
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Ayala Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

82-3578375
(I.R.S. Employer
Identification No.)

**Oppenheimer 4
Rehovot 7670104, Israel
(857) 444-0553**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**MWE Corporate Services LLC
1007 North Orange Street, 10th Floor
Wilmington, DE 19801**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

**Peter N. Handrinos
Keith L. Halverstam
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
(617) 948-6000**

**Ivan K. Blumenthal
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Chrysler Center
666 Third Avenue
New York, NY 10017
(212) 692-6784**

**Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

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 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

[Table of Contents](#)

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated July 8, 2022

PRELIMINARY PROSPECTUS



Shares of Common Stock
Warrants to Purchase up to Shares of Common Stock

We are offering _____ shares of common stock, par value \$0.01 per share, together with warrants to purchase _____ shares of common stock. The common stock and warrants will be sold in combination, with one warrant to purchase _____ shares of common stock accompanying each share of common stock. The combined public offering price for each share of common stock and accompanying warrant is \$ _____.

Each warrant will have an exercise price of \$ _____ per share, will be exercisable immediately upon issuance and will expire five years from the date of issuance. The shares of common stock and warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. This offering also relates to the shares of common stock issuable upon exercise of the warrants sold in this offering.

Our common stock is listed on The Nasdaq Global Market under the symbol "AYLA." On July 7, 2022, the last reported sale price of our common stock on The Nasdaq Global Market was \$1.20 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited.

Investing in our common stock and warrants involves a high degree of risk. See "[Risk Factors](#)" beginning on page 8 of this prospectus and in our reports and other filings with the Securities and Exchange Commission that are incorporated by reference in this prospectus, for a discussion of information that you should consider before investing in our common stock and warrants.

	Per Share and Warrant	Total
Public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us ⁽²⁾	\$	\$

(1) See "Underwriting" beginning on page 29 for additional information regarding underwriting compensation.
(2) The amount of proceeds, before expenses, to us does not give effect to any exercise of the warrants.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock and warrants on or about _____, 2022.

Sole Book-Running Manager

Oppenheimer & Co.

The date of this prospectus is _____, 2022.

TABLE OF CONTENTS

	Page
FORWARD-LOOKING STATEMENTS	1
PROSPECTUS SUMMARY	2
THE OFFERING	7
RISK FACTORS	8
USE OF PROCEEDS	10
CAPITALIZATION	11
DILUTION	13
DIVIDEND POLICY	15
DESCRIPTION OF CAPITAL STOCK	16
DESCRIPTION OF SECURITIES WE ARE OFFERING	20
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS	22
UNDERWRITING	29
LEGAL MATTERS	35
EXPERTS	35
WHERE YOU CAN FIND MORE INFORMATION	36
INCORPORATION BY REFERENCE	37

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock and warrants offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock and warrants. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

We use our trademarks and our logo in this prospectus. This prospectus also include trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

FORWARD-LOOKING STATEMENTS

This prospectus, including the information incorporated by reference into this prospectus, contains “forward-looking statements.” We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this prospectus are forward-looking statements, including but not limited to statements regarding:

- statements relating to our development of AL101 and AL102;
- our ability to continue as a going concern;
- our future capital needs and our need to raise additional funds;
- the promise and potential impact of our preclinical or clinical trial data;
- the timing of and plans to initiate additional clinical trials of AL101 and AL102;
- the timing and results of any clinical trials or readouts;
- the anticipated impact of COVID-19 on our business; and
- our use of the proceeds from this offering.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements are identified by these terms or expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including but not limited to, the risk factors set forth in the section titled “Risk Factors” in this prospectus and the risk factors set forth in the documents incorporated by reference in this prospectus.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward- looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. You should read this prospectus and the documents incorporated by reference herein completely and with the understanding that our actual future results may be materially different from what we expect and should not place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information contained in other parts of this prospectus, including any applicable free writing prospectus and the documents incorporated by reference herein. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus carefully, especially the “Risk Factors” section beginning on page 8 and in the documents incorporated by reference herein and our financial statements and the related notes incorporated by reference herein, before deciding to invest in our common stock and warrants. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our” and “Ayala” refer to Ayala Pharmaceuticals, Inc. and its subsidiaries.

Company Overview

We are 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. Our differentiated development approach is predicated on identifying and addressing tumorigenic drivers of cancer, through a combination of our bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. Our current portfolio of product candidates, AL101 and AL102, targets the aberrant activation of the Notch pathway using gamma secretase inhibitors, or GSIs. Gamma secretase is the enzyme responsible for Notch activation and, when inhibited, turns off the Notch pathway activation. Aberrant activation of the Notch pathway has long been implicated in multiple solid tumor and hematological cancers and has often been associated with more aggressive cancers. In cancers, Notch is known to serve as a critical facilitator in processes such as cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, all of which contribute to a poorer patient prognosis. AL101 and AL102 are designed to address the underlying key drivers of tumor growth, and our initial Phase 2 clinical data of AL101 suggest that our approach may address the shortcomings of existing treatment options. We believe that our novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from rare and aggressive cancers.

We are currently evaluating AL102 in the RINGSIDE pivotal Phase 2/3 clinical trial in desmoid tumors and intend to commence a Phase 2 clinical trial of AL102 for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia in the second half of 2022. We are currently evaluating AL101 as a monotherapy in the ACCURACY open-label Phase 2 clinical trial for the treatment of recurrent/metastatic adenoid cystic carcinoma, or R/M ACC, for patients bearing Notch-activating mutations. AL101 was granted Orphan Drug Designation in May 2019 for the treatment of adenoid cystic carcinoma, or ACC, and fast track designation in February 2020 for the treatment of R/M ACC.

