

**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): January 4, 2023

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 8.01. Other Events.

As previously announced, on October 18, 2022, Ayala Pharmaceuticals, Inc. (“Ayala”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Advaxis, Inc., a Delaware corporation (“Advaxis”), and Doe Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Advaxis (“Merger Sub”), pursuant to which Merger Sub will merge with and into Ayala, with Ayala as the surviving corporation and a wholly-owned subsidiary of Advaxis (the “Merger”). On December 12, 2022, Ayala filed a definitive proxy statement on Schedule 14A (the “Proxy Statement”) with the U.S. Securities and Exchange Commission (the “SEC”) relating to the special meeting of Ayala’s stockholders to approve certain matters related to the Merger, which will be held on January 13, 2023.

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

The Complaint asserts claims against all defendants under Section 14(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Rule 14a-9 promulgated thereunder for omitting or misrepresenting material information from Ayala’s Proxy Statement and against the individual defendants under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such alleged omissions and misrepresentations. The allegations in the Complaint include that the Proxy Statement omitted material information regarding Ayala’s financial projections and Torreya’s financial analyses. The Complaint seeks, among other relief, (1) to enjoin defendants from consummating the Merger; (2) to enjoin a vote on the Merger; (3) to rescind the Merger Agreement or recover damages, if the Merger is completed; (4) a declaration that defendants violated Sections 14(a) or 20(a) and Rule 14a-9 of the Exchange Act; and (5) attorneys’ fees and costs.

In addition, as of the date of this Current Report on Form 8-K, nine purported Ayala stockholders sent letters to those noted in the above-referenced Complaint alleging similar deficiencies in Ayala’s Proxy Statement (collectively, the “Demand Letters”).

Ayala believes that the Proxy Statement complies fully with all applicable law and that the allegations in the Complaint and the Demand Letters are without merit. Additional lawsuits arising out of the Merger may be filed in the future. No assurances can be made as to the outcome of such lawsuits, the Complaint or the Demand Letters.

Supplemental Proxy Statement Disclosure

Ayala does not believe, with respect to the Complaint or Demand Letters, that supplemental disclosures are required or necessary under applicable laws or that any information contained herein is material. However, solely to moot the unmeritorious disclosure claims and minimize the risk, costs, burden, nuisance and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, Ayala is electing to make the supplemental disclosures to the Proxy Statement set forth below in response to the Complaint and Demand Letters. These supplemental disclosures should be read in conjunction with, and incorporated by reference into, the Proxy Statement. Ayala denies the allegations in the Complaint and Demand Letters, and denies any violation of law. Ayala believes that the Proxy Statement disclosed all material information required to be disclosed therein, and denies that the supplemental disclosures are material or are otherwise required to be disclosed. Nothing in the supplemental disclosures should be deemed an admission of the legal necessity or materiality of any supplemental disclosures under applicable laws.

SUPPLEMENT TO PROXY STATEMENT/PROSPECTUS

*This supplemental information should be read in conjunction with the Proxy Statement, which should be read in its entirety. Page references in the below disclosures are to the pages in the Proxy Statement, and defined terms used but not defined herein have the meanings set forth in the Proxy Statement. Without admitting in any way that the disclosures below are material or otherwise required by law, Ayala makes the following amended and supplemental disclosures. For clarity, new text within the amended or amended and restated portions of the Proxy Statement is highlighted with **bold, underlined text**, and deleted text is denoted with a strikethrough.*

The section of the Proxy Statement entitled “The Merger” is amended and supplemented as follows:

The disclosure on page 141 of the Proxy Statement below the subheading “Background of the Merger” is amended and supplemented by amending and restating the second paragraph under the subheading as follows:

On May 11, 2022, the Ayala Board held a meeting, together with members of Ayala’s management and representatives of Ernst & Young Global (“Ernst & Young”) and Latham & Watkins LLP (“Latham”). At the meeting, among other items, members of Ayala’s management discussed the company’s cash balance and projected cash runway and representatives of Oppenheimer & Co. Inc. (“Oppenheimer”) joined the meeting to provide a market update and discuss the potential for an equity financing. The Ayala Board then discussed the potential engagement of (i) Oppenheimer as a financial advisor for a potential equity financing and (ii) Torrey Capital, LLC (“Torrey”) for financial and strategic advice. After such discussion, the Ayala Board approved the engagement of Oppenheimer. **Ayala did not pay Oppenheimer any fee in connection with the proposed equity financing because it was not consummated, but Ayala reimbursed Oppenheimer for its legal expenses. Oppenheimer served as an underwriter of Ayala’s initial public offering in 2020, for which it received its share of the \$1.05 per share underwriting discount, and expense reimbursement to the extent set forth in the underwriting agreement. Other than these engagements, Oppenheimer has not been engaged to provide financial advisory or other services to Ayala during the preceding two years. In late 2021, Oppenheimer had been among the investment banks to advise Advaxis in connection with a proposed offering of securities of Advaxis, which was announced in November 2021 but not ultimately consummated as the conditions precedent to such offering were not satisfied.**

