

**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): March 25, 2024

Ayala Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36138

(Commission
File Number)

84-1521955

(IRS Employer
Identification No.)

**9 DEER PARK DRIVE, SUITE K-1
MONMOUTH JUNCTION, New Jersey**

(Address of principal executive offices)

08852

(Zip code)

Registrant's telephone number, including area code (732) 545-1590

Not Applicable

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

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class

Trading Symbol(s)

Name of each exchange on which registered

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 (see General Instruction A.2. below):

- 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))

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 2.01. Completion of Acquisition or Disposition of Assets.**Sale of Assets to Immunome, Inc.**

On February 5, 2024, Ayala Pharmaceuticals, Inc., a Delaware corporation (the “Company”), and Immunome, Inc. (“Purchaser”), entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) pursuant to which Purchaser agreed to acquire, and the Company agreed to sell, certain of the Company’s assets and liabilities related to its AL101 and AL102 programs (the “Asset Sale”), which constitute substantially all of the Company’s assets.

On March 25, 2024, the Company and Purchaser consummated the Asset Sale pursuant to the Asset Purchase Agreement, such that Purchaser (i) paid an upfront purchase price of \$20.0 million in cash to the Company, less certain adjustments, (ii) issued the Company 2,175,489 shares of Immunome’s common stock (the “Shares”), (iii) assumed specified liabilities from the Company, and (iv) reimbursed the Company for certain costs incurred by the Company associated with the assets being purchased. Purchaser may pay the Company up to \$37.5 million after the Asset Purchase Closing upon the achievement of certain development and commercial milestones.

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

The foregoing description of the Asset Purchase Agreement and the transactions contemplated by the Asset Purchase Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Asset Purchase Agreement, which was previously filed as Exhibit 2.1 to the Registrant’s Current Report on Form 8-K filed on February 6, 2024 with the Securities and Exchange Commission and is incorporated by reference herein.

Item 3.02. Unregistered Sales of Equity Securities.

As previously disclosed, on March 1, 2024, the Company issued Senior Convertible Promissory Notes (collectively, the “March 1 Convertible Notes”), in an aggregate amount of \$2.0 million, to several existing lenders and investors in the Company, including Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. and Biotel Limited. The March 1 Convertible Notes were convertible into shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), at any time at the option of the noteholders, and subject to mandatory conversion upon certain events, including a Change of Control Transaction, as defined in the March 1 Convertible Notes, at a conversion price equal to the lower of (i) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Conversion, subject to certain adjustments. In connection with the issuance of the March 1 Convertible Notes, the Company also issued to the noteholders warrants (the “Warrants”) to purchase an aggregate of 7,500,000 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis.

In connection with the closing of the Asset Sale, on March 25, 2024, March 1 Convertible Notes were automatically converted in full utilizing a conversion price equal to 50% of the Common Stock’s price per share as of market close on March 22, 2024. As a result, an aggregate of 6,666,666 shares of Common Stock were issued by the Company to the noteholders and pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, afforded by Section 4(a)(2) thereof, for the sale of securities not involving a public offering

Item 7.01. Regulation FD Disclosure.

On March 25, 2024, the Company and Purchaser issued a joint press release announcing the execution of the Asset Purchase Agreement. A copy of that press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the foregoing information, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall such information, including Exhibit 99.1, be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward-Looking Statement

The statement contained in this Form 8-K that Purchaser may pay the Company up to \$37.5 million after the Asset Purchase Closing upon the achievement of certain development and commercial milestones may be considered a forward-looking statement, as such involving a number of risks and uncertainties, including. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, risks and uncertainties related to: the potential benefit of the Asset Sale and whether the milestones relating to such potential payments will be realized, which will depend on factors such as Purchaser’s ability to grow and successfully execute on its business plan, including the development and commercialization of the AL101 and AL102 programs. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 – Financial Statements and Exhibits.**(b) Pro forma financial information.**

The Company intends to amend this Current Report on Form 8-K to include the pro forma financial information related to the Asset Sale promptly after it files its Annual Report on Form 10-K for the year ended December 31, 2023.

(d) Exhibits

Exhibit Number	Description
2.1+†	Asset Purchase Agreement, dated as of February 5, 2024, by and between Ayala Pharmaceuticals, Inc. and Immunome, Inc. (incorporated by Reference to Exhibit 2.1 to the Current Report on Form 8-K of the Registrant, filed with the SEC on February 6, 2024).
99.1	Press release dated March 25, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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

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

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.

March 29, 2024

AYALA PHARMACEUTICALS, INC.

By: /s/ Kenneth A. Berlin

Name: Kenneth A. Berlin

Title: President and Chief Executive Officer

Ayala Pharmaceuticals Announces Completion of Sale of AL102 to Immunome

MONMOUTH JUNCTION, NJ, March 26, 2024 – Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced the completion of the previously announced sale of AL102, and related drug candidate AL101, to Immunome, Inc. (Nasdaq: IMNM).

As per the terms of the sale, Ayala received from Immunome \$20 million in cash and 2,175,489 shares of Immunome common stock, and Immunome assumed specified liabilities related to AL102. Ayala may also receive up to an additional \$37.5 million in development and commercial milestone payments.

“We are pleased that AL102 will now be advanced by the highly experienced team at Immunome,” said Ken Berlin, President and CEO of Ayala Pharmaceuticals. “I am deeply grateful to the team at Ayala for the work they have done over the last several years to assemble compelling clinical data and reach this point.”

A.G.P./Alliance Global Partners acted as strategic advisor to Ayala Pharmaceuticals, Inc. in connection with the transaction.

About Ayala Pharmaceuticals, Inc.

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company with expertise in developing small molecule therapeutics for rare tumors and aggressive cancers. Following the completed sale of AL102, an oral gamma secretase inhibitor in Phase 3 clinical development, and AL 101 to Immunome, Inc., Ayala's clinical assets include aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). For more information, visit www.ayalapharma.com.

Cautionary Statement Regarding Forward-Looking Statements

The statement contained in this release that Ayala may receive up to \$37.5 million after the consummation of the sale of AL 102 to Immunome upon the achievement of certain development and commercial milestones may be considered a forward-looking statement, as such involving a number of risks and uncertainties. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, risks and uncertainties related to: the potential benefit of the sale to Immunome and whether the milestones relating to such potential payments will be realized, which will depend on factors such as Immunome's ability to grow and successfully execute on its business plan, including the development and commercialization of the AL101 and AL102 programs. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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