of which were full time employees. Of our full-time employees, seven hold a M.D. or Ph.D. degree. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

As part of a cost reduction plan, during the year ended December 31, 2023, we had a reduction in workforce in which the employment of approximately 50% of our employees was terminated. During the first quarter of 2024, we gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company.

Properties

Our principal office is located at Oppenheimer 4, Rehovot 7670104, Israel. Our principal U.S. 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. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. For more information regarding legal proceedings involving the Company, please see Note 7 – Commitments and Contingencies to our consolidated financial statements.

Item 1A. Risk Factors.

Omitted.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

As a regular part of our ordinary business operations, we collect and store data, including information necessary for our operations, information from our customers, employees, and our business partners. We recognize these networks and systems may be subject to increasing and continually evolving cybersecurity risks. Our Audit Committee is responsible for overseeing risk management and cybersecurity is an integral part of the Company's overall risk management program. Our risk management process is designed to identify, prioritize, and monitor risks that could affect our ability to execute our corporate strategy and fulfill our business objectives and to appropriately mitigate such risks.

Our management team is involved in assessing and managing the Company's material risks from cybersecurity threats, including by hiring appropriate personnel, considering cybersecurity risk in our enterprise risk management strategy, helping prepare for cybersecurity incidents, and participating in the cybersecurity incident response and remediation process for incidents escalated to it including determining materiality. Our management that is involved in these processes includes our Chief Financial Officer, our VP of regulatory affairs as well as an external IT company, who collectively share risk management, compliance and technical experience. Management also escalates, as appropriate, reports relating to cybersecurity incidents or threats to our Board or to its Audit Committee.

While we have not yet experienced any material impacts from a cyber-attack, any one or more future cyber-attacks could materially adversely impact the Company, including a loss of trust among our customers, departures of key employees, general diminishment of our reputation and financial losses from remediation actions, loss of business or potential litigation or regulatory liability. Further, evolving market dynamics are increasingly driving heightened cybersecurity protections and mandating cybersecurity standards for our products, and we may incur additional costs to address these increased risks and to comply with such demands.

Item 2. Properties.

Our principal office is located at Oppenheimer 4, Rehovot 7670104, Israel, where we lease office and laboratory space under a lease agreement that terminates in 2025. Our principal U.S. office is located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

See the matters set forth in note 7, "Commitment and Contingent Liabilities – Purported Stockholder Claims" in the Notes to Consolidated Financial Statements included herein.

Item 4. Mine Safety Disclosures.

Not applicable.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS AND DIRECTORS

The following table sets forth information regarding our executive officers and directors as of the filling date of this Annual Report on Form 10-K.

Name	Age	Position
Executive Officers		
Kenneth A. Berlin	59	President and Chief Executive Officer, Director
Roy Golan, CPA, LLM	50	Chief Financial Officer

Executive Officers

Kenneth 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 the Company, 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.

Roy Golan, CPA, LLM, has served as our Chief Financial Officer since October 2023. Mr. Golan is a registered CPA with a broad experience in aspects of Nasdaq, IPOs and M&As. Prior to joining Ayala, Mr. Golan served in several financial management positions in the biotech industry, including as the EVP and CFO of Biosight from 2019 until the merger with Ayala in October 2023. From 2014 to 2018 Mr. Golan served as CFO of Neuroderm, where he had a pivotal role in their successful Nasdaq IPO, two Follow-On Offerings, and Neuroderm's acquisition by Mitsubishi Tanabe Pharmaceutical Corporation for a total of $1.1 billion. Mr. Golan started his career at PriceWaterhouseCoopers (PWC). Mr. Golan is a registered CPA, holds a B.A. in Accounting and Business from the Israeli College of Management School of Business and an LL.M. in Law from Bar Ilan University.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our common stock is quoted on the OTCQX under the symbol "ADXS".

As of December 31, 2023 there were approximately 117 holders of record of our common stock. The actual number of holders of our 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.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future.

Recent Sales of Unregistered Securities

All information required by Item Furnish the information required by Item 201 of Regulation S-K and Item 701 of Regulation S-K as to all equity securities that we sold during the period covered by this Annual Report on Form 10-K that were not registered under the Securities Act has been included in our previously filed Quarterly Reports on Form 10-Q or Current Reports on Form 8-K and is thus not furnished here.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

A discussion of the fiscal year ended December 31, 2022 compared to the fiscal year ended December 31, 2021, which constitute our financial statements for such periods, has been reported previously in Old Ayala's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

See "*Introductory Note*" beginning on page 3 of this Annual Report on Form 10-K for a description of certain transactions that have occurred since the beginning of our fiscal year ended December 31, 2023.

Because the Asset Sale was consummated following the end of our fiscal year ended December 31, 2023, the financial results discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations describe our business as it existed during that period. For a description of this business, please refer to:

- the description of the business of Old Ayala set forth in pages 233-273 of the Definitive Proxy Statement of Old Ayala for the Special Meeting of Stockholders of Old Ayala held on January 13, 2023, which was filed with the Commission on December 12, 2022 and which pages are set forth on Exhibit 99.1 to this Annual Report on Form 10-K, and are, in accordance with Rule 12b-23 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), incorporated by reference herein.

Following the completion of the Asset Sale on March 25, 2024, the Company is a clinical-stage oncology company whose primary clinical assets currently include aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). BST-236 is a novel prodrug of cytarabine, enabling delivery of high cytarabine doses with reduced systemic toxicity, creating a potential new backbone for AML combination regimens. We believe that our novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from solid and hematological cancers. We also continue to conduct certain operations relating to former Advaxis' operations as clinical-stage biotechnology company focused on the development and commercialization of proprietary Listeria monocytogenes ("Lm")-based antigen delivery products. These efforts are primarily focused on the development of ADXS-504, an Lm-based therapy for early-stage prostate cancer.

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 New Ayala, 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 New Ayala, the stockholders of New Ayala and us. As a result of the Share Exchange, New Ayala 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 New Ayala. 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. Shares of New Ayala's common stock are currently quoted on the OTCQX under the symbol "ADXS." Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and conducting research and development activities for our product candidates. To date, we have funded our operations primarily through the sales of common stock convertible notes, warrants and convertible preferred stock.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. Our net losses were $48.1 million and $38.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $197.2 million. We anticipate that our expenses will increase significantly as we:

- Continue to conduct certain operations related to advancing the development of BST-236
- Satisfy certain debts and obligations remaining from our operations prior to the consummation of the Asset Sale

We do not expect to generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. Additionally, we currently use contract research organizations, or CROs, to carry out our clinical development activities. Furthermore, we incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding to support our continuing operations, pursue our growth strategy and continue as a going concern. Until such time as we can generate significant revenue from product sales, if ever, we expect to fund our operations through public or equity offerings or debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current or any future product candidates.

Because of the numerous risks and uncertainties associated with therapeutics product development, we are unable to predict accurately the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

The Company has incurred recurring losses since inception as a research and development organization. For the year ended December 31, 2023, the Company used approximately $29.5 million of cash in operations and incurred a net loss of $48.1 million. As of December 31, 2023, the Company had $4.9 million in cash and cash equivalents, $25.0 million in current liabilities and an accumulated deficit of $197.2 million.

Upon closing of the Asset Sale, on March 25, 2024, the Company received $13.0 million in cash, and Immunome paid $3.0 million of the Company's liabilities directly to vendors of the Company. In addition, under the Asset Sale Agreement the Company received 2,175,489 shares of Immunome's common stock (the "Immunome Shares"). The Asset Sale Agreement prohibits the Company from selling more than 50% of the Immunome Shares in the first six months following the closing of the Asset Sale. In addition, on March 1, 2024, the Company issued additional convertible notes and warrants in exchange for $2.0 million in funding from the Convertible Notes investors. As of the date of this filing, the cash proceeds received from the Asset Sale and the convertible notes sold on March 1, 2024 were not sufficient to pay the Company's existing liabilities. Therefore, the Company has limited available cash resources and requires additional financing, through the sale of a portion of the Immunome Shares or otherwise, in order to continue to fund its current operations beyond May 2024.

Raising additional funds or the satisfactory sale of a portion of the Immunome Shares prior to the end of May 2024 is essential to provide sufficient cash flow to meet future liabilities and other obligations, such as tax payments arising from the Asset Sale. Furthermore, even if the Company is successful in selling a portion of the Immunome Shares or raising additional funds through other means, the Company cannot give any assurance that it will, in the future, be able to achieve a level of profitability from the sale of its products to sustain its operations.

If the Company is unable to obtain funding, or able to receive sufficient funds from the sale of a portion of the Immunome Shares, the Company would be forced to delay, reduce, or eliminate its research and development programs, 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.

As part of a cost reduction plan, during the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. During the first quarter of 2024, the Company gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company. The Company expects to be able to meet its financial obligations to its employees.

The Company can give no assurances that it will be successful in raising funds through the sale of a portion of the Immunome Shares or any other alternative. Any inability to so obtain additional financing or funding will likely cause the Company to cease business operations. 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, 2023, 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.

Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources at December 31, 2023, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern through May 2024. See "—Liquidity and Capital Resources." Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, and because the extent to which we may enter into collaborations with third parties for the development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

License Agreements

Bristol-Myers Squibb

Our financial results for the periods ended December 31, 2023 and 2022, as discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations, largely related to our AL101 and AL102 programs, which we sold to Immunome on March 25, 2024. We had licensed those assets pursuant to an exclusive worldwide license agreement with Bristol-Myers Squibb Company, or BMS, which we describe herein. We transferred this license agreement to Immunome as part of the Asset Sale.

We entered into the license agreement with BMS in November 2017. Under the terms of the license agreement, we licensed the exclusive worldwide development and commercialization rights for AL101 (previously known as BMS-906024) and AL102 (previously known as BMS-986115).

Under the license agreement, we were responsible for all future development and commercialization of AL101 and AL102. In consideration for the rights granted under the agreement, we 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. We were obligated under the license agreement 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, we were obligated under the license agreement 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. Both we and BMS had the right to terminate the BMS License Agreement in its entirety upon written notice to the licensee under certain circumstances described therein.

Components of Results of Operations

Revenue Recognition

We recognize 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.

In December 2018, we entered into an agreement with Novartis Agreement for which we paid for its research and development costs. This agreement was terminated in 2022.

We 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 amount of $13 thousand was recognized in the year ended December 31, 2023, compared to $0.7 million in fiscal year 2022.

We 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. We periodically review and update our 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.

Operating Expenses

Our 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 our research activities, including the development of and pursuit of regulatory approval of our lead product candidates, including AL101 and AL102 (which were disposed of in early 2024), Lm-based products and BST-236, 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 our product candidates, including under agreements with CROs, investigative sites and consultants;
- costs of manufacturing our product candidates for use in our preclinical studies and clinical trials, as well as manufacturers that provide components of our product candidates for use in our preclinical and current and potential future clinical trials;
- costs associated with our 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 our facility, utilities, depreciation and other supplies.

We expense research and development costs as incurred. Our external research and development expenses consist primarily of costs such as fees paid to consultants, contractors and CROs in connection with our preclinical and clinical development activities. We typically use our employee and infrastructure resources across our development programs and we do not allocate personnel costs and other internal costs to specific product candidates or development programs with the exception of the costs to manufacture our product candidates.

The following table summarizes our research and development expenses by product candidate or development program for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	**2022**
Program-specific costs:		
AL101		
ACC	$ 395	$ 3,601
TNBC	509	3,747
General Expenses	322	2,533
AL102		
General Expenses	282	295
Desmoid	20,458	17,675
Other R&D expenses (Mainly Lm -based products and BST-236)	2,115	-
Total research and development expenses	$ 24,081	$ 27,851

Research and development activities are central to our 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. We expect that our research and development expenses will continue to be significant in the future to the extent that we initiate additional clinical trials, scale our manufacturing processes, continue to develop additional product candidates and hire additional clinical and scientific personnel.

The successful development of Lm-based products and BST-236 and any future product candidate is highly uncertain. Accordingly, at this time, we 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. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of preclinical studies, clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of clinical trials with adequate safety, tolerability and efficacy profiles for any potential future product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority;
- approval of INDs for Lm-based products and BST-236 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 our product candidates;
- obtaining, maintaining, protecting and enforcing patent and other intellectual property rights and regulatory exclusivity for our 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 our 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 us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we 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.