The disclosure on page 142 of the Proxy Statement below the subheading “Background of the Merger” is amended and supplemented by amending and restating the first paragraph on page 142 as follows:

Throughout July 2022, Torrey Capital contacted 95 companies that included strategic buyers, publicly listed biotechnology companies that had more cash than required for their existing or failed pipelines (“Cash Shells”), and privately owned companies that were interested in a merger with a public company in order to expand their drug development pipelines and become listed on Nasdaq. Even with Ayala’s low share price during this period, interest from strategic buyers and privately owned companies was limited. As a result and given Ayala’s diminished cash runway, Ayala and Torrey Capital prioritized Cash Shells that could sustain Ayala’s operations through its next milestone event. During July, Ayala entered into non-disclosure agreements with six companies. **Three of the non-disclosure agreements did not include a standstill provision, and three of the non-disclosure agreements contained a customary standstill provision, including a “don’t ask don’t waive” provision, but permitted a party to make a confidential proposal to the other party’s board following such other party’s announcement of a business combination transaction.** Each company conducted diligence by holding a call with Ayala’s management at which Ayala’s business was discussed and reviewing Ayala’s publicly available filings with the SEC and other publicly available documents. One was a private company, which terminated discussions after an introductory call with Ayala in order to pursue its own fundraising activities. ~~Four~~ **Three** of the companies, after analysis of Ayala and its programs, indicated that they were not interested in a merger transaction, but might be interested in regional licensing transactions that would require several months to complete.

The disclosure on page 150 of the Proxy Statement below the subheading “Background of the Merger” is amended and supplemented by amending and restating the second paragraph on page 150 as follows:

In addition to the foregoing, at the meeting, the Ayala Board reviewed and discussed Letter Agreements to be entered into with Dr. Mamluk, Mr. Maimon and Dr. Gordon. Under the terms of the Letter Agreements with Dr. Mamluk and Mr. Maimon, each agreed, among other things, that his or her employment would terminate immediately following the closing of the Merger and that each would be entitled to certain cash severance payments and the acceleration of all unvested equity awards. The Letter Agreement with Dr. Gordon provided for certain severance benefits upon his termination without cause or his resignation for justified reason within 12 months following the closing of the Merger. For a detailed discussion of the Letter Agreements, please see “—Interests of Ayala Directors and Executive Officers in the Merger—Executive Officer Employment Agreements” beginning on page 172 of this proxy statement/prospectus. Following discussion, the Ayala Board unanimously approved the Letter Agreements. **No other post-closing employment arrangements for members of Ayala senior management were negotiated with, or secured by, Advaxis.**

The disclosure on page 164 of the Proxy Statement below the subheading “Opinion of Ayala’s Financial Advisor–Torreya Capital, LLC — Summary of Financial Analysis by Torreya — Discounted Cash Flow Analysis” is amended and supplemented by amending and restating the second paragraph under the subheading in its entirety as follows:

The free cash flow analysis assumed a starting net operating loss balance based on Ayala’s operating losses incurred to date of \$130 million as of December 31, 2022 and forecasts negative cash flow through 2026 of approximately \$100 million. To finance these losses, Torreya projected financing fees and other transaction expenses of \$10 million. Torreya also assumed a 20% discount on the current share price for each share offered as part of the hypothetical financing. Torreya then discounted the projected free cash flows for fiscal years ending December 31, 2023, through 2033 for Ayala using a discount rate of 12% based on the share price and managements forecast, **and no terminal value**. The DCF analysis resulted in estimated total enterprise value of Ayala of \$394 million. While Torreya recognized the implied enterprise value of Ayala indicated by the DCF analysis, Torreya considered (1) that the DCF analysis does not consider market sentiment where approximately 200 US-listed biotech companies are trading below their own cash amounts and (2) the Ayala Projections are not achievable without significant additional funding to bring Ayala through 2026. Ayala ran a full financing process in the first half of 2022 and was unable to find a viable source of any financing to bring Ayala through 2026, leading Ayala to search for a strategic alternative to unlock its intrinsic value.