Recent Developments

On July 5, 2022, we announced interim data from Part A of our ongoing RINGSIDE pivotal Phase 2/3 clinical trial evaluating AL102 in desmoid tumors. In February 2022, Part A completed enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102: 1.2 mg daily, 2 mg twice weekly, and 4 mg twice weekly with initial follow up to evaluate safety, tolerability and tumor volume by MRI after 16 weeks. As of the cut-off date of May 1, 2022, 13 patients had reached the 16-week mark, at which time 10 had a completed central reading of their MRI scans. Of these 10 patients, nine showed a decrease in tumor volume. In addition, one patient showed an unconfirmed partial response as measured by RECIST 1.1. AL102 was generally observed to be well tolerated at all dose levels with no dose-limiting toxicities and no Grade 4 or 5 adverse events observed. The most common treatment-related adverse events were Grade 1 and 2 and included diarrhea, fatigue, skin rash and nausea.

On June 6, 2022, we announced updated data from the ACCURACY Phase 2 clinical trial of AL101. The Phase 2 ACCURACY trial assessed the clinical activity of AL101 using radiographic assessments of patients with R/M ACC demonstrating disease progression within 6 months prior to dosing. A total of 87 patients were enrolled (all with RECIST 1.1 evaluable disease or bone exclusive disease deemed evaluable by MD Anderson Bone Response criteria) and of these, 77 were evaluable for efficacy. Approximately 90% of the patients had metastatic disease at screening. The patients in this trial were heavily pretreated with over half having previously received some form of systemic therapy.

The results from the trial, as of a cut-off date of April 14, 2022, showed the following:

- in the 4 mg dose cohort, 6 patients (14.6%) had a partial response, including three confirmed responses, two unconfirmed responses, and one response identified in a bone exclusive patient, and 23 patients (56.1%) had stable disease, for an overall disease control rate of 70.7%;
- in the 6 mg dose cohort, 3 patients (8.3%) had a partial response, including two confirmed responses and one unconfirmed response, and 21 patients (58.3%) had stable disease, for an overall disease control rate of 66.7%;
- 23 patients (56.1%) in the 4 mg dose cohort and 13 patients (36.1%) in the 6 mg dose cohort showed some degree of tumor regression;
- the median progression free survival, or PFS, in each of the 4 mg and 6 mg dose cohorts was 3.7 months, with 6.7 months of PFS among the patients across both cohorts who had a partial response;
- median overall survival was 9.3 months among the 4 mg and 6 mg cohorts, and 12.1 months among the patients who had a partial response; and
- both dose regimens demonstrated substantial inhibition of the Notch pathway consistent with previous studies, however, the higher dose did not improve the observed outcomes.

AL101 was adequately tolerated with most adverse events being Grade 1 or 2. Among all 87 patients, 54 (62%) had treatment emergent Grade 3 or 4 adverse events (49% in the 4 mg dose cohort and 76% in the 6 mg dose cohort). There were nine deaths in the trial of which two were considered to be treatment related.

Risk Factors

Our business and this offering are subject to numerous risks and uncertainties, including those in the section titled “Risk Factors” and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in the other documents we file with the U.S. Securities and Exchange Commission, or the SEC, which are incorporated by reference in this prospectus. These risks include, but are not limited to, the following:

- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability;
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of AL101 and AL102;
- Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern;
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;
- We are heavily dependent on the success of AL101 and AL102, our most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed;

- Due to our limited resources and access to capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business;
- The outbreak of COVID-19 may adversely affect our business, including our clinical trials;
- Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations;
- Our product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to marketable products;
- We were not involved in the early development of our lead product candidates; therefore, we are dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for our product candidates;
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control;
- If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed;
- Our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- The market opportunities for AL101 and AL102, if approved, may be smaller than we anticipate;
- We may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations;
- We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates;
- The price of our common stock may be volatile and fluctuate substantially, and you may not be able to resell your shares at or above the price you paid for them;
- Even if we obtain approval from the U.S. Food and Drug Administration, or FDA, for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential;
- We have been granted Orphan Drug Designation for AL101 for the treatment of ACC and may seek Orphan Drug Designation for other indications or product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for our other product candidates;
- Although we have received fast track designation for AL101, and may seek fast track designation for our other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process;
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- We are dependent on a small number of suppliers for some of the materials used to manufacture our product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of our product candidates;
- Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set;

- If we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our markets;
- We may engage in acquisitions or in-licensing transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources;
- Risks related to our operations in Israel could materially adversely impact our business, financial condition and results of operations;
- There is no public market for the warrants being offered by this prospectus; holders of our warrants will have no rights as a common stockholder; and the warrants may have no value if the trading price of our common stock does not exceed the exercise price of the warrants; and
- Management will have broad discretion as to the use of the proceeds from this offering and may not use the proceeds effectively.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are otherwise applicable to public companies. These exemptions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency,” and “say-on-golden-parachutes;”
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering. However, if prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.07 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in the previous three-year period or (iii) we become a “large accelerated filer” (as defined in Rule 12b-2 under the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a “large accelerated filer” at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and in the filings we make with the SEC. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies that are not emerging growth companies.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to “opt out” of the exemption for the delayed adoption of certain accounting standards, and, therefore, we adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company” as defined under the Securities Act and Exchange Act. We may continue to be a smaller reporting company so long as either (i) the market value of shares of our common stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of shares of our common stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company under the requirements of (ii) above, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Corporate Information

We were incorporated under the laws of the state of Delaware in November 2017. Our principal executive offices are located at Oppenheimer 4, Rehovot 7670104, Israel, and our telephone number is (857) 444-0553. Our website address is www.ayalapharma.com. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