We expect to continue to incur expenses associated with being a public company, including the costs of personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Securities and Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs.

Financial Income, Net

Financial income, net primarily consists of an immediate loss and a revaluation of Convertible Note and Warrant Liability offset by interest income earned on our cash and cash equivalents and restricted bank deposits.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our 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 us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe 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 our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Warrant Liabilities

The Company analyzes warrants issued to determine whether they meet the classification as liabilities or equity under US GAAP. Warrant liabilities are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded as finance expenses (income) in the statement of operations. The Company uses a fair valuation specialist to estimate the value of these instruments using numerous iterations using the Black–Scholes option price model.

The key assumptions used in the models are the expected future volatility in the price of the Company's shares and the expected life of the warrants.

Convertible Notes

The Company analyzes convertible notes issued to determine whether they meet the classification as liabilities or equity under US GAAP. Convertible notes are adjusted to reflect fair value at each reporting period, with any increase or decrease in the fair value recorded as finance expenses (income) in the statement of operations. The Company uses a fair valuation specialist to estimate the value of these instruments using numerous iterations using the Monte Carlo Simulation.

The key assumptions used in the models are the expected future outcome as well as volatility in the price of the Company's shares and the expected life of the notes.

Business Combination

We account for business combinations in accordance with ASC 805, "Business Combinations". ASC 805 requires recognition of assets acquired and liabilities assumed at the acquisition date, measured at their fair values as of that date. The Company determines the recognition of intangible assets based on the following criteria: (i) the intangible asset arises from contractual or other rights; or (ii) the intangible asset is separable or divisible from the acquired entity and capable of being sold, transferred, licensed, returned or exchanged. The excess of the fair value of the purchase price over the fair values of the identifiable assets and liabilities is recorded as goodwill. Determining the fair value of the identifiable assets and liabilities requires management to use significant judgment and estimates including the forecasted revenue and revenues growth rates, discount rates, customer contract renewal rates and customer attrition rates.

The process of estimating the fair values requires significant estimates, especially with respect to intangible assets. Critical estimates in valuing certain intangible assets include, but are not limited to, future expected cash flows and discount rates. The Company estimates fair value based upon assumptions that are believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

Impairment of long-lived assets

Long-lived assets, including property and equipment and finite-lived intangible assets, are reviewed for impairment whenever facts or circumstances either internally or externally may indicate that the carrying value of an asset may not be recoverable. If there are indications of an impairment, the Company tests for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset to the carrying amount of the asset or asset group. If the asset or asset group is determined to be impaired, any excess of the carrying value of the asset or asset group over its estimated fair value is recognized as an impairment loss.

Goodwill and intangible assets

Goodwill and acquired intangible assets have been recorded in the Company's financial statements resulting from the a business combinations. Goodwill represents the excess of the purchase price in a business combination over the fair value of identifiable tangible and intangible assets acquired and liabilities assumed. Goodwill is subject to an annual impairment test.

Reporting units are evaluated when changes in the Company's operating structure occur, and if necessary, goodwill would be reassigned using a relative fair value allocation approach. The Company operates in one operating segment, and this segment is the only reporting unit.

ASC 350, Intangibles—*Goodwill and Other* ("ASC 350") requires goodwill to be tested for impairment at least annually and, in certain circumstances, between annual tests. The accounting guidance gives the option to perform a qualitative assessment to determine whether further impairment testing is necessary. The qualitative assessment considers events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount. If it is determined, as a result of the qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative test is performed.

The Company elects to perform an annual impairment test of goodwill as of December 31 of each year, or more frequently if impairment indicators are present. The Company performed its annual goodwill impairment test on December 31, 2023, and the Company concluded that no additional goodwill impairment should be recorded. There were no impairments of goodwill during the year ended December 31, 2023.

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date.

In process technology are amortized on a straight-line basis over the estimated useful life of the assets: approximately four years from the start of revenue which is estimated to start in 2030. Amortization of in process technology is presented within Research and Development in the consolidated statement of operations.

Income Taxes

We calculate income tax provisions based on our results in each jurisdiction in which we operate. The calculation is based on estimated tax consequences and on assumptions as to our entitlement to various benefits under the applicable local tax laws.

Significant judgment is required in evaluating our uncertain tax positions. We establish reserves for uncertain tax positions based on the evaluation of whether or not our uncertain tax position is "more likely than not" to be sustained upon examination based on our technical merits. We record estimated interest pertaining to our uncertain tax positions in the financial statements as income tax expense.

Deferred tax assets are recognized for unused tax losses, unused tax credits, and deductible temporary differences to the extent that it is probable that future taxable profits will be available, against which they can be used. Deferred taxes for each jurisdiction are presented as a net asset or liability, net of any valuation allowances. We estimate the need for any valuation allowance by applying significant judgment and considering all available evidence including past results and future projections. We reassess our estimates periodically and record a partial or full valuation allowance release if needed.

We cannot assure that future final tax outcomes will not be different than our tax provisions and reserves for uncertain tax positions. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the provision for income taxes in the period in which such determination is made.

Stock-Based Compensation

We measure 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 recognize compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. We apply 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.

We estimate 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 our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Previously, as a private company with no active public market for our common stock, our board of directors historically determined the fair value of our common stock on each date of grant, with input from management. Our board of directors periodically determined the estimated per share fair value of our common stock at various dates using valuations performed by third parties. All options to purchase shares of our common stock were intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. Our determinations of the fair value of our 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.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- the lack of an active public market for our common stock;
- our results of operations and financial condition, including cash on hand;
- the material risks related to our business;
- our stage of development and business strategy;
- the composition of, and changes to, our 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 given prevailing market conditions.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates are management's best estimates and include assumptions regarding our 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 we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been different.

Results of Operations

Comparison of the year ended December 31, 2023 and 2022

The following table summarizes our results of operations for the year ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,		
	2023	**2022**	**Change**
Revenue from license agreement	$ 13	$ 692	(679)
Cost of revenue	(13)	(602)	589
Gross profit	-	90	(90)
Operating expenses:			
Research and development	24,081	27,851	(3,770)
General and administrative	12,185	9,742	2,443
Operating loss	(36,266)	(37,503)	(1,327)
Financial income (expense), net	(15,718)	74	(15,792)
Loss before income tax	(51,984)	(37,429)	(14,555)
Taxes on income	3,912	(584)	4,496
Net loss	$ (48,072)	$ (38,013)	(10,059)

Revenue

Revenue associated with the research and development services mainly under the Novartis Agreement in the amount of $13 thousand was recognized in the year ended December 31, 2023, compared to $0.7 million recognized in fiscal year 2022.

Research and Development Expenses

Research and development expenses were $24.1 million for the year ended December 31, 2023 compared to $27.9 million for the year ended December 31, 2022, a decrease of $3.8 million. The decrease was due to the termination of the TENACITY trial and winding down of the ACCURACY trial offset by expenses incurred by the programs of former Advaxis and Biosight.

General and Administrative Expenses

General and administrative expenses were $12.2 million for the year ended December 31, 2023 compared to $9.7 million for the year ended December 31, 2022, an increase of $2.4 million. The increase was mainly due to severance agreement obligations recognized in the period to former executives of $0.9 million in salary compensation and $0.9 million in stock-based compensation due to acceleration of options as part of severance agreement.

Financial Income (expense), net

Financial expense, net was $15.7 million for the year ended December 31, 2023 compared to financial income, net of $74 thousand for the year ended December 31, 2022. The increase in financial expenses was mainly due to revaluation of convertible notes side letter agreements and warrants issued.

Liquidity and Capital Resources

Sources of Liquidity

The Company has incurred recurring losses since inception as a research and development organization. For the year ended December 31, 2023, the Company used approximately $29.5 million of cash in operations and incurred a net loss of $48.1 million. As of December 31, 2023, the Company had $4.9 million in cash and cash equivalents, $25.0 million in current liabilities and an accumulated deficit of $197.2 million.

Upon closing of the Asset Sale, on March 25, 2024, the Company received $13.0 million in cash, and Immunome paid $3.0 million of the Company's liabilities directly to vendors of the Company. In addition, under the Asset Sale Agreement the Company received 2,175,489 shares of Immunome's common stock (the "Immunome Shares"). The Asset Sale Agreement prohibits the Company from selling more than 50% of the Immunome Shares in the first six months following the closing of the Asset Sale. In addition, on March 1, 2024, the Company issued additional convertible notes and warrants in exchange for $2.0 million in funding from the Convertible Notes investors. As of the date of this filing, the cash proceeds received from the Asset Sale and the convertible notes sold on March 1, 2024 were not sufficient to pay the Company's existing liabilities. Therefore, the Company has limited available cash resources and requires additional financing, through the sale of a portion of the Immunome Shares or otherwise, in order to continue to fund its current operations beyond May 2024.

Raising additional funds or the satisfactory sale of a portion of the Immunome Shares prior to the end of May 2024 is essential to provide sufficient cash flow to meet future liabilities and other obligations, such as tax payments arising from the Asset Sale. Furthermore, even if the Company is successful in selling a portion of the Immunome Shares or raising additional funds through other means, the Company cannot give any assurance that it will, in the future, be able to achieve a level of profitability from the sale of its products to sustain its operations.

If the Company is unable to obtain funding, or able to receive sufficient funds from the sale of a portion of the Immunome Shares, the Company would be forced to delay, reduce, or eliminate its research and development programs, 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.

As part of a cost reduction plan, during the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. During the first quarter of 2024, the Company gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company. The Company expects to be able to meet its financial obligations to its employees.

The Company can give no assurances that it will be successful in raising funds through the sale of a portion of the Immunome Shares or any other alternative. Any inability to so obtain additional financing or funding will likely cause the Company to cease business operations. 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, 2023, 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.

On February 19, 2021, Old Ayala entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, Old Ayala agreed to sell (i) an aggregate of 62,467 shares of Old Ayala's common stock (the "Private Placement Shares"), par value $0.01 per share, together with warrants to purchase an aggregate of 21,863 shares of Old Ayala's common stock with an exercise price of $96.58 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 249,867 shares of our common stock with an exercise price of $0.05 per share (the "Pre-Funded Warrants" and collectively with the Common Warrants, the "Private Placement Warrants"), together with an aggregate of 87,453 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 exercise price and the number of shares of 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 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, Old Ayala registered the Private Placement Shares and Private Placement Warrants for resale by the Investors on a registration statement on Form S-3 (the "Private Placement Registration Statement").

In June 2021, Old Ayala entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which Old Ayala was able to, 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 a registration statement on Form S-3 filed with the SEC. Sales of common stock, if any, pursuant to the Sales Agreement, could 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. During the year ended December 31, 2022, Old Ayala sold a total of 310,417 shares of its common stock for total gross proceeds of approximately $526 thousand. The Sales Agreement was terminated in January 2023.

On October 18, 2022, the Company, which at the time was named Advaxis, Inc., entered into a Merger Agreement (the "Merger Agreement"), with an entity then known as Ayala Pharmaceuticals, Inc. (which shortly prior to the closing of the merger in January 2023 changed its name to Old Ayala, Inc., ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Company (the "January 2023 Merger"). Immediately after the January 2023 Merger, former Advaxis stockholders as of immediately prior to the Merger own approximately 37.5% of the outstanding shares of the combined Company and former Old Ayala shareholders own approximately 62.5% of the outstanding shares of the combined Company.

At the effective time of the January 2023 Merger (the "Effective Time"), each share of share capital of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of the Company's common stock, par value $0.001 per

share, equal to the exchange ratio, 0.1874 shares of the Company's common stock per Old Ayala share.

On August 7, 2023, the Company entered into an agreement for the issuance of Senior Secured Convertible Promissory Notes (the "Secured Notes") to Israel Biotech Fund I, L.P. The Secured Notes provided for the borrowing by the Company of up to $2.0 million dollars, which borrowings which the Company received on September 1, 2023.

