

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): November 10, 2022

Ayala Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39279
(Commission
File Number)

82-3578375
(IRS Employer
Identification No.)

Oppenheimer 4
Rehovot, Israel 7670104
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (857) 444-0553

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	AYLA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 10, 2022, Ayala Pharmaceuticals, Inc. (the “Company”) received written notice (the “Equity Notice”) from The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that the Company’s stockholders’ equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the “Form 10-Q”), did not satisfy the continued listing requirement under Nasdaq Listing Rule 5450(b)(1)(A) for the Nasdaq Global Market, which requires that a listed company’s stockholders’ equity be at least \$10 million. As reported on its Form 10-Q, the Company’s stockholders’ equity as of September 30, 2022 was approximately \$8.16 million. Additionally, on November 16, 2022, the Company received written notice (the “Bid Price Notice” and, together with the Equity Notice, the “Notices”) from Nasdaq notifying the Company that, for the last 30 consecutive business days, the bid price for the Company’s common stock had closed below the \$1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the “Bid Price Requirement”).

The Notices have no immediate effect on the listing or trading of the Company’s common stock on the Nasdaq Global Market and the Company’s common stock will continue to trade under the symbol “AYLA”.

With respect to the Equity Notice, and in accordance with Nasdaq Listing Rules, the Company has 45 calendar days from the date of the Equity Notice, or until December 27, 2022, to submit a plan to regain compliance with Nasdaq Listing Rule 5450(b)(1)(A). If the Company’s compliance plan is accepted by Nasdaq, then Nasdaq may, in its discretion, grant the Company up to 180 calendar days from the date of the Equity Notice, or until May 9, 2023, to evidence compliance. If Nasdaq does not accept the Company’s plan, then the Company will have the opportunity to appeal that decision to a Nasdaq Hearings Panel.

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

If the Company does not regain compliance with the Bid Price Requirement by May 15, 2023, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company would need to transfer the listing of the Common Stock to the Nasdaq Capital Market, provided that it meets the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, the Company would also need to pay an application fee to Nasdaq and will need to provide written notice to the Staff of its intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, the Staff will make a determination of whether it believes the Company will be able to cure this deficiency.

The Company is currently evaluating various alternative courses of action, including transferring to the Nasdaq Capital Market, or submitting to Nasdaq a plan to regain compliance with the Nasdaq Global Market listing requirements before December 27, 2022. However, there can be no assurance that the Company will be able to satisfy the Nasdaq Capital Market’s continued listing requirements, regain compliance with the minimum stockholders’ equity requirement or the Bid Price Requirement, or maintain compliance with the other listing requirements.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the Company’s intent or ability to transfer the listing of its common stock to the Nasdaq Capital Market,

its intent or ability to submit a plan regarding regaining compliance with the Nasdaq Global Market listing requirements, and its intent or ability to regain compliance with Nasdaq listing requirements. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties and other important factors, including the risks that the Company may not be able to satisfy Nasdaq listing requirements, the Company may not be able to meet the minimum stockholders' equity requirement by May 9, 2023 or in the future, the Company may not be able to meet the Bid Price Requirement by May 15, 2023 or in the future, Nasdaq may not grant the Company relief from delisting if necessary, and the Company may not ultimately meet applicable Nasdaq requirements if any such relief is necessary, among other risks and uncertainties. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's most recent annual report on Form 10-K and the Company's quarterly reports on Form 10-Q filed with the Securities and Exchange Commission. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in its expectations.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ayala Pharmaceuticals, Inc.

Date: November 17, 2022

By: /s/ Roni Mamluk
Roni Mamluk, Ph.D.
Chief Executive Officer and President