THE OFFERING

Securities offered by us	Up to shares of our common stock and warrants to purchase shares of common stock. The shares of common stock and warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. Each warrant will have an exercise price of \$ per whole share of common stock, will be exercisable immediately on or after the date of issuance and will expire five years from the date of issuance. See “Description of Securities We Are Offering”. We are also registering shares of our common stock issuable upon exercise of the warrants.
Common stock outstanding after this offering	shares of common stock (assuming none of the warrants issued in this offering are exercised).
Use of proceeds	We estimate the net proceeds from this offering will be approximately \$ million (assuming none of the warrants issued in this offering are exercised), after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for working capital and general corporate purposes. See “Use of Proceeds” on page 10 of this prospectus.
Risk factors	See “Risk Factors” beginning on page 8 and the documents incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.
Nasdaq Global Market Symbol	Our common stock is listed on The Nasdaq Global Market under the symbol “AYLA.” There is no established trading market for the warrants, and we do not expect a trading market to develop. We do not intend to list the warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be extremely limited.
Transfer Agent	American Stock Transfer & Trust Company, LLC
The number of shares of our common stock to be outstanding after this offering is based on 14,503,743 shares of our common stock outstanding as of June 30, 2022, and excludes:	
<ul style="list-style-type: none">• 1,159,169 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of June 30, 2022 at a weighted average exercise price of \$7.60 per share;• 479,416 shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan as of June 30, 2022;• 583,332 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2022 at a an exercise price of \$18.10 per share; and• 1,333,333 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2022 at an exercise price of \$0.01 per share.	
Unless otherwise indicated, all information contained in this prospectus assumes:	
<ul style="list-style-type: none">• no exercise of the outstanding options or warrants described above; and• no exercise of the warrants in this offering.	

RISK FACTORS

You should carefully consider the risks described below and those discussed under the section titled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2021, together with other information in this prospectus, the information and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially and adversely from those anticipated in any forward-looking statements in this prospectus as a result of certain factors, including those set forth below. See “Forward-Looking Statements.”

Risks Related to This Offering

Purchasers of common stock and accompanying warrants in this offering will experience immediate and substantial dilution in the book value of their investment. You may experience further dilution upon exercise of options and warrants.

The public offering price per share of common stock and accompanying warrants in this offering is substantially higher than the net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase common stock in this offering, you will incur immediate substantial dilution of approximately \$ _____ per share, representing the difference between the public offering price per share of common stock and accompanying warrants and our as adjusted net tangible book value as of March 31, 2022 (without giving effect to the potential exercises of the warrants offered hereby). Furthermore, if outstanding options or warrants or the warrants offered hereby are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus entitled “Dilution.”

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock or the warrants.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock offered hereby or issuable upon exercise of the warrants offered hereby will be, freely tradable without restriction or further registration under the Securities Act. Because the warrants are exercisable into our common stock, volatility or a reduction in the market price of our common stock could have an adverse effect on the market price of the warrants.

There is no public market for the warrants to purchase shares of our common stock being offered in this offering.

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Global Market. Without an active market, the liquidity of the warrants will be limited.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of the warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

[Table of Contents](#)

The warrants offered by this prospectus may not have any value.

The warrants offered by this prospectus will be exercisable for five years from the date of issuance. There can be no assurance that the market price of our common stock will ever exceed the exercise price of the warrants. In the event that our common stock price does not exceed the exercise price of the warrants during the term of the warrants, the warrants may not have any value.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock or warrants.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We intend to use the net proceeds for working capital and other general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline and could have an adverse effect on the market price of the warrants.

The trading price of our common stock has been highly volatile, and purchasers of our common stock and accompanying warrants could incur substantial losses.

The trading price of our common stock has been highly volatile, particularly over the last year. For example, on June 30, 2021, the closing price of our common stock was \$10.19 per share and on June 30, 2022 it was \$1.09 per share. This volatility may affect the price at which you are able to sell shares of our common stock or the warrants, and the sale of our common stock and the accompanying warrants in this offering could adversely affect the price of our common stock. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and economic factors that are beyond our control. As a result, you may not be able to sell your shares of common stock or the accompanying warrants at or above the price at which you purchase them. In addition, while the stock market in general has experienced high volatility, biotechnology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to operating performance. Broad market and industry factors may negatively affect the market price of our common stock and warrants, regardless of our actual operating performance.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.

We have never paid dividends and do not anticipate paying dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you sell our common stock thereafter.

If we fail to continue to meet all applicable Nasdaq Global Market requirements, Nasdaq may delist our common stock, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on The Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common stock falls below \$1.00 per share for 30 consecutive trading days, Nasdaq could determine to delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, customers and employees.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ _____ million, assuming a public offering price of \$ _____ per share of common stock and accompanying warrant, which was the last reported sale price per share of our common stock on The Nasdaq Global Market on _____, 2022, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the warrants being issued in this offering.

We intend to use the net proceeds of this offering for working capital and other general corporate purposes.

Based on our planned use of the net proceeds from this offering and our existing cash, cash equivalents and short-term restricted bank deposits, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements _____. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. In any event, we will require additional funding to complete the clinical development of, and commercialize, our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Each \$0.25 increase (decrease) in the assumed public offering price of \$ _____ per share and accompanying warrant, which is the last reported sale price of our common stock on The Nasdaq Global Market on _____, 2022, would increase (decrease) the net proceeds to us from this offering by approximately \$ _____ million, assuming that the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us. An increase (decrease) of 1,000,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ _____ million, assuming no change in the assumed public offering price and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds received by us in this offering. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of our existing product candidates and to develop any future product candidates. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term and intermediate-term, investment-grade, interest-bearing instruments and U.S. government securities.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term restricted bank deposits, and our capitalization as of March 31, 2022:

- on an actual basis; and
- on a pro forma basis to give effect to the sale of _____ shares of common stock and accompanying warrants to purchase up to _____ shares of common stock in this offering, at an assumed public offering price of \$ _____ per share and accompanying warrant, which was the last reported sale price of our common stock on The Nasdaq Global Market on _____, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the warrants being issued in this offering.

Our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our financial statements and the related notes and the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, each as incorporated by reference in this prospectus.