On November 17, 2023, the Company issued Senior Convertible Promissory Notes (collectively, the "Senior Convertible Notes"), in an aggregate amount of $4.0 million, to several existing lenders and investors in the Company, including Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. and Biotel Limited. The amounts borrowed by the Company under the Senior Convertible Notes were funded to the Company on November 20, 2023. The Senior Convertible Notes were convertible into shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at any time at the option of the noteholders, and were subject to mandatory conversion upon certain events, including a change of control transaction and certain financing transactions involving the Company, at a conversion price equal to the lower of (i) 50% of the Common Stock's price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock's price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Conversion, subject to certain adjustments. In connection with the issuance of the Senior Convertible Notes, the Company issued to the noteholders warrants to purchase an aggregate of 15,000,000 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock's price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock's price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis.

The noteholders also had the right, pursuant to a Side Letter Agreement between the noteholders and the Company, to lend an additional $4.0 million dollars to the Company on the same terms.

The Company and Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P. also agreed to amend and restate the terms of Secured Notes to conform to the terms of the Senior Convertible Notes, and issued to the holders of the Secured Notes warrants to purchase an aggregate of 7,500,000 shares of the Common Stock on the terms of the above-described warrants.

In February 2024, the Secured Notes and the Senior Convertible Notes, and the warrants issued in connection with all of them, were converted into shares of the Company's common stock under the terms described in such notes and warrants.

Cash Flows

The following table provides information regarding our total cash and cash equivalents and restricted bank cash at December 31, 2023 and 2022 (in thousands):

	As of December 31,	
	2023	**2022**
Cash and cash equivalents and restricted cash	$ 5,212	$ 2,724

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (29,485)	$ (34,510)
Net cash provided by (used in) investing activities	5,946	(2)
Net cash provided by financing activities	26,001	103
Effect of exchange rate changes on cash, cash equivalents and restricted cash	26	-
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 2,488	$ (34,615)

Net Cash Used in Operating Activities

The cash used in operating activities resulted primarily from expenses associated with our clinical development programs and early-stage research and general and administrative expenses.

Net cash used in operating activities during the year ended December 31, 2023 of $29.5 million was primarily attributable to our net loss of $48.1 million, adjusted for non-cash expenses of $17.5 million, which includes revaluation of warrants and convertible notes of $15.7 and stock-based compensation of $1.2 million, and a net increase in working capital of $1.1 million.

Net cash used in operating activities during the year ended December 31, 2022 of $34.5 million was primarily attributable to our net loss of $38.0 million, adjusted for non-cash expenses of $2.7 million, which includes stock-based compensation of $2.2 million and a net increase in working capital of $0.8 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities of $5.9 million during the year ended December 31, 2023 was mainly attributable to $4.0 million in proceeds from the sale of our AL 101 and AL 102 assets and $1.9 million of proceeds received in connection with the merger with Biosight.

Net cash used in investing activities during the year ended December 31, 2022, of $2 thousand was attributable to purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the year ended December 31, 2023 of $26.0 million was primarily attributable to the January 2023 Merger and the Convertible Loans.

Net cash provided by financing activities during the year ended December 31, 2022, of $0.1 million was primarily attributable to our issuance of shares at market, net of issuance costs.

Funding Requirements and Going Concern

Our future capital requirements are difficult to forecast and will depend on many factors, including our ability to raise additional funding. To the extent that we continue the research and development for, initiate later-stage clinical trials for, and seek marketing approval for, our product candidates, we expect our expenses would increase. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

The Company has incurred recurring losses since inception as a research and development organization. For the year ended December 31, 2023, the Company used approximately $29.5 million of cash in operations and incurred a net loss of $48.1 million. As of December 31, 2023, the Company had $4.9 million in cash and cash equivalents, $25.0 million in current liabilities and an accumulated deficit of $197.2 million.

Upon closing of the Asset Sale, on March 25, 2024, the Company received $13.0 million in cash, and Immunome paid $3.0 million of the Company's liabilities directly to vendors of the Company. In addition, under the Asset Sale Agreement the Company received 2,175,489 shares of Immunome's common stock (the "Immunome Shares"). The Asset Sale Agreement prohibits the Company from selling more than 50% of the Immunome Shares in the first six months following the closing of the Asset Sale. In addition, on March 1, 2024, the Company issued additional convertible notes and warrants in exchange for $2.0 million in funding from the Convertible Notes investors. As of the date of this filing, the cash proceeds received from the Asset Sale and the convertible notes sold on March 1, 2024 were not sufficient to pay the Company's existing liabilities. The Company does not believe it has sufficient capital to fund its current obligations, as they become due, as the Company has limited available cash resources and requires additional funds in order to continue to fund its current operations , and to pay existing and future liabilities and other obligations. Our future capital requirements will depend on many factors, including:

- the ability to successfully sale a portion of the Immunome Shares received in the Asset Sale;.
- The cost of conducting and completing clinical trials of BST-236;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop or acquire, if any;
- the costs, timing and outcome of regulatory review of our 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 our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting and enforcing our intellectual property rights and defending intellectual property-related claims;
- 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 we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted.. Any debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Omitted.

Item 8. Financial Statements and Supplementary Data.

AYALA PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

Kost Forer Gabbay & Kasierer

144 Menachem Begin Road, Building A

Tel-Aviv 6492102, Israel

Tel: +972-3-6232525

Fax: +972-3-5622555

ey.com

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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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.

KOST FORER GABBAY & KASIERER

A Member of EY Global

We have served as the Company's auditor since 2017.

Tel-Aviv, Israel

April 16, 2024

AYALA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and Cash Equivalents	$ 4,882	$ 2,408
Trade Receivables	-	234
Prepaid Expenses and Other Current Assets	2,646	546
Total Current Assets	7,528	3,188
Long-Term Assets:		
Deferred issuance costs	-	1,953
Intangible assets, net	3,898	-
Goodwill	4,500	-
Operating lease right of use asset	102	1,462
Property and Equipment, Net	540	960
Other Assets	11	206
Total Long-Term Assets	9,051	4,581
Total Assets	**$ 16,579**	**$ 7,769**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Trade Payables	$ 6,076	$ 4,080
Operating lease liabilities	166	419
Accrued expenses and other payables	5,554	708
Side Agreement and reinvestment rights**	8,436	
Accrued payroll and employee benefits	786	994
Proceed from Asset Sale	4,000	-
Total Current Liabilities	25,018	6,201
Long-Term Liabilities:		
Long-term warrant liability**	6,057	-
Convertible Note**	8,141	-
Uncertain tax position	1,771	1,335
Long-term operating lease liabilities	9	1,332
Total Long-Term Liabilities	$ 15,978	$ 2,667
Stockholders' Equity:		
Common Stock of $0.001 par value per share; 170,000,000 and 37,480,000* shares authorized at December 31, 2023 and 2022, respectively; 11,896,845 and 2,695,067* shares issued at December 31, 2023 and 2022, respectively; 11,857,393 and 2,638,663* shares outstanding at December 31, 2023 and 2022, Respectively.	$ 12	$ 3
Additional Paid-in Capital	172,797	148,052
Accumulated Deficit	(197,226)	(149,154)
Total Stockholders' Equity	(24,417)	(1,099)
Total Liabilities and Stockholders' Equity	**$ 16,579**	**$ 7,769**

The accompanying notes are an integral part of the consolidated financial statements.

* All of the Common Stock, additional paid-in capital and per share data have been retroactively adjusted for the impact of the January 2023 merger between Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and Ayala Pharmaceutical, Inc.(f/k/a Advaxis, Inc.). See note 1.

** Received from related party see note 14.

AYALA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars in thousands (except shares and per shares data)

	Year ended December 31, 2023	Year ended December 31, 2022
Revenue	$ 13	$ 692
Cost of Revenue	(13)	(602)
Gross Profit	-	90
Research and Development	$ 24,081	$ 27,851
General and Administrative	12,185	9,742
Operating Loss	(36,266)	(37,503)
Financial income (expenses), net	(15,718)	74
Loss before taxes on income	(51,984)	(37,429)
Taxes on Income	3,912	(584)
Net Loss	$ (48,072)	$ (38,013)
Net Loss per Share attributable to Common Stockholders, Basic and Diluted	$ (7.99)	$ (13.13)
Weighted Average Shares Used to Compute Net Loss per Share, Basic and Diluted	6,019,063	2,895,130

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)

	Common Stock**		Additional paid-in	Accumulated	Total Stockholders' (Deficit)
	Number	Amount	Capital**	Deficit	Equity
Balance as of December 31, 2021	2,615,360	$ 3	$ 145,296	$ (111,141)	$ 34,158
Proceeds from Issuance of common stock, net of issuance cost of $14	58,172	*	512	—	512
Stock Based Compensation	21,535	*	2,244	—	2,244
Net Loss	—	—	—	(38,013)	(38,013)
Balance as of December 31, 2022	2,695,067	$ 3	$ 148,052	$ (149,154)	$ (1,099)
exercise of warrants	246,192	*	-	-	-
Issuance of shares upon January 2023 Merger, net of issuance costs of $3,153	1,815,951	2	16,947	-	16,949
Issuance of shares upon Bio sight Merger	5,913,480	6	5,508	-	5,514
Conversion of SAFE	1,145,053	1	1,067	-	1,068
Share based compensation	41,650	-	1,223	-	1,223
Net Loss	-	-	-	(48,072)	(48,072)
Balance as of December 31, 2023	11,857,393	12	172,797	(197,226)	(24,417)

* Represents an amount lower than $1.

** All of the Common Stock and per share data have been retroactively adjusted and Additional paid in Capital to adjust for common stock amount, for the impact of the January 2023 merger between Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and Ayala Pharmaceutical, Inc.(f/k/a Advaxis, Inc.). See note 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, 2023	Year Ended December 31, 2022
Cash Flows from Operating Activities:		
Net Loss	$ (48,072)	$ (38,013)
Adjustments to reconcile Net Loss to Net Cash used in Operating Activities:		
Shared Based Compensation	1,223	2,244
Depreciation and Amortization	369	162
Asset write-downs	145	-
Remeasurement of long-term warrant liability	5,854	-
Remeasurement of Side Letter Agreements	7,751	-
Remeasurement of convertible note	2,141	-
(Increase) Decrease in Prepaid Expenses and other Assets	(1,491)	2,232
Decrease (Increase) in Trade Receivables	234	(234)
Decrease in Trade Payables	(724)	(472)
Decrease in operating lease right-of-use assets	1,429	288
Decrease in operating lease liabilities	(1,641)	(536)
Increase (decrease) in accrued expenses and other payables	3,123	121
Increase (decrease) in accrued payroll and employee benefits	(248)	(767)
Changes in uncertain tax position	448	465
Other	(26)	-
Net Cash used in Operating Activities	(29,485)	(34,510)
Cash Flows from Investing Activities:		
Proceed from Asset Sale	4,000	-
Cash acquired from the Biosight Merger	1,909	-
Other	37	(2)
Net Cash used in Investing Activities	5,946	(2)
Cash Flows from Financing Activities:		
Proceeds from issuance of convertible note from related party	6,000	-
Proceeds from issuance of shares, net of issuance cost of $14	-	512
Issuance of shares upon January 2023 Merger, net of issuance costs	20,001	(615)
Net Cash used in Financing Activities	26,001	(103)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	26	
Increase (decrease)in Cash and Cash Equivalents and Restricted Cash	2,488	(34,615)
Cash and Cash Equivalents and Restricted Cash at Beginning of the Year	2,724	37,339
Cash and Cash Equivalents and Restricted Cash at End of the Year	$ 5,212	$ 2,724
Supplemental Disclosure of investing and financing Activities		
Lease liabilities arising from new right-of-use assets	$ -	$ 537
Deferred issuance costs accrued but not yet paid	$ -	$ 1,338
Supplemental Disclosures of Cash Flow Information		
Cash Paid for Income Taxes	$ 371	$ 244

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash and Cash Equivalents	$ 4,882	$ 2,408
Restricted Cash in Prepaid Expenses and Other Current Assets	330	110
Restricted Cash in Other Assets	-	206
Cash and Cash Equivalents and Restricted Cash at End of the Year	$ 5,212	$ 2,724

The accompanying notes are an integral part of the consolidated financial statements.