The disclosure on page 166 of the Proxy Statement below the subheading “Opinion of Ayala’s Financial Advisor–Torreya Capital, LLC — Summary of Financial Analysis by Torreya — Comparable Transactions Analysis” is amended and supplemented by amending and restating the table under the subheading in its entirety as follows:

Announced Date	Closing Date	Transaction	AssetCo	AssetCo Cash (m)	AssetCo Cash as % of combined total	AssetCo Ownership %
Mergers where AssetCo cash amount strongly influenced relative ownership post-merger						
Jul-5-22	Sep-15-22	Syros-Time	Syros	\$ 50	45%	46%
Sep-6-22	Merger agreement terminated on Dec-23-22	Equillium-Metacrine	Equillium	\$ 24	48%	75%
Sep-28-22	Not yet completed	Aceragen-Idera	Aceragen	\$ 17	63%	67%
Mergers where AssetCo cash show limited correlation to relative ownership post-merger						
Jul-21-22	Nov-8-22	ARS-Silverback	ARS	\$ 25	9%	63%
Apr-27-22	Sep-15-22	Cend-Caladrius	Cend	\$ 17	27%	50%
Sep-21-22	Not yet completed	Carisma-Sesen	Carisma	\$ 38	21%	58%

The disclosure on page 166 of the Proxy Statement below the subheading “Opinion of Ayala’s Financial Advisor–Torreya Capital, LLC — Summary of Financial Analysis by Torreya — Miscellaneous” is amended and supplemented by adding the following sentence to the end of the first paragraph:

During the two years preceding the date of the Torreya Opinion, Torreya has not been engaged to provide financial advisory services or other services to Advaxis, and Torreya has not received any compensation from Advaxis during such period.

The disclosure on page 167 of the Proxy Statement below the subheading “Certain Prospective Financial Information of Advaxis; Certain Adjustments by Advaxis to Financial Information of Ayala—Adjustments by Advaxis to Certain Summary Projected Financial Information of Ayala” is amended and supplemented by amending and restating the first paragraph under the subheading in its entirety as follows:

The Ayala projections, as prepared by Ayala management and set forth below under “The Merger—Certain Prospective Financial Information of Ayala,” were adjusted by Advaxis management to reflect reductions in projected revenues relating to its assessment of the commercial potential and probability of success for Ayala’s lead product candidates **based on the views of Advaxis management as to the probability of technical and regulatory success for drugs similar to such product candidates**, as shown in the table below, for purposes of Cantor Fitzgerald’s financial analyses described above in “The Merger—Opinion of Advaxis’ Financial Advisor—Cantor Fitzgerald”.

The disclosure on page 169 of the Proxy Statement below the subheading “Certain Prospective Financial Information of Ayala — Summary of the Ayala Projections” is amended and supplemented by amending and restating the first paragraph and table under the subheading in their entirety as follows:

Set forth below is a summary of the Ayala Projections. The Ayala Projections reflect: (1) Ayala management’s assessment of the commercial potential and probability of success for Ayala’s lead product candidates, **which was estimated to be 30% for AL101 and 60% for AL102**; (2) Ayala’s existing and future net operating loss, or NOL, carryforwards, estimated using a starting NOL balance as of January 1, 2022 of \$130 million; (3) Ayala’s estimated cost of goods and operational costs, including research and development and general and administrative costs; (4) a tax rate of 21% for Ayala; (5) estimated royalties and milestone payments for Ayala and (6) capital expenditure and working capital estimates for Ayala.

(\$ in millions)	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
AL101 Revenue	0	0	6	13	28	35	43	45	45	45	45
AL102 Revenue	0	0	6	13	37	79	128	173	212	243	255
Total Revenue	0	0	3	26	65	115	171	218	247	288	300
Total Cost of Goods Sold	0	0	0	1	2	4	6	9	11	13	14
Gross Profit	0	0	6	25	63	111	165	210	246	275	286
Operating Expenses:											
AL101 Research & Development	9	9	1	1	0	0	0	0	0	0	0
AL102 Research & Development	19	21	7	3	0	0	0	0	0	0	0
Selling, General & Administrative	10	10	14	17	26	31	32	40	45	50	52
Royalty to BMS	0	0	1	2	6	10	15	20	24	28	29
Milestones to BMS	0	0	4	8	0	5	0	6	0	0	0
EBIT⁽¹⁾	(37)	(40)	(21)	(6)	31	65	117	144	176	198	205
Taxes (NOL-adj) ⁽²⁾	0	0	0	0	1	3	5	8	37	42	43
Net Income	(37)	(40)	(21)	(6)	30	62	112	136	139	156	162
EBIT⁽¹⁾	(37)	(40)	(21)	(6)	31	65	117	144	176	198	205
Taxes (NOL-adj) ⁽²⁾	0	0	0	0	1	3	5	8	37	42	43
Capital Expenditures	2	2	1	1	1	1	1	1	1	0	0
Changes in Working Capital	0	0	1	2	4	5	6	5	4	3	1
Free Cash Flow ⁽³⁾	(35)	(38)	(21)	(7)	27	58	107	132	136	153	162

(1) EBIT is defined as Ayala’s revenues, less cost of goods sold and operating expenses.