	As of March 31, 2022	
	Actual	Pro Forma(1)
	(in thousands, except share data)	
Cash and cash equivalents and short-term restricted bank deposits	\$ 27,172	
Long-term debt, net of current portion	\$ 472	
Stockholders’ equity		
Preferred stock, \$0.01 par value per share; 10,000,000 shares authorized and no shares issued and outstanding, actual and pro forma		—
Common Stock, \$0.01 par value per share; 200,000,000 shares authorized, actual and pro forma; 14,085,283 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma		139
Additional paid-in capital		145,847
Accumulated deficit		(121,168)
Total stockholders’ equity	\$ 24,818	\$ _____
Total capitalization	\$ 25,290	\$ _____

- (1) Each \$0.25 increase or decrease in the assumed public offering price per share of common stock and accompanying warrant of \$ _____, which was the last reported sale price of our common stock on The Nasdaq Global Market on _____, 2022, would increase (decrease) the pro forma amount of each of cash and cash equivalents and short-term restricted bank deposits, additional paid-in capital, total stockholders’ equity and total capitalization by \$ _____ million, assuming that the number of share of common stock and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma amount of each of cash and cash equivalents and short-term restricted bank deposits, additional paid-in capital, total stockholders’ equity and total capitalization by \$ _____ million, assuming no change in the assumed public offering price and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

The number of shares in the table above does not include:

- 1,150,423 shares of common stock issuable upon the exercise of outstanding options to purchase shares of common stock as of March 31, 2022 at a weighted average exercise price of \$7.79 per share;
- 906,622 shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan as of March 31, 2022;

[Table of Contents](#)

- 583,332 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2022 at a an exercise price of \$18.10 per share; and
- 1,333,333 share of common stock issuable upon exercise of warrants outstanding as of March 31, 2022 at an exercise price of \$0.01 per share.

DILUTION

If you invest in our common stock and warrants in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of common stock and accompanying warrant, assuming no value is attributable to the warrant, and the as adjusted net tangible book value per share of common stock after this offering.

As of March 31, 2022, our net tangible book value was \$24.8 million, or \$1.78 per share. Our net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding as of March 31, 2022.

After giving further effect to our sale in this offering of _____ shares of common stock and accompanying warrants at an assumed public offering price per share of common stock and accompanying warrant of \$ _____, which was the last reported sale price of common stock on The Nasdaq Global Market on _____, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and without giving effect to the exercise of the warrants issued in this offering, our as adjusted net tangible book value as of March 31, 2022 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution in as adjusted net tangible book value of \$ _____ per share to investors purchasing shares of common stock and accompanying warrants in this offering.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share of common stock and accompanying warrants	\$
Net tangible book value per share as of March 31, 2022	\$1.78
Increase in net tangible book value per share attributable to investors purchasing in this offering	_____
As adjusted net tangible book value per share as of March 31, 2022 after this offering	_____
Dilution per share to new investors purchasing in this offering	\$ _____

Each \$0.25 increase (decrease) in the assumed public offering price of \$ _____ per share and accompanying warrant, which is the last reported sale price of our common stock on The Nasdaq Global Market on _____, 2022, would increase (decrease) as adjusted net tangible book value per share by \$ _____ per share and dilution to new investors by \$ _____ per share, assuming that the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. An increase of 1,000,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase as adjusted net tangible book value per share by \$ _____ per share and decrease dilution to new investors by \$ _____ per share and a decrease of 1,000,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would decrease as adjusted net tangible book value per share by \$ _____ per share and increase dilution to new investors by \$ _____ per share, assuming no change in the assumed public offering price and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

The foregoing table and calculations are based on 14,085,283 shares of our common stock outstanding as of March 31, 2022, and exclude:

- 1,150,423 shares of common stock issuable upon the exercise of outstanding options to purchase shares of common stock as of March 31, 2022 at a weighted average exercise price of \$7.79 per share;
- 906,622 shares of common stock reserved for future issuance under our 2017 Stock Incentive Plan as of March 31, 2022;

[Table of Contents](#)

- 583,332 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2022 at a an exercise price of \$18.10 per share; and
- 1,333,333 share of common stock issuable upon exercise of warrants outstanding as of March 31, 2022 at an exercise price of \$0.01 per share.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for the operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. The payment of dividends, if any, will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in any future debt agreements, and other factors that our board of directors may deem relevant.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation, which has been publicly filed with the SEC. See “Where You Can Find More Information; Incorporation by Reference.”

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Elections of directors by our stockholders are determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our restated certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. There are no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Registration Rights

Certain of our stockholders are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an amended and restated investors’ rights agreement by and among us and certain of our stockholders, until the rights otherwise terminate pursuant to the terms of the investors’ rights agreement. Additionally, holders of warrants to purchase our common stock are entitled to certain rights with respect to the registration for public resale under the Securities Act of shares of our common stock issued or issuable upon exercise of such warrants, pursuant to a securities purchase agreement by and among certain purchasers named therein. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Piggyback Registration Rights

If we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 Registration Rights

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of at least 20% of the registrable securities then outstanding request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated aggregate offering amount, net of expenses, of at least \$3,000,000, we will be required to effect such registration.

Expenses and Indemnification

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders and blue sky fees and expenses. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

Termination of Registration Rights

The registration rights terminate upon the earlier of the date that is five years after the closing of our initial public offering, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holders' shares without limitation during a three-month period without registration and the closing of a deemed liquidation event, as defined in the investors' rights agreement.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

[Table of Contents](#)

Stockholder Meetings

Our restated certificate of incorporation and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation does not provide the right to our stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for:

[Table of Contents](#)

(1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Under our restated certificate of incorporation, this exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to these choice of forum provisions. It is possible that a court of law could rule that either or both of the choice of forum provisions contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Stock Exchange Listing

Our common stock is listed on The Nasdaq Global Market under the symbol “AYLA.”

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering _____ shares of common stock, together with warrants to purchase _____ shares of common stock. Each warrant will have an exercise price of \$ _____ per share. The shares of common stock and the warrants are immediately separable and will be issued separately, but must be purchased together in this offering.