1. General

In these financial statements, unless otherwise stated or the context otherwise indicates, references to "New Ayala" and the "Company," refers to Ayala Pharmaceuticals, Inc., a Delaware corporation, which prior to the change of its name effected on January 19, 2023, was known as Advaxis, Inc. The name change was affected in connection with the January 2023 Merger, as described below. References to "former Advaxis" refer to the Company solely in the period prior to the January 2023 Merger.

Prior to the January 2023 Merger, the Company was a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. These efforts utilized the Company *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, the Company has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™.

Following the January 2023 Merger, the Company became primarily 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. The Company differentiated development approach is predicated on identifying and addressing tumorigenic drivers of cancer, through a combination of the Company's bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. The Company's portfolio of product candidates following the January 2023 Merger, AL101 and AL102, targets the aberrant activation of the Notch pathway using gamma secretase inhibitors. All of the Company's assets relating to AL 101 and AL 102 were sold on March 25, 2024 in the Asset Sale (as defined below). Following the January 2023 Merger, the Company also continued to conduct certain operations relating to former Advaxis' operations as a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. These efforts are primarily focused on the development of ADXS-504, a *Lm*-based therapy for early-stage prostate cancer. See note 3.

On July 26, 2023, the Company and its wholly owned subsidiary organized under the laws of the State of Israel, Advaxis Israel Ltd. ("Biosight Merger Sub"), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Biosight Ltd. ("Biosight"), a privately-held Israeli pharmaceutical company developing innovative therapeutics for hematological malignancies and disorders. Under the terms of the Merger Agreement, on October 18, 2023, Merger Sub merged with and into Biosight, which is now a wholly owned subsidiary of the Company (the "Biosight Merger"). See note 3.

Based on the agreement, Ayala Pharmaceuticals, Inc. was the legal acquirer in the Biosight Merger. In addition, the Company considered ASC 805-10-55 to determine the accounting acquirer in the Biosight Merger. As the Company holds a majority of the members of the governing body of the combined Company and the Company's former management dominates the majority of the senior management of the combined Company, and after considering all other factors according to ASC 805-10-55, the Company was identified as the accounting acquirer in the Biosight Merger. The Company has accounted for the Biosight Merger as a business combination according to ASC 805 "Business Combinations".

On February 5, 2024, the Company and Immunome, Inc. ("Immunome"), entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") pursuant to which Immunome agreed to acquire certain of the Company's assets and liabilities related to its AL101 and AL102 programs (the "Asset Sale"), which constitute substantially all of the Company's assets.

On March 25, 2024, the Company and Immunome consummated the Asset Sale pursuant to the Asset Purchase Agreement. Immunome paid to the Company an aggregate purchase price of $20.0 in cash (of which $4.0 had been paid upon entering into the Asset Purchase Agreement), subject to certain adjustments, and issued to the Company 2,175,489 shares (the "Shares") of Immunome's common stock, $0.0001 par value. The Asset Purchase Agreement further provides that Immunome may pay the Company up to $37.5 million in cash due upon the Immunome's achievement of certain development and commercial milestone events set forth in the Asset Purchase Agreement. At the March 25, 2023 closing of the Asset Sale, Immunome paid the remaining $16.0 million of cash consideration to the Company and, at the Company's direction, to certain vendors of the Company.

The Asset Purchase Agreement contains customary representations, warranties, conditions and covenants, including covenants (i) concerning the conduct of business by the Company prior to the closing of the Asset Sale, (ii) prohibiting the Company and its representatives from soliciting, initiating or knowingly inducing, encouraging or facilitating any competing acquisition proposal, (iii) prohibiting the Company and its controlled affiliates from competing with Immunome for five years following the closing of the Asset Sale in certain fields, and (iv) restricting the Company's ability to make distributions to stockholders, dissolve or wind up its business or file for bankruptcy for six months following the closing of the Asset Sale.

In the Asset Sale, the Company disposed of the assets relating to AL102, an oral gamma secretase inhibitor in Phase 3 clinical development, and AL 101, and as such, the Company's clinical assets currently include aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML).

During the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. This reduction in workforce has not yet required the Company to cease any major development efforts. Following the reduction in workforce, the Company had 21 employees. See note 17 for information regarding the additional reduction of 18 employees and one officer during the first quarter of 2024, with the employment of a second officer to terminate on June 25, 2024.

Going Concern

The Company has incurred recurring losses since inception as a research and development organization. For the year ended December 31, 2023, the Company used approximately $29.5 million of cash in operations and incurred a net loss of $48.1 million. As of December 31, 2023, the Company had $4.9 million in cash and cash equivalents, $25.0 million in current liabilities and an accumulated deficit of $197.2 million.

Upon closing of the Asset Sale, on March 25, 2024, the Company received $13.0 million in cash, and Immunome paid $3.0 million of the Company's liabilities directly to vendors of the Company. In addition, under the Asset Sale Agreement the Company received 2,175,489 shares of Immunome's common stock (the "Immunome Shares"). The Asset Sale Agreement prohibits the Company from selling more than 50% of the Immunome Shares in the first six months following the closing of the Asset Sale. In addition, on March 1, 2024, the Company issued additional convertible notes and warrants in exchange for $2.0 million in funding from the Convertible Notes investors. As of the date of this filing, the cash proceeds received from the Asset Sale and the convertible notes sold on March 1, 2024 were not sufficient to pay the Company's existing liabilities. Therefore, the Company has limited available cash resources and requires additional financing, through the sale of a portion of the Immunome Shares or otherwise, in order to continue to fund its current operations beyond May 2024.

Raising additional funds or the satisfactory sale of a portion of the Immunome Shares prior to the end of May 2024 is essential to provide sufficient cash flow to meet future liabilities and other obligations, such as tax payments arising from the Asset Sale. Furthermore, even if the Company is successful in selling a portion of the Immunome Shares or raising additional funds through other means, the Company cannot give any assurance that it will, in the future, be able to achieve a level of profitability from the sale of its products to sustain its operations.

If the Company is unable to obtain funding, or able to receive sufficient funds from the sale of a portion of the Immunome Shares, the Company would be forced to delay, reduce, or eliminate its research and development programs, 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.

As part of a cost reduction plan, during the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. During the first quarter of 2024, the Company gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company. The Company expects to be able to meet its financial obligations to its employees.

The Company can give no assurances that it will be successful in raising funds through the sale of a portion of the Immunome Shares or any other alternative. Any inability to so obtain additional financing or funding will likely cause the Company to cease business operations. 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, 2023, 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

Basis of Presentation

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 Cash and Cash Equivalents

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 carrying value which approximate their fair values. Restricted Cash and Cash Equivalents 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	7-9%

Leasehold improvements are amortized on a straight-line basis over the shorter of the assets' estimated useful life (10%) or the remaining term of the lease (10-50%).

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 (assets group) may not be recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets (assets group) are expected to generate are less than the carrying value of the assets (assets group), the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values. During the years ended December 31, 2023, and 2022, no impairment loss have been recorded.

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 $0.2 million and $0.3 million for the years ended December 31, 2023 and 2022, 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, 2023, and 2022, the Company has matched 100% of all employee contributions, up to 6% of the employee's base salary.

Leases

The Company's leases include offices for its facilities, as well as car leases, which are all classified as operating leases. Short-term leases with a term of 12 months or less are not recorded on the balance sheet. The Company does not separate lease components from non-lease components.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Operating lease liabilities and their corresponding right-of-use assets are recorded at commencement date. The Company records lease liabilities based on the present value of lease payments over the lease term. The ROU asset also includes any lease payments made and excludes lease incentives. The Company generally uses an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that The Company will exercise its option.

Certain lease agreements contain variable payments, which are expensed as incurred and not included in the operating lease right-of-use ("ROU") assets and liabilities.

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 Cash and Cash Equivalent, 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.

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. For reoccurring services fees, the Company records the services over the time period which services will are based on inputs received from CRO. If the actual timing of the performance of services varies from the calculation, the Company adjusts the accrual or amount of prepaid expenses accordingly to adjust for such changes in time.

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. See Note 7.

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. Although the Company believes that it has adequately reserved for its uncertain tax positions (including net interest and penalties), it can provide no assurance that the final tax outcome of these matters will not be materially different. The Company makes adjustments to these reserves when facts and circumstances change, such as the closing of a tax audit or the refinement of an estimate. To the extent that the final tax outcome of these matters is different from the amounts recorded, such differences will affect the income tax expense in the period in which such determination is made.

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.

The Company did not have any customers as of December 31, 2023. The Company's trade receivables as of December 31, 2022 were from one customer. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored on an ongoing basis.

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. 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, and 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 valued at the fair value of shares on the 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.

Business combinations

The Company accounts for business combinations by applying the provisions of ASC 805, Business Combination ("ASC 805") and allocates the fair value of the purchase consideration to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. The excess of the fair value of purchase consideration over the fair value of these identifiable assets and liabilities is recorded as goodwill. When determining the fair value of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets.

Acquisition-related expenses are expensed as incurred.

Goodwill and acquired intangible assets

Goodwill and acquired intangible assets recorded in the Company's financial statements result from both business combinations. Goodwill represents the excess of the purchase price in a business combination over the fair value of identifiable tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized as it is estimated to have an indefinite life. As such, goodwill is subject to an annual impairment test.

The Company allocates goodwill to reporting units based on the expected benefit from the business combination. Reporting units are evaluated when changes in the Company's operating structure occur, and if necessary, goodwill is reassigned using a relative fair value allocation approach. The Company operates in one operating segment, and this segment is the only reporting unit.

ASC 350, *Intangibles—Goodwill and Other* ("ASC 350") requires goodwill to be tested for impairment at least annually or more frequently if events or changes in circumstances indicate that goodwill may be impaired. The Company elects to perform an annual impairment test of goodwill as of December 31 of each year. The accounting guidance gives the option to perform a qualitative assessment to determine whether further impairment testing is necessary. The qualitative assessment considers events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount. If it is determined, as a result of the qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative test is performed.

During the last quarter of 2023, the Company experienced a significant decline in the stock price, which might suggest the fair value of the reporting unit is less than its carrying amount. However, when the Company performed its annual goodwill impairment test on December 31, 2023, it was noted that the reporting unit have a negative carrying amount. The Company concluded that no goodwill impairment should be recorded since after performing a quantitative test, the reporting unit's fair value is not less than its carrying amount.

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date. Acquired identifiable finite-lived intangible assets are amortized on a straight-line basis over the estimated useful life of the respective asset. Each period the Company evaluates the estimated remaining useful lives of its intangible assets and whether events or changes in circumstances warrant a revision to the remaining period of amortization. Acquired indefinite-lived intangible assets are not amortized but are tested for impairment at least annually or more frequently if events or changes in circumstances indicate that the intangible asset may be impaired.

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.

The geographical regions of the Company's intangible assets are as follows:

	Year ended	
	December 31, 2023	**December 31,** 2022
Israel	3,800	-
United States	98	-
Total	**3,898**	-

The geographical regions of the Company's long lived asset including rights of use are as follows:

	Year ended December 31, 2023	**Year ended December 31,** 2022
Israel	600	2,392
United States	42	30
Total	**642**	**2,422**

All of the Company's revenues are generated in the United States.

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 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.

Recently Adopted Accounting Pronouncements

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 new guidance was effective for the Company on January 1, 2023 and the adoption did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

3. Mergers

Merger with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Company, which at the time was named Advaxis, Inc., entered into a Merger Agreement (the "Merger Agreement"), with an entity then known as Ayala Pharmaceuticals, Inc. (which shortly prior to the closing of the merger in January 2023 changed its name to Old Ayala, Inc., ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Company (the "January 2023 Merger"). Immediately after the January 2023 Merger, former Advaxis stockholders as of immediately prior to the Merger own approximately 37.5% of the outstanding shares of the combined Company and former Old Ayala shareholders own approximately 62.5% of the outstanding shares of the combined Company.

At the effective time of the January 2023 Merger (the "Effective Time"), each share of share capital of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of the Company's common stock, par value $0.001 per share, equal to the exchange ratio, 0.1874 shares of the Company's common stock per Old Ayala share.