(2) **Assumes a net operating loss starting balance of \$130 million as of December 31, 2022.**

(3) Free cash flow is defined as Ayala’s EBIT **plus less** tax expense (NOL adjusted), **capital expenditures** and **depreciation and amortization, less** increases in net working capital.

Important Information about the Merger and Where to Find It

This communication relates to a proposed transaction between Ayala Pharmaceuticals, Inc. (“Ayala”) and Advaxis, Inc. (“Advaxis”). In connection with the proposed transaction, Advaxis filed with the Securities and Exchange Commission (“SEC”) a registration statement on Form S-4 that includes a proxy statement of Ayala and that constitutes a prospectus with respect to shares of Advaxis’s common stock to be issued in the proposed transaction (“Proxy Statement/Prospectus”). Each of Ayala and Advaxis may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the Proxy Statement/Prospectus or any other document which Ayala or Advaxis may file with the SEC. INVESTORS, AYALA STOCKHOLDERS AND ADVAXIS STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT ARE OR WILL BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors, Ayala stockholders and Advaxis stockholders will also be able to obtain free copies of the Proxy Statement/Prospectus and other documents containing important information about Ayala, Advaxis and the proposed transaction that are or will be filed with the SEC by Ayala or Advaxis through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Advaxis will also be available free of charge on Advaxis’s website at <https://www.advaxis.com/financial-information/sec-filings> or by contacting Advaxis’s investor relations department by email at ir@advaxis.com. Copies of the documents filed with the SEC by Ayala will also be available free of charge at <https://ir.ayalapharma.com/financial-information/sec-filings> or by contacting Ayala’s investor relations department by email at jallaire@lifesciadvisors.com.

Participants in the Solicitation

Ayala and Advaxis and certain of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information regarding Ayala’s directors and executive officers, including a description of their direct or indirect interests, by security holdings or otherwise, is contained in Ayala’s proxy statement for its 2022 annual meeting of stockholders which was filed with the SEC on April 27, 2022. Information regarding Advaxis’s directors and executive officers, including a description of their direct or indirect interests, by security holdings or otherwise, is contained in Advaxis’s proxy statement for its 2022 annual meeting of stockholders which was filed with the SEC on February 28, 2022. Additional information regarding the direct and indirect interests of the participants in the solicitation of proxies in connection with the proposed transaction, including the interests of Ayala and Advaxis directors and executive officers in the transaction, which may be different than those of Ayala and Advaxis stockholders generally, is contained in the Proxy Statement/Prospectus and any other relevant documents that are or will be filed with the SEC relating to the transaction. You may obtain free copies of these documents using the sources indicated above.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to sell or the solicitation of an offer to buy or sell any securities or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the proposed transaction involving Ayala and Advaxis and related transactions, their ability to consummate the proposed transaction, and the timing for closing of the proposed transaction. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “anticipate,” “plan,” “likely,” “believe,” “estimate,” “project,” “intend,” and other similar expressions among others. Statements that are not historical facts are forward-looking statements. 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: (i) the risk that the conditions to the closing of the proposed transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the proposed transaction or the failure to timely or at all obtain any required regulatory clearances; (ii) uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Ayala and Advaxis to consummate the proposed transaction; (iii) the ability of Ayala and Advaxis to integrate their businesses successfully and to achieve anticipated synergies; (iv) the possibility that other anticipated benefits of the proposed transaction will not be realized, including without limitation, anticipated revenues, expenses, earnings and other financial results, and growth and expansion of the combined company's operations, and the anticipated tax treatment of the combination; (v) potential litigation relating to the proposed transaction that could be instituted against Ayala, Advaxis or their respective directors; (vi) possible disruptions from the proposed transaction that could harm Ayala's and/or Advaxis's respective businesses; (vii) the ability of Ayala and Advaxis to retain, attract and hire key personnel; (viii) potential adverse reactions or changes to relationships with customers, employees, suppliers or other parties resulting from the announcement or completion of the proposed transaction; (ix) potential business uncertainty, including changes to existing business relationships, during the pendency of the proposed transaction that could affect Ayala's or Advaxis's financial performance; (x) certain restrictions during the pendency of the proposed transaction that may impact Ayala's or Advaxis's ability to pursue certain business opportunities or strategic transactions; (xi) legislative, regulatory and economic developments; (xii) unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as management's response to any of the aforementioned factors; and (xiii) such other factors as are set forth in Ayala's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Ayala's Form 10-K for the fiscal year ended December 31, 2021, and Advaxis's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Advaxis's Form 10-K for the fiscal year ended October 31, 2021. Ayala can give no assurance that the conditions to the proposed transaction will be satisfied. Except as required by applicable law, Ayala 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.

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: January 4, 2023

By: /s/ Roni Mamluk

Roni Mamluk, Ph.D.

Chief Executive Officer and President