Common Stock

The material terms and provisions of our common stock are described under the section titled “Description of Capital Stock” on page 16.

Warrants

The following summary of certain terms and provisions of the warrants is not complete and is subject to, and qualified in its entirety by, the provisions of the warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price

Each warrant offered hereby will have an initial exercise price equal to \$ _____ per share of common stock. The warrants will be exercisable on or after the date of issuance and will expire five years from the date of issuance. We may at any time during the term of each warrant reduce the then current exercise price to any amount and for any period of time deemed appropriate by our board of directors. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, recapitalization or similar events affecting our common stock and the exercise price. The warrants will be issued separately from the common stock.

Exercisability

The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder’s warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants and in accordance with the rules and regulations of the SEC.

Cashless Exercise

If, at the time a holder exercises its warrants, a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Table of Contents

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be extremely limited. Our common stock is currently listed on The Nasdaq Global Market.

Right as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board of directors, the holders of the warrants have the right to require us or a successor entity to redeem the warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our board of directors, the holders of the warrants have the right to require us or a successor entity to redeem the warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the warrant on the date of the consummation of the fundamental transaction.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of certain material U.S. federal income tax considerations relating to the purchase, ownership and disposition of the Units or components thereof issued pursuant to this offering and shares of our common stock received upon exercise of the warrants, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of warrants or shares of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of the Units, common stock, warrants, and shares of our common stock received upon the exercise of the warrants.

This discussion is limited to holders that hold Units, warrants or shares of our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder’s particular circumstances, including the impact of the alternative minimum tax and the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding warrants or shares of our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell warrants or shares of our common stock under the constructive sale provisions of the Code;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to warrants or shares of our common stock being taken into account in an “applicable financial statement” (as defined in the Code);
- persons who hold or receive warrants or shares of our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds warrants or shares of our common stock, the tax treatment of a partner in the partnership will depend on the status of the

[Table of Contents](#)

partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding warrants or shares of our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF UNITS, COMMON STOCK, WARRANTS AND SHARES OF OUR COMMON STOCK RECEIVED UPON THE EXERCISE OF THE WARRANTS ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Characterization of Units

Each Unit will be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our common stock and one warrant to purchase one share of common stock. In determining their tax basis for the common stock and the warrant constituting a Unit, purchasers of Units should allocate their purchase price between such share of common stock and warrant based on their respective fair market values at the time of issuance. We do not intend to advise purchasers of the Units with respect to this determination, and purchasers of the Units are advised to consult their tax and financial advisors with respect to the relative fair market values of the common stock and the warrants for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Definition of a U.S. Holder

For purposes of this discussion, a “U.S. holder” is any beneficial owner of warrants or shares of our common stock that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) have the authority to control substantial decisions of the trust, or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a United States person for U.S. federal income tax purposes.

Sale or Other Disposition, Exercise or Expiration of Warrants

Upon the sale or other disposition of a warrant (other than by exercise), a U.S. holder will generally recognize capital gain or loss equal to the difference between the amount realized on the sale or other disposition and the U.S. holder’s tax basis in the warrant. This capital gain or loss generally will be long-term capital gain or loss if the U.S. holder’s holding period in such warrant is more than one year at the time of the sale or other disposition. The deductibility of capital losses is subject to limitations.

In general (and subject to the discussion of cashless exercise, below), a U.S. holder will not be required to recognize income, gain or loss upon exercise of a warrant for its exercise price. A U.S. holder’s tax basis in a share of our common stock received upon exercise of the warrants will be equal to the sum of (1) the U.S. holder’s tax basis in the warrants exchanged therefor and (2) the exercise price of such warrants. A U.S. holder’s holding period in the shares of our common stock received upon exercise will commence on the day

[Table of Contents](#)

after such U.S. holder exercises the warrants. Although there is no direct legal authority as to the U.S. federal income tax treatment of an exercise of a warrant on a cashless basis, we intend to take the position that such exercise will not be taxable, either because the exercise is not a gain realization event or because it qualifies as a tax-free recapitalization. In the former case, the holding period of the shares of our common stock received upon exercise of warrants should commence on the day after the warrants are exercised. In the latter case, the holding period of the shares of our common stock received upon exercise of warrants would include the holding period of the exercised warrants. However, our position is not binding on the IRS, and the IRS may treat a cashless exercise of a warrant as a taxable exchange. U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of a warrant on a cashless basis, including with respect to their holding period and tax basis in the common stock received.

If a warrant expires without being exercised, a U.S. holder will recognize a capital loss in an amount equal to such holder's tax basis in the warrant. Such loss generally will be long-term capital loss if the U.S. holder's holding period in such warrant is more than one year at the time of expiration. The deductibility of capital losses is subject to limitations.

Constructive Dividends on Warrants

As described in the section entitled "Dividend Policy," we do not expect to pay any cash dividends on our common stock in the foreseeable future. However, if the exercise price of the warrants is adjusted as a result of certain events affecting our common stock (or in certain circumstances, there is a failure to make adjustments), such adjustments may result in the deemed payment of a taxable dividend to a U.S. holder. U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the exercise price of the warrants.

We are currently required to report the amount of any deemed distributions on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of deemed distributions, as well as obligations of withholding agents and filing and notice obligations of issuers in respect of such deemed distributions. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the distribution of cash or property that results in the deemed distribution and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Distributions on Common Stock

As described in the section entitled "Dividend Policy," we do not expect to pay any cash dividends on our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock (other than certain distributions of common stock), such distributions will constitute dividends to the extent paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Dividends received by a corporate U.S. holder may be eligible for a dividends received deduction, subject to applicable limitations. Dividends received by certain non-corporate U.S. holders, including individuals, are generally taxed at the lower applicable capital gains rate provided certain holding period and other requirements are satisfied. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital and first be applied against and reduce a U.S. holder's adjusted tax basis in its common stock, as the case may be, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock, as applicable.