The January 2023 Merger has been accounted for as a reverse merger with Old Ayala as the accounting acquirer and former Advaxis as the accounting acquiree. In identifying Old Ayala as the accounting acquirer, the companies considered ASC 805-10-55 including the structure of the January 2023 Merger, relative outstanding share ownership at closing and the composition of the combined Company's board of directors and senior management. The financial reporting reflects the accounting from the perspective of Old Ayala ("accounting acquirer"), except for the legal capital, which has been retroactively adjusted to reflect the capital of former Advaxis ("accounting acquiree") in accordance with ASC 805-40-45. As such, the historical financial information presented is that of Old Ayala as the accounting acquirer in the January 2023 Merger.

Because most of the value of the assets of former Advaxis was in cash and cash equivalents, the January 2023 Merger is treated primarily as a financing transaction for accounting purposes with a small component as a business acquisition. Therefore, no gain or loss is recorded as a result of the January 2023 Merger. Old Ayala's transaction costs were capitalized and offset against the shareholder's equity upon the January 2023 Merger, and former Advaxis' transaction costs were expensed as merger costs. The consolidated financial statements from the closing date of the January 2023 Merger include the assets, liabilities, and results of operations of the combined company.

Fair Value Allocation

The following sets forth the fair value of acquired identifiable assets and assumed liabilities of former Advaxis which includes adjustments to reflect the fair value of intangible assets acquired (in thousands) as of January 19, 2023:

	Amounts
Cash and cash equivalents	$ 22,539
Prepaid expenses and other current assets	300
Property and equipment, net	34
Intangible assets	130
Operating right-of-use asset	5
Other assets	11
Total assets	23,019
Common stock warrant liability	(203)
Other current liabilities and trade payables	(2,714)
Total liabilities	(2,917)
Net assets acquired	$ 20,102

The fair value estimate for all identifiable assets and liabilities assumed 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 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 Company recognized intangible assets related to the January 2023 Merger, which consist of the Patents and License agreements valued at $130 thousand with an estimated useful life of four years. Acquired identifiable finite-lived intangible assets are amortized on a straight-line basis over the estimated useful lives of the assets. The basis of amortization approximates the pattern in which the assets are utilized, over their estimated useful lives. The Company routinely reviews the remaining estimated useful lives of finite-lived intangible assets. In case the Company reduces the estimated useful life for any asset, the remaining unamortized balance is amortized or depreciated over the revised estimated useful life.

The results of operations of Advaxis have been included in the consolidated financial statements since the acquisition date of January 19, 2023.There is no practical way to determine net income attributable to the former Advaxis due to integration.

Merger with Biosight Ltd.

On July 26, 2023, the Company and its wholly owned subsidiary organized under the laws of the State of Israel, Advaxis Israel Ltd. (“Biosight Merger Sub”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Biosight Ltd. (“Biosight”), a privately-held Israeli pharmaceutical company developing innovative therapeutics for hematological malignancies and disorders. Under the terms of the Merger Agreement, on October 18, 2023, Merger Sub merged with and into Biosight, which is now a wholly owned subsidiary of the Company (the “Biosight Merger”). At completion of the Biosight Merger, Ayala’s then-current equity holders own approximately 45% and the former Biosight equity holders own approximately 55% of Ayala’s common stock.

Based on the agreement, the Company was the legal acquirer in the Biosight Merger. In addition, the Company considered ASC 805-10-55 to determine the accounting acquirer in the Biosight Merger. As the Company holds a majority of the members of the governing body of the combined Company and the Company’s former management dominates the majority of the senior management of the combined Company, and after considering all other factors according to ASC 805-10-55, the Company was identified as the accounting acquirer in the Biosight Merger. The Company has accounted for the Biosight Merger as a business combination according to ASC 805 “Business Combinations”.

Fair Value Allocation

The following sets forth the fair value of acquired identifiable assets and assumed liabilities of Biosight which includes to reflect the fair value of intangible assets acquired (in thousands) as of October 18, 2023:

	Amounts
Cash and cash equivalents	$ 1,909
Fixed Assets, net	64
Prepaid expenses and other current assets	89
Intangible assets	3,800
Goodwill	4,500
Total assets	10,363
Side Letter Agreement Liability	(685)
SAFE liability	(1,068)
Other current liabilities and trade payables	(3,096)
Total liabilities	(4,849)
Net assets acquired	$ 5,514

The fair value estimate for all identifiable assets and liabilities assumed 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. Such estimates are subject to change during the measurement period, which is not expected to exceed one year. Any adjustments identified during the measurement period will be recognized in the period in which the adjustments are determined.

The Company recognized intangible assets related to the Biosight Merger, consisting of certain patents and license agreements ("In Process Technology") valued at $3.8 million. Such assets were fair valued using the discounted cash flow method. Acquired indefinite-lived intangible assets will remain indefinite-lived assets until the completion or abandonment of these assets. The Company also recognized goodwill assets related to the Biosight Merger, valued at $4.5 million with an estimated indefinite useful life. The Company did not recognize any changes as of December 31, 2023, in the value of the Biosight that suggested impairment to both intangible asset and goodwill. The goodwill is not deductible for tax purposes

Acquisition-related transaction costs are not included as components of consideration transferred but are accounted for as expenses in the period in which the costs are incurred. The Company incurred transaction costs of $1.0 million during the year ended December 31, 2023 which were included in general and administrative expenses in the consolidated statements of operations (loss).

The results of operations of Biosight have been included in the consolidated financial statements since the acquisition date of October 18, 2023. There is no practical way to determine net income attributable to Biosight due to integration.

The following unaudited table provides certain pro forma financial information for the Company as if the January 2023 Merger and the Biosight Merger occurred on January 1, 2022 (in thousands except per share amounts):

	Year ended December 31, 2023	Year ended December 31, 2022*
	Unaudited	Unaudited
Revenue	$ 13	$ 942
Net loss	$ (57,344)	$ (63,011)

* The pro forma amounts above are derived from historical numbers of the Company, Old Ayala and Biosight. The results of operations for the year ended December 31, 2022 include the operations of the Company for the period from November 1, 2022 to October 31, 2023 which was the fiscal year 2022 prior to the change in the Company's fiscal year end from October 31 to December 31, which change was effected in January 2023. There are no such adjustments for Biosight as the fiscal year ended on December 31, 2023.

The unaudited pro forma results have been prepared based on estimates and assumptions, which we believe are reasonable; however, they are not necessarily indicative of the consolidated results of operations had the acquisition occurred on January 1, 2022, or of future results of operations.

4. Property and Equipment, net

Property and Equipment, net consists of the following:

	December 31, 2023	December 31, 2022
	(in thousands)	
Cost:		
Computers and Software	$ 60	$ 73
Lab Equipment	95	296
Office Furniture and Equipment	92	146
Leasehold Improvements	1,105	1,105
	1,352	**1,620**
Less: Accumulated Depreciation	812	660
Property and Equipment, Net	**$ 540**	**$ 960**

Depreciation expenses for the years ended December 31, 2023, and 2022 was approximately $334 thousand and $162 thousand, respectively.

During the year ended December 31, 2023 the Company recorded a write down to assets due to inactivity of lab equipment and intention to dispose or sell all of them of $145 thousand.

5. Leases

The Company adopted ASC 842, relating to lease accounting, in the first quarter of 2022 using the modified retrospective method. Results for reporting periods beginning after December 31, 2021, have been presented in accordance with the standard. The cumulative effect of initially applying the new leases standard was recognized as an adjustment to the opening consolidated balance sheet as of January 1, 2022.

The Company elected a package of practical expedients for leases that commenced prior to January 1, 2022, and did not reassess historical conclusions on: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases.

This standard had a significant impact on the Company's consolidated balance sheet but did not have a significant impact on the Company's consolidated statements of operations. The most significant effects relate to the recognition on the consolidated balance sheet of ROU assets and lease liabilities for offices and for car operating leases.

Upon adoption, the Company recognized lease liabilities and corresponding ROU assets, adjusted for the accrued rent and remaining lease incentives received on the adoption date, as follows:

	January 1, 2022	
	ROU assets	Lease liabilities
Offices	$ 1,448	$ 2,020
Cars	302	267
Total operating leases	**$ 1,750**	**$ 2,287**

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 an amount of approximately $0.5 million paid in arrears for of leasehold improvements. The amount was recorded as an incentive and is taken into account when computing the ROU asset.

A subsidiary of the Company obtained a bank guarantee in the amount of approximately $0.2 million for the office lease agreement.

On March 25, 2021, the Company entered into a one-year lease agreement for its corporate office/lab with base rent of approximately $29 thousand per year, plus other expenses. In September 2021, the Company exercised its option to renew the lease, extending the lease term until March 31, 2023. On March 25, 2023 the Company signed an extension up to March 31, 2025, with base rent of approximately $36 thousand per year. The Company recorded an ROU asset and liability of approximately $65 thousand.

The Company did not extend the lease for an additional five years, and as such the Company recognized a gain of $238 thousand in the consolidated income statement due to early termination of the lease liabilities.

The Company has the following operating ROU assets and lease liabilities:

	December 31, 2023	
	ROU assets	Lease liabilities
Offices	$ 42	$ 134
Cars	60	41
Total operating leases	**$ 102**	$ **175**

	December 31, 2022	
	ROU assets	Lease liabilities
Offices	$ 1,273	$ 1,612
Cars	189	139
Total operating leases	$ **1,462**	**$ 1,751**

	December 31, 2023	December 31, 2022
	Lease liabilities	Lease liabilities
Current lease liabilities	$ 166	$ 419
Non-current lease liabilities	9	1,332
Total lease liabilities	**$ 175**	**$ 1,751**

The following table summarizes the lease costs recognized in the consolidated statement of operations:

	December 31, 2023	December 31, 2022
Operating lease cost	$ 457	$ 442
Variable lease cost	19	10
Total lease cost	**$ 476**	**$ 452**

As of December 31, 2023, the weighted-average remaining lease term and weighted-average discount rate for operating leases are 0.7 years and 14.16%, respectively.

The following table summarizes the future payments of the Company for its operating lease liabilities:

	December 31, 2023
2024	171
2025	9
Total undiscounted lease payments	$ 180
Less: Interest	(5)
Total lease liabilities - operating	**$ 175**

6. Goodwill and intangible assets, net

Goodwill

The following table represents the changes in the carrying amounts of the Company's total goodwill:

	Carrying Amount
Balance as of December 31, 2022	-
Addition from acquisitions	4,500
Balance as of December 31, 2023	4,500

Intangible assets, net

	December 31, 2023	December 31, 2023
	Unamortized	Amortized
Cost:		
In Process Technology	$ 3,800	$ 130
Less - accumulated amortization	-	32
Intangible assets, net	$ 3,800	$ 98

As of December 31, 2023, the Company did not have any acquired intangible assets.

Estimated amortization expense for the years ended:

2024	$ 33
2025	33
2026	32
2027	-
Thereafter	3,800
	$ 3,898

Amortization expense of $32 thousand related to intangible assets, net was included in the consolidated statements of operations as Research and Development cost.

For the year ended December 31, 2022, the Company did not have acquired intangible assets.

7. Commitments and Contingent Liabilities

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. On March 25, 2024, we sold our assets and liabilities related to AL101 and AL102 programs to Immunome, and the Company transferred the BMS License Agreement to Immunome as part of such transaction.

Under the BMS License Agreement, we were obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product, and had 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. Under the BMS License Agreement, we had 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.

The Company was 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 was 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.

Both we and BMS had the right to terminate the BMS License Agreement in its entirety upon written notice to the licensee under certain circumstances described therein.

On March 25, 2024, the Company sold the assets and liabilities related to the AL101 and AL102 programs to Immunome, and the Company transferred the BMS License Agreement to Immunome as part of such transaction.

Exclusive worldwide license agreement with Penn.

The Company 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 the Company, including, but not limited to, a material breach by the Company of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to the company.

The license provides the Company 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 the Company 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 thousand 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 thousand 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 the Company 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.

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 is 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, the Company 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.

Purported Stockholder Claims

Purported Stockholder Claims Related to January 2023 Merger with Old Ayala

On December 15, 2022, a purported stockholder of Old Ayala filed a complaint in the U.S. District Court for the Southern District of New York against Old Ayala and the members of its Board, captioned Stephen Bushansky v. Ayala Pharmaceuticals, Inc., Case No.1:22-cv-10621 (S.D.N.Y.) (the "Complaint").