Sale or Other Disposition of Common Stock

Upon a sale or other disposition of our common stock, a U.S. holder generally will recognize capital gain or loss equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in our common stock. Such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for our common stock is more than one year at the time of disposition. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally are subject to reduced rates of taxation. The deductibility of capital losses is subject to limitations.

Information Reporting and Backup Withholding

A U.S. holder may be subject to information reporting and backup withholding when such holder receives payments (including constructive dividends) or receives proceeds from the sale or other taxable disposition of shares of our common stock or warrants. Certain U.S. holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Tax Considerations Applicable to Non-U.S. Holders

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of warrants or shares of our common stock that is neither a U.S. holder nor an entity treated as a partnership for U.S. federal income tax purposes.

Exercise of Warrants

A non-U.S. holder generally will not be subject to U.S. federal income tax on the exercise of warrants into shares of our common stock. However, if a cashless exercise of the warrants results in a taxable exchange, as described in "— Tax Considerations Applicable to U.S. Holders — Sale or Other Disposition, Exercise or Expiration of Warrants," the rules described below under "Sale or Other Disposition of Common Stock or Warrants" would apply.

Constructive Dividends on Warrants

As described in the section entitled "Dividend Policy," we do not expect to pay any cash dividends on our common stock in the foreseeable future. However, if the exercise price of a Warrant is adjusted as a result of certain events affecting our common stock (or in certain circumstances, there is a failure to make adjustments), such adjustments may result in the deemed payment of a taxable dividend to a non-U.S. holder. Any resulting withholding tax attributable to deemed dividends may be collected from other amounts payable or distributable to, or other assets of, the non-U.S. holder. See the section above entitled "—Tax Considerations Applicable to U.S. Holders—Constructive Dividends on Warrants." Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the exercise price of the Warrants.

Distributions on Common Stock

As described in the section entitled “Dividend Policy,” we do not expect to pay any cash dividends on our common stock in the foreseeable future. However, if we do make distributions of cash or property (other than certain distributions of common stock) on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder’s adjusted tax basis in its common stock, as the case may be, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend.

Dividends paid to a non- U.S. holder of our common stock that are not effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable tax treaties.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Sale or Other Disposition of Common Stock or Warrants

A non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale, or other disposition of our warrants or our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);

[Table of Contents](#)

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our warrants or our common stock constitute a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

A non-U.S. holder will not be subject to backup withholding with respect to distributions on our common stock we make to the non-U.S. holder (including constructive dividends with respect to the warrants) provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our common stock and warrants to the non-U.S. holder, regardless of whether any tax was actually withheld.

Information reporting and backup withholding may apply to the proceeds of a sale or other disposition of our common stock or warrants within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other disposition of our common stock or warrants outside the United States conducted through certain U.S.- related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of our common stock or warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, warrants or our common stock paid to, a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or “United States owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including deemed dividends). While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock or warrants on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

UNDERWRITING

We entered into an underwriting agreement with the underwriters named below on _____, 2022. Oppenheimer & Co. Inc. is acting as representative of the underwriters.

The underwriting agreement provides for the purchase of a specific number of shares of common stock and accompanying warrants to purchase shares of common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares and warrants, but is not responsible for the commitment of any other underwriter to purchase shares or warrants. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares and warrants set forth opposite its name below:

<u>Underwriter</u>	<u>Number of Shares of Common Stock</u>	<u>Number of Warrants</u>
Oppenheimer & Co. Inc.		
Total		

The underwriters have agreed to purchase all of the shares and warrants offered by this prospectus, if any are purchased.

The shares and warrants offered hereby are expected to be ready for delivery on or about _____, 2022 against payment in immediately available funds. The shares and warrants are immediately separable and will be issued separately in this offering.

The underwriters are offering the shares and accompanying warrants subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose to offer the shares and accompanying warrants to the public at the public offering price set forth on the cover page of this prospectus and to dealers at a price less a concession not in excess of \$ _____ per share and accompanying warrants. After the shares and accompanying warrants are released for sale to the public, the representative may change the offering price, the concession, and other selling terms at various times.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses:

	<u>Total Per Share and Accompanying Warrants</u>
Public offering price	\$ _____
Underwriting discounts and commissions ⁽¹⁾	\$ _____
Proceeds, before expenses, to us	\$ _____

(1) We have agreed to pay the underwriters a commission of _____ % of the gross proceeds of this offering.

We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately \$ _____. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$ _____.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

In connection with this offering, we, our directors, executive officers, and certain stockholders have agreed not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of

Table of Contents

our common stock or securities convertible into or exchangeable for, or that represent the right to receive, shares of common stock, for a period of 90 days following the closing of the offering of the shares. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Oppenheimer & Co. Inc.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares of common stock before the distribution of the shares of common stock is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions – The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares of common stock, so long as stabilizing bids do not exceed a specified maximum.
- Penalty bids – If the representative purchases shares of common stock in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares of common stock as part of the offering.
- Passive market making – Market makers in the shares of common stock who are underwriters or prospective underwriters may make bids for or purchases of shares of common stock, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of the shares of common stock may have the effect of raising or maintaining the market price of the shares of common stock or preventing or mitigating a decline in the market price of the shares of common stock. As a result, the price of the shares of common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares of common stock if it discourages resales of the shares of common stock.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares of common stock. These transactions may occur on The Nasdaq Global Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Preliminary Prospectus

A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in the offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

Belgium

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the shares of common stock has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission ("Commission bancaire, financière et des assurances/Commissie voor het Bank, Financierie en Assurantiewezen"). Any representation to the contrary is unlawful.

Each underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any shares of common stock, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the shares of common stock or to the offering in a manner which would be

[Table of Contents](#)

construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Directive 2003/71/EC which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the company to be in violation of the Belgian securities laws.

Canada

This document constitutes an “exempt offering document” as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein, or the Securities. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts (“NI 33-105”). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to “connected issuer” and/or “related issuer” relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in the offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions*, or NI-45-106 or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration*

Table of Contents

Exemptions and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

France

Neither this prospectus nor any other offering material relating to the shares of common stock has been submitted to the clearance procedures of the Autorité des marchés financiers in France. The shares of common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares of common stock has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the shares of common stock to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d’investisseurs*), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des marchés financiers*, does not constitute a public offer (*appel public à l’épargne*). Such shares of common stock may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code *monétaire et financier*.

Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, investors listed in the first addendum to the Israeli Securities Law, or the Addendum, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Italy

The offering of the shares of common stock offered hereby in Italy has not been registered with the *Commissione Nazionale per la Società e la Borsa*, or CONSOB, pursuant to Italian securities legislation

Table of Contents

and, accordingly, the shares of common stock offered hereby cannot be offered, sold or delivered in the Republic of Italy, or Italy, nor may any copy of this prospectus or any other document relating to the shares of common stock offered hereby be distributed in Italy other than to professional investors (*operatori qualificati*) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the shares of common stock offered hereby or distribution of copies of this prospectus or any other document relating to the shares of common stock offered hereby in Italy must be made:

- (a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993, or the Banking Act;
- (b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and
- (c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

Sweden

This prospectus has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus may not be made available, nor may the shares of common stock offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980).

Switzerland

The shares of common stock offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The company has not applied for a listing of the shares of common stock being offered pursuant to this prospectus on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The shares of common stock being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of shares of common stock.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in shares of common stock.

European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom, each referred to as a Relevant State, no shares of common stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of shares of common stock may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

Table of Contents

provided that no such offer of shares of common stock shall require us or any of underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares of common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares of common stock being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

We, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the United Kingdom, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d), or high net worth companies, unincorporated associations etc., of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or FSMA,) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

LEGAL MATTERS

The validity of the securities being offered in this offering will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

EXPERTS

The consolidated financial statements of Ayala Pharmaceuticals, Inc. appearing in Ayala Pharmaceuticals, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2021 and incorporated herein by reference, have been audited by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements). Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the SEC. The SEC maintains a web site that contains reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is <http://www.sec.gov>.

Our web site address is <https://www.ayalapharma.com>. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith or the documents incorporated by reference herein. For further information about us and the common stock and warrants offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto and to the documents incorporated by reference herein. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement or to a document incorporated by reference herein are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement or a document incorporated by reference herein.

INCORPORATION BY REFERENCE

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus incorporates by reference the documents set forth below that have previously been filed with the SEC:

- our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2021, filed with the SEC on March 28, 2022;
- our [Definitive Proxy Statement](#) on Schedule 14A, filed with the SEC on April 27, 2022;
- our Quarterly Report on [Form 10-Q](#) for the quarterly period ended March 31, 2022, filed with the SEC on May 16, 2022; and
- our Current Reports on Form 8-K filed with the SEC on [June 3, 2022](#), [June 14, 2022](#) and [July 5, 2022](#).

For so long as we are a smaller reporting company, all reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange prior to the termination of this offering, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

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

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus or any accompanying prospectus supplement. You may also access any of the documents incorporated by reference in this prospectus by visiting our web address at <https://www.ayalapharma.com>. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

Shares of Common Stock
Warrants to Purchase **Shares of Common Stock**



PROSPECTUS

Sole Book-Running Manager

Oppenheimer & Co.

, 2022

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses in connection with the issuance and distribution of the securities being registered (excluding the underwriting discount). Except for the Securities and Exchange Commission registration fee and the FINRA filing fee, all amounts are estimates.

	<u>Amount Paid or to be Paid</u>
SEC registration fee	\$ 2,781.00
FINRA filing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing expenses	*
Transfer agent fees and expenses	*
Miscellaneous	*
Total	<u> </u>

* To be completed by amendment

Each of the amounts set forth above, other than the SEC registration fee and FINRA filing fee, is an estimate.

Item 14. Indemnification of Directors and Officers.

Subsection (a) of Section 145 of the General Corporation Law of the State of Delaware, or the DGCL, empowers a corporation to indemnify any person who was or is a party or who is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Subsection (b) of Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person acted in any of the capacities set forth above, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Section 145 further provides that to the extent a director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against

Table of Contents

expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith; that indemnification provided for by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and the indemnification provided for by Section 145 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person's heirs, executors and administrators. Section 145 also empowers the corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

Section 102(b)(7) of the DGCL provides that a corporation's certificate of incorporation may contain a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit.]

Any underwriting agreement or distribution agreement that the registrant enters into with any underwriters or agents involved in the offering or sale of any securities registered hereby may require such underwriters or dealers to indemnify the registrant, some or all of its directors and officers and its controlling persons, if any, for specified liabilities, which may include liabilities under the Securities Act of 1933, as amended.

Our restated certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

Table of Contents

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 15. Recent Sales of Unregistered Securities

The following is a summary of transactions during the preceding three fiscal years involving sales of our securities that were not registered under the Securities Act.

In February and May 2019, we issued 653,331 shares of Series B Preferred Stock for a total amount of \$5.2 million, at a price equal to \$7.91 per share to accredited investors, pursuant to Section 4(a)(2) of the Securities Act or Rule 506 as a transaction not involving a public offering.

In May 2020, we granted stock options to purchase 47,299 shares of common stock and issued 58,561 additional shares of common stock pursuant to restricted stock grants to certain of our executive officers and employees for a total amount of \$1.59 million, each at an exercise price of \$15.00 per share in connection with services provided to us, pursuant to Rule 701.