The Complaint asserts claims against all defendants under Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Rule 14a-9 promulgated thereunder for omitting or misrepresenting material information from Old Ayala's Proxy Statement and against the individual defendants under Section 20(a) of the Exchange Act for alleged "control person" liability with respect to such alleged omissions and misrepresentations. The allegations in the Complaint include that the Proxy Statement omitted material information regarding Old Ayala's financial projections and the financial analyses of Old Ayala's financial advisor for the January 2023 Merger. The Complaint seeks, among other relief, (1) to enjoin defendants from consummating the January 2023 Merger; (2) to enjoin a vote on the January 2023 Merger; (3) to rescind the January 2023 Merger Agreement or recover damages, if the Merger is completed; (4) a declaration that defendants violated Sections 14(a) or 20(a) and Rule 14a-9 of the Exchange Act; and (5) attorneys' fees and costs. The complaint was never served on all defendants.

In addition, approximately nine purported stockholders of Old Ayala sent letters to those noted in the above-referenced Complaint alleging similar deficiencies in Old Ayala's Proxy Statement (collectively, the "Demand Letters").

A final settlement agreement relating to these claims was entered into on March 21, 2024, and in connection therewith, the Company has accrued $200 thousand of expense.

Stockholder letter with regards to breaches of fiduciary duty

On March 6, 2024, a stockholder of Ayala Pharmaceuticals, Inc. (the "Company"), submitted a letter (the "Letter") threatening legal action against the Company and alleging breaches of fiduciary duty in connection with the Company's January 9, 2023 merger with Advaxis, Inc., the Company's October 19, 2023 merger with Biosight, Ltd., the Company's November 17, 2023 issuance of Senior Convertible Promissory Notes and warrants for the purchase of 15,000,000 shares of the Company's stock, and the Company's February 5, 2024 Asset Purchase Agreement with Immunone, Inc. The attorney representing the stockholder thereafter made a monetary demand in exchange for a release of the claims asserted in the Letter. Settlement negotiations are ongoing.

At this time, the Company is unable to predict the likelihood of an unfavorable outcome with respect to the Demand Letter.

8. Common Stock Purchase Warrants and Warrant Liability

Common Stock Rights

The Common Stock Rights confer upon the holders the right to 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.

Warrants

As of December 31, 2023 there were 22,965,771 warrants outstanding of which 22,790,706 were exercisable warrants to purchase shares of our common stock, with exercise prices ranging from $0.34 to $224.00 per share. As of December 31, 2022, there were outstanding and exercisable warrants to purchase 337,320 shares of our common stock with exercise prices ranging from $0.05 to $96.58 per share. Information on the outstanding warrants as of December 31, 2023 is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Type of Financing
$ 2.79	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)
$ 96.58	87,453*	February 2024	February 2021 Private Placement (issued by Old Ayala)
$ 0.34	22,500,500**	November 2028	November 17, 2023 Financing
Grand Total	22,965,771		

On November 17, 2023, the Company issued securities convertible into or exercisable for 22,500,500 shares of common stock as part of the Convertible Loans. See Convertible Loan bellow.

As of December 31, 2023, the Company had 289,327 of its total 22,965,771 outstanding warrants classified as equity. As of December 31, 2022, all outstanding warrants were classified as equity. At issuance, equity warrants are recorded in additional paid-In capital.

A summary of warrant activity for the year ended December 31, 2023 was as follows (in thousands, except share and per share data):

	Shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding and Exercisable Warrants at December. 31 2022	337,320	$ 25.08	1.14	$ 144,083
Merged Warrants	377,818	$ 53.45		
Issued as part of November 17 financing	22,500,500	$ 0.34		
Exercised	(249,867)	$ 0.05		
Outstanding Warrants at December 31, 2023	22,965,771	$ 1.58	4.84	$ 7,537,668
Exercisable Warrants at December 31, 2023	22,790,706	$ 1.15	4.84	$ 7,537,668

* Exercise price and warrant numbers have been retroactively adjusted for the impact of the January 2023 Merger, see note 1.
** See details under Warrant Liability Senior Convertible Notes for information on the exercise price

Shares Issued for Warrants Exercises

During the year ended December 31, 2023, 249,867 warrants were exercised in exchange for 246,192 shares of the Company's common stock on a cash less exercise basis.

Convertible Note

Following the consummation of the January 2023 Merger, management of the Company, in consultation with the Board, determined that the Company would require additional financing to further the development of Old Ayala's late-stage program. As a result, the Company continued to pursue potential financing alternatives. However, despite significant efforts in this regard over a number of months, the Company was not able to find such feasible financing alternatives.

On August 7, 2023, having concluded that there were at that time no other readily available alternatives, and in order to obtain temporary financing as it pursued its ongoing efforts to achieve longer-term financing, the Company entered into an agreement for the issuance of Senior Secured Convertible Promissory Notes (the "Secured Notes") to Israel Biotech Fund I, L.P. The Secured Notes provided for the borrowing by the Company of up to $2.0 million dollars, which borrowings which the Company received on September 1, 2023.

On November 17, 2023, having once again concluded that there were at that time no other readily available alternatives, and in order to obtain temporary financing as it pursued its ongoing efforts to achieve longer-term financing, and having concluded that the Company would not able to survive financially without additional funds the Company issued Senior Convertible Promissory Notes (collectively, the "Senior Convertible Notes"), in an aggregate amount of $4.0 million, to several existing lenders and investors in the Company, including Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. and Biotel Limited. The amounts borrowed by the Company under the Senior Convertible Notes were funded to the Company on November 20, 2023. The Senior Convertible Notes were convertible into shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at any time at the option of the noteholders, and were subject to mandatory conversion upon certain events, including a change of control transaction and certain financing transactions involving the Company, at a conversion price equal to the lower of (i) 50% of the Common Stock's price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock's price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Conversion, subject to certain adjustments. In connection with the issuance of the Senior Convertible Notes, the Company issued to the noteholders warrants to purchase an aggregate of 15,000,000 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock's price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock's price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis.

The noteholders also obtained the right, pursuant to a Side Letter Agreement between the noteholders and the Company, to lend an additional $4.0 million dollars to the Company on the same terms.

The Company has elected the fair value option to measure the Secured Notes and the Senior Convertible Notes upon issuance and conversion, in accordance with ASC 825-10. Under the fair value option, the Secured Notes and the Senior Convertible Notes are measured at fair value each period with changes in fair value reported in the consolidated statements of operations. According to ASC 825-10, changes in fair value that are caused by changes in the instrument-specific credit risk will be presented separately in other comprehensive income (loss). Prior to the modification of the terms of the Secured Notes, the Company has elected the fair value option to measure the Secured Notes. The change in fair value as a result of the modification was recorded in the consolidated statement of operation.

The Convertible Notes were valued at the end of the year using a probability-weighted expected return model, which incorporated significant unobservable inputs such as the likelihood of a voluntary note conversion (60% likelihood), the notes being held to maturity (20% likelihood) and the mandatory conversion of the notes in a PIPE (20% likelihood). This resulted in an implied borrowing rate of 50% was used as an input to the fair value measurement. None of the change in fair value was deemed to be attributable to instrument-specific credit risk and thus the full amount of such change was recognized in the statements of operations.

As discussed above, the Company had no financial alternatives at that time of the issuance of the Senior Convertible Notes and the Company issued the notes to its principal stockholders, which are also related parties of the Company. The Company received $4.0 million, while at the time the Senior Convertible Notes were issued with fair value of $6.6 million. In addition, as noted above, in connection with the issuance of the Senior Convertible Notes, the Company modified certain terms of the Secured Notes to be consistent with the terms of the Senior Convertible Notes, which resulted in a revaluation of the Secured Notes resulting in expense of $0.6 million to the Company. Furthermore, the Company issued warrants to the recipients of the Senior Convertible Notes , which at time of grant had fair value of $7.1 million. When determining whether fair value at initial recognition equals the transaction price, the Company considered the specific factors of the transaction and noted that the transaction took place under duress, the Company was forced to accept the price in the transaction and the transaction was with the Company's related parties. In addition, the Company noted that the transaction does not represent a pro-rata distribution. Since the estimated fair value of the items above exceeded the proceed received and after considering the transaction specific factors, the excess of the estimated fair value over the proceed received described above were recorded on November 17, 2023 in financial expenses, net in the Company's consolidated statements of operations.

The Company used the following significant inputs in measuring the Secured Notes and Senior Convertible Notes :

	December 31, 2023	November 17, 2023	August 7, 2023
Stock price	$ 0.67	$ 0.77	$ 1.15
Interest rate	12.4	7.2%	7.3%
Implied discount	47.7%	75.2%	(32.4)%
Risk Free Rate	5.60%	4.50%	4.20%

Warrant Liability Senior Convertible Notes

On November 17, 2023, in connection with the issuance of the Senior Convertible Notes, the Company amended the Secured Notes to match the same terms described above, and issued to the holders of the Secured Notes and Senior Convertible Notes, collectively, warrants to purchase an aggregate of 22,500,500 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock's price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock's price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis. The warrants require liability classification as the warrants contains an unpermitted adjustment to the exercise price, which precludes an equity classification. The Company used the Black Scholes model to calculate the fair value of these warrants at the issuance and at each reporting date

In measuring the warrant liability for the warrants issued on November 17, 2023 at December 31, 2023, the Company used the following inputs in its Black Scholes model:

	December 31, 2023	November 17, 2023
Assumed Exercise Price	$ 0.04	$ 0.05
Diluted Stock Price	$ 0.26	$ 0.31
Expected Term	4.9 years	5.0 years
Volatility %	95.7%	96.3%
Risk Free Rate	3.85%	4.45%

For the year ended December 31, 2023, the Company reported a loss of approximately $6.0 million due to changes in the fair value of the warrant liability.

Side Agreement and reinvestment rights

On September 11, 2023, the Company entered into the Side Letter Agreement for Conversion ("September Side Agreement") in reference to the Simple Agreement for Future Equity ("SAFE") by and between Biosight Ltd. and various investors. The September Side Agreement provided that amounts invested in Biosight Ltd under the SAFE shall convert to shares of the Common Stock upon the closing of the Biosight Merger. In addition the uninvested amount of $1.8 million as of the close of the Merger shall convert to shares of the Common Stock (at a 35% discount to the lowest effective price per share at which stock is purchased) upon the closing of the private investment in public equity ("PIPE)". Should a PIPE transaction not close within six months, the SAFE may be converted into shares of Common Stock at a 35% discount to the Company's stock price (based on the average closing price of the Company's stock on the five trading days immediately preceding the date of exercise) for a period of 30 days.

The September Side Agreement is a freestanding equity contract which is considered issued for accounting purposes. As the September Side Agreement does not meet all the conditions to be classified as equity pursuant to ASC 815-40-25-10, the Company classified the September Side Agreement as a liability with changes in fair value recorded in the consolidated statements of operations.

On November 17, 2023, as part of the Senior Convertible Notes (with the same terms as the Senior Convertible Notes described above) an additional side letter agreement was signed ("November Side Agreement"), allowing a portion ($1,458 thousand) of the September Side Agreement investors to instead convert the SAFE uninvested amount into Convertible Promissory and warrants under the same terms as the Senior Convertible Notes, resulting in $349 thousand remaining under the September Side Agreement as of December 31, 2023.

In addition to conversion of the first September Side Agreement, and as part of the Senior Convertible Notes, the November Side Agreement also allowed investors of the Senior Convertible Notes to re-invest up to their original investment (up to $4.0 million collectively) in the same terms as the Senior Convertible Notes. The November Side Agreement is a freestanding equity contract which is considered issued for accounting purposes. As the November Side Agreement does not meet all the conditions to be classified as equity pursuant to ASC 815-40-25-10, the Company classified the November Side Agreement as a liability with changes in fair value recorded in the consolidated statements of operations. The portion of the modified September Side Agreement resulted in expense of $2.2 million on the modification date which was recorded in the consolidated statements of operations.

For the year ended December 31, 2023, the Company reported a loss of approximately $7.2 million due to changes in the fair value of the September and November Side Agreements liability.

Warrant Liability April 2021 Private Placement and The September 2018 Public Placement

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 December 31, 2023, such an amendment has not been filed, and thus the warrants have not become exercisable. 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 the merger and reporting date.

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 December 31, 2023, the down round feature was triggered five times and the exercise price of the warrants were reduced from $1,800.00 to $2.79. 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. In addition, the contract contains an unpermitted adjustment to the exercise price, and therefore precludes an equity classification. As a result, net cash settlement is assumed, and liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at the merger and reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement and September 2018 Public Offering at December 31, 2023, the Company used the following inputs in its Black Scholes model:

	December 31, 2023	January 19, 2023
Exercise Price	$ 55.73	$ 55.73
Stock Price	$ 0.67	$ 2.95
Expected Term	4.98 years	4.98 years
Volatility %	127%	117%
Risk Free Rate	3.85%	3.60%

For the year ended December 31, 2023, the Company reported a gain of approximately $161 due to changes in the fair value of the warrant liability.

9. Fair Value Measurements

As of December 31, 2022 the Company did not have any assets or liabilities carried at fair value on a recurring basis. The following table provide the liabilities carried at fair value measured on a recurring basis as of December 31, 2023:

Fair Value Measured at December 31, 2023

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value:				
Convertible note	$ -	-	$ 8,141	$ 8,141
Side Letter Agreements	-	-	8,436	8,436
Long term warrant liability	-	-	6,057	6,057
Total financial liabilities at fair value	**$ -**	**$ -**	**$ 22,634**	**$ 22,634**

The changes in the fair value of the Company's Level 3 financial liabilities, which are measured on a recurring basis are as follows (in thousands):

	For the year ended December 31, 2023
December 31, 2022	-
Long term warrant assumed from January 2023 Merger	203
Proceed from issuance of Convertible Notes	$ 2,000
Side Letter Agreement in connection with Biosight Merger	685
SAFE assumed from Biosight Merger	1,068
Conversion of of shares to SAFE	(1,068)
Proceed from issuance of Senior Convertible Notes	4,000
Remeasurement recorded in financial loss, net	15,746
December 31, 2023	**22,634**

10. 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, 2023 and 2022.

* Does not include 39,452 and 80,839 shares of restricted Common Stock issued but not outstanding in 2023 and 2022, respectively.

** All of the Common Stock and per share data have been retroactively adjusted for the impact of the January 2023 merger between Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and Ayala Pharmaceutical, Inc.(f/k/a Advaxis, Inc.). See note 1

11. Stock-Based Plans

The. 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 81,248 shares.

As of December 31, 2023, there were 69,513 shares available for issuance under the 2015 Plan.

Pursuant to the January 2023 merger, the Company assumed 117,360 restricted shares, all of which are issued and outstanding, and 107,623 outstanding options.

The following table set forth the parameters used in the computation of the fair value of options granted to employees:

	Year ended December 31,	
	2023*	**2022**
Expected volatility	-%	80%
Expected dividends	-%	0%
Expected term (in years)	-	6.34
Risk free rate	-%	0.98%-3.53%

* no shares have been granted

The Company recorded stock-based compensation for the period indicated as follows (in thousands):

	Year ended December 31, 2023	**Year ended December 31, 2022**
Research and Development	$ 119	$ 717
General and Administrative	1,104	1,527
Total Stock-Based Compensation	$ **1,223**	$ **2,244**

A summary of the Company's stock option activity granted to employees under the Plan is as follows:

	Year ended December 31, 2023			
	Number of options	**Weighted average exercise price**	**Weighted average remaining contractual term (in years)**	**Aggregate intrinsic value**
Outstanding at Beginning of Year	197,897	$ 38.34	6.10	$ -
Assumed in advaxis merger	9,815	1,243.88	6.30	
Granted	-	-	-	-
Forfeited	(6,539)	38.34	7.30	
Expired	(98,281)	38.91	5.92	
Outstanding, December 31, 2023	102,892	$ 151.86	6.20	$ -
Exercisable Options, December 31, 2023	90,596	$ 131.77	6.02	$ -

The Company did not grant any options during 2023. The weighted-average grant date per-share fair value of stock options granted during 2022 was $5.74. No stock options were exercised during the years ended December 31, 2023 and 2022. As of December 31, 2023, there was approximately $0.1 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 1.14 years.

Company's restricted shares:

In May 2022, the Company granted 80,050 restricted shares to officers and employees of the Company. The restricted shares vest over three years starting May 15, 2022.

In August 2022, the Company granted 4,947 restricted shares to employees of the Company. The restricted shares vest over four years starting Aug 14, 2022.

The following table summarizes information relating to restricted shares, as well as changes to such awards during the fiscal years ended December 31, 2023 and 2022:

	Year ended December 31, 2022	Weighted average Fair value on grant date	Year ended December 31, 2023	Weighted average Fair value on grant date
Opening balance	23,303	$ 58.09	80,840	18.78
Forfeited	(5,926)	16.67	(5,176)	10.67
Granted	84,997	10.42	-	-
Vested	(21,534)	28.92	(58,607)	21.37
	80,840	$ 18.78	17,057	

The weighted average fair value at grant date of restricted shares granted for the year ended December 31, 2022 was $2.00, per share. There were no grants during 2023.

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.

12. 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, 2023	Year ended December 31, 2022
United States	$ (49,912)	$ (36,674)
Israel	(2,072)	(755)
Net loss before tax	$ (51,984)	$ (37,429)

Income tax expense is summarized as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Current:		
Domestic	$ (4,335)	$ 57
Foreign	423	527
	$ (3,912)	$ 584
Income tax expense	$ (3,912)	$ 584

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 2023	Year ended December, 31 2022
U.S. federal tax provision at statutory rate	21.00%	21.00%
State and local tax, net of federal benefit	37.96	0.72
Foreign rate differences	0.03	(0.06)
Non-deductible stock compensation	(0.49)	(1.26)
Section 951A GILTI	0.00	0.00
Effect of other permanent differences	(0.05)	(0.01)
Uncertain tax positions	(0.81)	(1.15)
Change in valuation allowance	(48.44)	(25.51)
Federal Tax Reform Rate Change	0.00	0.00
Tax Credits	-	4.14
Provision to Return	(1.68)	1.67
Other adjustments	(0.01)	(1.10)
Effective tax rate	7.51%	(1.56)%

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):

	($ in thousands) As of December 31,	
	2023	**2022**
Deferred tax assets:		
Federal net operating loss carry forwards	$ 69,040	$ 27,592
Tax credit carry forwards	16,668	4,862
Intangible and other related assets	3,095	2,990
Research and Development Costs	36,632	3,074
Accrued expenses	169	72
Warrant and other fair value Liabilities	5,142	-
Stock Based Compensation	4,782	-
Lease Liability	460	410
Total deferred tax assets before valuation allowance	135,988	39,000
Valuation allowance	(135,570)	(38,652)
Total deferred tax assets	418	348
Deferred tax liabilities:		
Right of Use Asset	418	348
Total deferred tax liabilities	418	348
Net deferred tax assets	$ -	$ -

As of December 31, 2023, the Company has provided a valuation allowance of approximately $135.6 million in respect of the Company's deferred tax assets resulting from tax loss carryforwards, tax credits 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, 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

At December 31, 2023, the Company had federal net operation loss (NOL) carryforwards of approximately $214.9 million. At December 31, 2023, the Company had federal research and development credit carryforwards of approximately $11.4 million. The federal net operating loss carryforwards begin to expire in 2028, losses generated in 2018 or later of $190.5 million will carry forward indefinitely. The federal credit carryforwards begin to expire in 2032. Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company may be subject to the net operating loss utilization provision of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation of the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

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, 2023, and 2022, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of approximately $1.8 million, and $1.3 million, respectively. As of December 31, 2023, the Company has not accrued penalties for uncertain tax positions. A reconciliation of the Company's unrecognized tax benefits is below:

	2023	**2022**
	(in thousands)	**(in thousands)**
Uncertain tax position at the beginning of year	$ 1,335	$ 858
Additions for uncertain tax position of prior years (foreign exchange and interest)	13	36
Additions for tax positions of current year	423	441
Uncertain tax position at the end of the year	$ 1,771	$ 1,335

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 2018, 2019, 2020, 2021 and 2022 for all tax jurisdictions.

Israel:

The Israeli corporate income tax rate was 23% in 2023 and 2022. Income not eligible for Preferred Enterprise benefits is taxed at the regular corporate tax rates as described above.

13. 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):

The table below sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share

	For the year Ended December 31,	
	2023	**2022**
Net loss attributable to common stockholders, basic and diluted	(48,072)	(38,013)
Weighted average common shares outstanding, basic and diluted*	**6,019,063**	**2,895,130**
Warrants	22,965,771	87,453
Stock options	102,892	197,897
Anti dilutive shares outstanding which were not included in the diluted calculation	23,068,663	285,350
Net loss per share attributable to common stockholders, basic and diluted	$ (7.99)	$ (13.13)

14. Related parties

a. Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. hold each 20% of the company, in addition after converting the Convertible Loan in 2024, they collectively hold 75% of the Company's shares, in addition they have three affiliated directors in the Company's Board of Directors.

b. The following related party balances are included in the consolidated balance sheets:

	December 31,	
	2023	**2022**
Convertible Loan (1)	$ 8,007	$ -
Long-term warrant liability (1)	$ 5,915	-
Side Letter Agreement liabilities	$ 8,175	$
Accrued expenses (2)	$ 118	$ 69

c. The following related party transactions are included in the consolidated statements of income (loss):

	Year ended December 31,	
	2023	**2022**
Financial expenses (income), net (1)	$ 8,351	$ -
General and Administrative (2)	$ 128	$ 65

(1) In August and November 2023, the Company entered into Convertible Note agreement. See note 8.
(2) For director fees to members of Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P.
(3) In November 2023, the Company entered into the Side Letter Agreement. See note 8.

15. Prepaid Expenses and Other Current Assets

	December 31,	
	2023	**2022**
Prepaid Insurances	$ 2,144	$ 431
Short-term restricted bank deposits	330	110
Other Assets	172	5
Total	$ 2,646	$ 546

16. Finance expenses net

	December 31,	
	2023	**2022**

Remeasurement of long-term warrant liability	$ 5,854	$ -
Remeasurement of Side Letter Agreements	7,751	-
Remeasurement of convertible note	2,141	-
Others	(28)	(74)
Total	$ 15,718	$ (74)

17. Subsequent Events

On February 5, 2024, the Company and Immunome, Inc. ("Immunome"), entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") pursuant to which Immunome agreed to acquire certain of the Company's assets and liabilities related to its AL101 and AL102 programs (the "Asset Sale"), which constitute substantially all of the Company's assets. See Note 1 for additional information.

On February 7, 2024, the Secured Notes issued in August 2023 and the Senior Convertible Notes issued in November 2023 were converted into 15,456,432 shares of Common Stock. In addition, the holders exercised warrants to purchase 22,500,500 shares of the Common Stock issued in connection with the November Financing, on a cashless basis, for 15,280,123 shares of the Common Stock.

On March 1, 2024, the Company issued an additional $2.0 million of convertible notes pursuant to the rights of the investors under the November 2023 side agreement, and received the proceeds of such loans.

On March 6, 2024, the Company received a letter from a stockholder threatening legal action against the Company and alleging breaches of fiduciary duty in connection with the Company's January 9, 2023 merger with Advaxis, Inc., the Company's October 19, 2023 merger with Biosight, Ltd., the Company's November 17, 2023 issuance of Senior Convertible Promissory Notes and warrants for the purchase of 15,000,000 shares of the Company's stock, and the Company's February 5, 2024 Asset Purchase Agreement with Immunone, Inc.

On March 21, 2024 the Company settled the Purported Stockholder Claims related to the January 2023 Merger with Old Ayala (see Note 7) for a cash settlement payment of $200 thousand.