In February 2021, we (i) sold an aggregate of 333,333 shares of our common stock, together with warrants to purchase an aggregate of 116,666 shares of common stock with an exercise price of \$18.10 per share, for an aggregate purchase price of \$4,999,995.00 to accredited investors; and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of common stock with an exercise price of \$0.01 per share, together with an aggregate of 466,666 warrants to purchase common stock, for an aggregate purchase price of \$19,986,661.67 to accredited investors, pursuant to Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
1.1**	Form of Underwriting Agreement.
3.1	Restated Certificate of Incorporation of Ayala Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 12, 2020).
3.2	Amended and Restated Bylaws of Ayala Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the SEC on May 12, 2020).
4.1	Specimen Stock Certificate Evidencing the Shares of Common Stock (incorporated by reference to the Amendment to the Company's Registration Statement on Form S-1/A, filed with the SEC on May 4, 2020).
4.2	Form of Common Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on February 22, 2021).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on February 22, 2021).

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
4.4	Form of Indenture (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-3 filed with the SEC on June 4, 2021).
4.5**	Form of Common Stock Warrant.
4.6	Amended and Restated Investors' Rights Agreement (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
5.1**	Opinion of Latham & Watkins LLP.
10.1	Amended 2017 Stock Incentive Plan and form of agreements thereunder (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
10.2	Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
10.3	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
10.4	Lease Agreement, dated January 24, 2019, between Ayala-Oncology Israel Ltd. and Ogen Real Estate Maniv Ltd. (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1 filed with the SEC on March 6, 2020).
10.5	Employment Agreement, dated December 26, 2017, between Ayala-Oncology Israel Ltd. and Roni Mamluk, Ph.D., as amended (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on March 6, 2020).
10.6	Employment Agreement, dated March 15, 2019, between Ayala-Oncology Israel Ltd. and Yossi Maimon, CPA, M.B.A., as amended (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed with the SEC on March 6, 2020).
10.7	Employment Agreement, dated July 24, 2019, between the Registrant and Bristol-Myers Squibb Company, as amended (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
10.8*	License Agreement, dated November 29, 2017, between the Registrant and Bristol-Myers Squibb Company, as amended (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1/A filed with the SEC on May 4, 2020).
10.9	Securities Purchase Agreement, dated February 19, 2021, by and among Ayala Pharmaceuticals, Inc. and the Investors named therein. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 22, 2021).
21.1	Subsidiaries of Ayala Pharmaceuticals, Inc. (incorporated by reference to Exhibit 21.1 of the Company's Registration Statement on Form S-1 filed with the SEC on March 6, 2020).
23.1**	Consent of Latham & Watkins LLP (included in Exhibit 5.1).
23.2	Consent of Ernst & Young Global.
24.1	Powers of Attorney (incorporated by reference to the signature page hereto).
107	Filing Fee table.

* Portions of this exhibit have been redacted in accordance with Regulation S-K Item 601(b)(10).

** To be filed by amendment.

(b) Financial Statement Schedules

All financial statement schedules have been omitted because they are not required or because the required information is given in the financial statements or notes to those statements.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Rehovot, Israel, on July 8, 2022.

AYALA PHARMACEUTICALS, INC.

By: /s/ Roni Mamluk

Roni Mamluk, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

Each of the undersigned officers and directors of the registrant hereby severally constitutes and appoints Roni Mamluk and Yossi Maimon, or either of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, and in any and all capacities, to file and sign any and all amendments, including post-effective amendments, to this registration statement and any other registration statement for the same offering that is to be effective under Rule 462(b) of the Securities Act of 1933, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney shall be governed by and construed with the laws of the State of Delaware and applicable federal securities laws.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Roni Mamluk</u> Roni Mamluk, Ph.D.	Chief Executive Officer and Director <i>(principal executive officer)</i>	July 8, 2022
<u>/s/ Yossi Maimon</u> Yossi Maimon	Chief Financial Officer <i>(principal financial officer and principal accounting officer)</i>	July 8, 2022
<u>/s/ David Sidransky</u> David Sidransky, M.D.	Chairman of the Board of Directors	July 8, 2022
<u>/s/ Vered Bisker-Leib</u> Vered Bisker-Leib, Ph.D.	Director	July 8, 2022
<u>/s/ Murray A. Goldberg</u> Murray A. Goldberg	Director	July 8, 2022
<u>/s/ Robert Spiegel</u> Robert Spiegel, M.D.	Director	July 8, 2022

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption “Experts” in this Registration Statement on Form S-1 and the related Prospectus of Ayala Pharmaceuticals, Inc. and to the incorporation by reference herein of our report dated March 28, 2022, with respect to the consolidated financial statements of Ayala Pharmaceuticals, Inc. (which contains an explanatory paragraph describing conditions that raise substantial doubt about the company’s ability to continue as a going concern as described in Note 1 to the consolidated financial statements), included in its Annual Report (Form 10-K) for the year ended December 31, 2021, filed with the Securities and Exchange Commission.

/s/ Kost Forer Gabbay & Kasierer
A Member of Ernst & Young Global

Tel-Aviv, Israel
July 08, 2022

Calculation of Filing Fee Tables

Form S-1

(Form Type)

Ayala Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees to Be Paid	Equity	Common Stock, \$0.01 par value per share	457(o)	—	—	\$15,000,000.00 ⁽¹⁾	0.0000927	\$1,390.50
Fees to Be Paid	Other	Warrants to purchase shares of Common Stock ⁽³⁾	Other	—	—	— ⁽³⁾	—	— ⁽³⁾
Fees to Be Paid	Equity	Common Stock, \$0.01 par value per share, issuable upon exercise of the Warrants ⁽²⁾	457(o)	—	—	\$15,000,000.00 ⁽¹⁾	0.0000927	\$1,390.50
Fees Previously Paid	—	—	—	—	—	—	—	—
	Total Offering Amounts					\$30,000,000.00		\$2,781.00
	Total Fees Previously Paid							—
	Total Fee Offsets							—
	Net Fee Due							\$2,781.00

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the “Securities Act”).

(2) Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(3) No separate registration fee required pursuant to Rule 457(g) of the Securities Act.