As part of a cost reduction plan, during the year ended December 31, 2023, the Company had a reduction in workforce in which the employment of approximately 50% of the Company's employees was terminated. During the first quarter of 2024, the Company gave notice of termination to 18 additional employees and two officers (including the Chief Financial Officer, whose employment will terminate on June 25, 2024). After the effectiveness of such terminations, the Chief Executive Officer will be the only employee of the Company. The Company expects to be able to meet its financial obligations to its employees.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Inherent Limitations on the Effectiveness of Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements could not be prevented or detected on a timely basis. We have identified material weaknesses in our controls to the aggregation of open control deficiencies across the Company's financial reporting processes, a lack of a formal review process over preparation of financial information and an inadequate number of personnel to properly implement control procedures because the controls were not fully designed and operating effectively.

As such, management determined that it did not fully implement components of the COSO framework, including elements of the control environment, information and communication, control activities and monitoring activities components, relating to: (i) providing sufficient and timely management oversight and ownership over the internal control evaluation process; (ii) hiring and training sufficient personnel to timely support the Company's internal control objectives; (iii) performing timely monitoring and oversight to ascertain whether the components of internal control are present and functioning effectively.

These deficiencies aggregated with other business process level control deficiencies could result in material misstatement in the financial statements and therefore constitute a material weakness. Based on this material weakness, the Company's management concluded that as of December 31, 2023, the Company's internal control over financial reporting was not effective.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, our disclosure controls and procedures were not designed and operating effectively.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with U.S. GAAP. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was not effective, management has identified a material weakness in internal controls related to the to the aggregation of open control deficiencies across the Company's financial reporting processes, a lack of a formal review process over preparation of financial information and an inadequate number of personnel to properly implement control procedures.

Our financial conditions has prevented us from being able to employ sufficient resources to enable us to have an adequate level of financial reporting and review processes within our system of internal control, including to employ sufficient resources to properly implement control procedures regarding the Company's financial reporting and review processes.

Therefore, it is difficult to ensure effective segregation of accounting and financial reporting duties or effective controls over financial reporting processes.

While we strive to remedy these controls as much as practicable, there is an insufficient volume of transactions at this point in time to justify additional full-time staff following the Company's financial conditions. We believe that this is typical in many development companies. We may not be able to fully remediate the material weakness until we commence operations at which time, we would expect to hire more staff. We will continue to monitor and assess the costs and benefits of additional staffing.

Notwithstanding the results of this evaluation, management believes that the consolidated financial statements in this Annual Report on Form 10-K present, in all material aspects, the Company's financial condition as reported in conformity with U.S. Generally Accepted Accounting Principles ("US GAAP").

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the SEC rules that require us to provide only management's report in this Annual Report.

Changes in Internal control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On April 15, 2024, the Company's Compensation Committee approved the payment to Roy Golan, the Company's Chief Financial Officer, on or promptly after June 25, 2024, and conditioned upon his employment with the Company through such date, of a cash retention bonus in the amount of $350,000, subject to any applicable withholding requirements.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

ITEM 10. ***DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

Information with respect to this item is incorporated by reference from the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement"), which is to be filed with the Securities and Exchange Commission no later than April 29, 2024 (the day that is 120 days after the last day of our 2023 fiscal year). If the 2024 Proxy Statement is not filed by April 29, 2024 an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

Information regarding our executive officers is included at the end of Item 1 in Part I of this report.

ITEM 11. ***EXECUTIVE COMPENSATION***

Information with respect to this item is incorporated by reference from the 2024 Proxy Statement. If the 2024 Proxy Statement is not filed by April 29, 2024 an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Information with respect to this item is incorporated by reference from the 2024 Proxy Statement. If the 2024 Proxy Statement is not filed by April 29, 2024 an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

Information with respect to this item is incorporated by reference from the 2024 Proxy Statement. If the 2024 Proxy Statement is not filed by April 29, 2024 an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information with respect to this item is incorporated by reference from the 2024 Proxy Statement. If the 2024 Proxy Statement is not filed by April 29, 2024 an amendment to this annual report on Form 10-K setting forth this information will be duly filed with the Securities and Exchange Commission.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The financial statements required by this item are listed in Item 8, “Financial Statements and Supplementary Data” herein.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Index

See the Exhibit Index in Item 15(b) below.

Exhibit Number	Description of Exhibits
2.1	Agreement and Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Old Ayala, dated as of October 18, 2022. Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed with the SEC on October 19, 2022.
2.2	Agreement and Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Biosight, Ltd., dated as of July 26, 2023. Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed with the SEC on August 1, 2023.
2.3+	Asset Purchase Agreement, dated as of February 5, 2024, by and between Ayala Pharmaceuticals, Inc. and Immunome, Inc. Incorporated by Reference to Exhibit 2.1 to the Current Report on Form 8-K of the Registrant, filed with the SEC on February 6, 2024.
3.1*	Restated Certificate of Incorporation of Ayala Pharmaceuticals, Inc., dated as of January 27, 2023. Incorporated by reference to Exhibit 2.1 to Annual Report on Form 10-K filed with the SEC on February 10, 2023.
3.2	Second Amended and Restated By-Laws of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on March 5, 2021.
3.3	Amendment No. 1 to the Second Amended and Restated By-Laws of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on September 20, 2021.
4.1	Form of Warrant Agency Agreement, dated as of September 11, 2018 between Advaxis, Inc. and Continental Stock Transfer and Trust Company (and Form of Warrant contained therein), Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 11, 2018.
4.2	Form of Common Warrant dated July 25, 2019 Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on July 25, 2019.
4.3	Form of Common Stock Warrant dated November 27, 2020. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on November 27, 2020.
4.4	Form of Pre-Funded Warrant. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.
4.5	Form of Accompanying Warrant. Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.
4.6	Form of Private Placement Warrant. Incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.
4.7(1)	Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Israel Biotech Fund I, L.P. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 5, 2024.
4.8	Description of each class of securities registered under Section 12 of the Securities Exchange Act of 1934. Incorporated by reference to Exhibit 4.7 to the Annual Report on Form 10-K filed with the SEC on February 10, 2023.
10.1	License Agreement, between the Trustees of the University of Pennsylvania and the registrant dated as of June 17, 2002, as Amended and Restated on February 13, 2007. Incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-KSB filed with the SEC on February 13, 2007.
10.2	Second Amendment to the Amended and Restated Patent License Agreement between the registrant and the Trustees of the University of Pennsylvania dated as of May 10, 2010. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 3, 2010.
10.3‡	2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.
10.4	Amendment No. 1, dated as of March 26, 2007, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.
10.5	Amendment No. 3, dated as of December 12, 2011, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.
10.6‡	Amendment No. 1 to 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on July 19, 2012.
10.7	Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013.

10.8	Exclusive License and Technology Transfer Agreement by and between Advaxis, Inc. and Global BioPharma, Inc., dated December 9, 2013. Incorporated by reference to Exhibit 10.79 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.
10.9	Distribution and Supply Agreement, dated as of January 20, 2014, by and between Advaxis, Inc. and Biocon, Limited. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2014.
10.10	Exclusive License Agreement, dated March 19, 2014, by and between Advaxis, Inc. and Aratana Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
10.11	Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis, Inc. and MedImmune, LLC. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.12	5th Amendment to the Amended & Restated License Agreement, dated July 25, 2014, by and between Advaxis, Inc. and University of Pennsylvania. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.13‡	Amendment No. 2 to the Advaxis, Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014.
10.14‡	Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.15	Master Services Agreement for Technical Transfer and Clinical Supply, dated February 5, 2014, by and between Advaxis, Inc. and SynCo Bio Partners B.V. Incorporated by reference to Exhibit 10.1 to Current Report to Form 8-K filed with the SEC on February 11, 2014.
10.16	Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014. Incorporated by reference to Exhibit 10.101 to Annual Report on Form 10-K filed with the SEC on January 6, 2015
10.17	Co-Development and Commercialization Agreement between Advaxis, Inc. and Especificos Stendhal SA de CV dated February 3, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016.
10.18‡	2015 Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 7, 2015.
10.19‡	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit B to DEF 14A Proxy Statement filed with the SEC on February 11, 2016.
10.20‡	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on February 10, 2017.
10.21‡	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on March 20, 2020.
10.22	Lease Agreement, dated March 25, 2021, by and between Advaxis, Inc. and Princeton Corporate Plaza, LLC. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 30, 2021.

10.23	Lease Termination and Surrender Agreement, dated March 26, 2021, by and between Advaxis, Inc. and 300 CR LLC. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 30, 2021
10.24	Securities Purchase Agreement dated April 12, 2021, by and among Advaxis, Inc. and the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.
10.25	Form of Investor Agreement. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.
10.26‡	Amendment to the Advaxis, Inc. 2015 Incentive Plan, dated as of February 11, 2021. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 4, 2021.
10.27‡	Employment Agreement between Advaxis, Inc. and Kenneth A. Berlin, dated April 23, 2018. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 23, 2018.
10.28	Securities Purchase Agreement, dated as of February 19, 2021, by and among Ayala Pharmaceuticals, Inc. and the Investors identified on Exhibit A named therein. Incorporate by reference to Exhibit 10.1 of the Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) Current Report on Form 8-K filed with the SEC on February 22, 2021 (File No. 001-39279).
10.29‡	Amendment No. 1 to the employment agreement between Advaxis, Inc. and Kenneth A. Berlin, dated September 12, 2022. Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on September 12, 2022.
10.30	Registration Rights Agreement, dated November 17, 2023, by and among Ayala Pharmaceuticals, Inc., Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P., Biotel Limited and Arkin Communication Ltd. Incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q filed with the SEC on November 20, 2023.
14.1	Code of Business Conduct and Ethics dated July 9, 2014. Incorporated by reference to Exhibit 14.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.
31.1*	Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of interim Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of interim Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002

99.1	Definitive Proxy Statement of Old Ayala (f/k/a Ayala Pharmaceuticals, Inc.). Incorporated by reference to the description of the business of Old Ayala set forth in pages 233-273 of the Definitive Proxy Statement of Old Ayala for the Special Meeting of Stockholders of Old Ayala held on January 13, 2023, filed with the SEC on December 12, 2022 (File No. 001-39279).
101.INS**	Inline XBRL Instance Document
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definitions Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

‡ Denotes management contract or compensatory plan or arrangement.

+ Certain schedules and exhibits to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission on request.

† Certain confidential information contained in this document, marked by ***, has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential.

(1) Pursuant to Instruction 2 to Item 601 of Regulation S-K, the Company has filed a copy of one Common Stock Purchase Warrant (Convertible Note), and has set forth as follows the other documents omitted. The Company acknowledges that the Commission may at any time in its discretion require filing of copies of any documents so omitted.

1. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Israel Biotech Fund II, L.P.

2. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Arkin Bio Ventures L.P.

3. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Biotel Limited.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Ayala Pharmaceuticals, Inc.

Date: April 16, 2024

By: */s/ Kenneth Berlin.*
Kenneth Berlin
President and Chief Executive Officer

Date: April 16, 2024

By: */s/ Roy Golan.*
Roy Golan
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Kenneth Berlin **Kenneth Berlin**	President, Chief Executive Officer and Director *(principal executive officer)*	April 16, 2024
/s/ Roy Golan. **Roy Golan**	Chief Financial Officer *(principal financial and accounting officer)*	April 16, 2024
/s/ David Sidransky **David Sidransky**	Chairman of the Board of Directors	April 16, 2024
/s/ Roni Appel **Roni Appel**	Director	April 16, 2024
/s/ Roni Appel **Roni Appel**	Director	April 16, 2024
/s/ Vered Bisker-Leib **Vered Bisker-Leib**	Director	April 16, 2024
/s/ Yuval Cabilly **Yuval Cabilly**	Director	April 16, 2024
/s/ Murray A. Goldberg **Murray A. Goldberg**	Director	April 16, 2024
/s/ Bridget Martell **Bridget Martell**	Director	April 16, 2024
/s/ Pini Orbach **Pini Orbach**	Director	April 16, 2024

Exhibit 31.1

CERTIFICATION

I, Kenneth Berlin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2024

By: */s/ Kenneth Berlin*

Kenneth Berlin
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Roy Golan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2024

By: */s/ Roy Golan.*

Roy Golan
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: */s/ Kenneth Berlin*
Kenneth Berlin
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: */s/ Roy Golan.*

Roy Golan
Chief Financial Officer
(principal financial officer)