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This filing relates to a proposed business combination involving Ayala Pharmaceuticals, Inc. and Advaxis, Inc.

Ayala Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 4, 2022

Entered into a definitive merger agreement with Advaxis Inc. – transaction expected to close by end of Q1 2023, subject to approval by Ayala's shareholders and the satisfaction of customary closing conditions

Interim positive data from Part A of the RINGSIDE study presented at ESMO demonstrated substantial anti-tumor activity for AL102 as monotherapy and supports continued development

AL102 granted Fast Track designation by U.S. FDA for the treatment of progressing desmoid tumors

REHOVOT, Israel and WILMINGTON, Del., Nov. 04, 2022 (GLOBE NEWSWIRE) — Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers, today announced third-quarter 2022 financial results and provided a corporate update.

"Our team looks forward to completing the recently announced merger with Advaxis which we believe will complement our pipeline. Importantly, we believe that the consummation of the merger will provide us with the financial resources to advance development of AL102 for desmoid tumors and enable an enhanced presence in the United States," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. "We remain focused on the continued development of our candidates AL102 and AL101. We had an opportunity to share the very promising interim results from Part A of the ongoing RINGSIDE study of AL102 with the broader oncology community at ESMO. We look forward to reporting longer-term data in 2023 and to executing on Part B, the randomized Phase 3 portion of RINGSIDE."

Third-quarter 2022 and Recent Business Highlights

- **In October, Ayala announced a definitive agreement to merge with Advaxis, Inc.:** The merger would result in a combined company that will focus on the development and commercialization of Ayala's lead program AL102 for the treatment of desmoid tumors. Ayala stockholders will own approximately 62.5% of the combined company's outstanding common stock and Advaxis stockholders will own approximately 37.5%, subject to the terms of the merger agreement. At the closing of the merger, Ayala will be delisted from The Nasdaq Global Market, and the combined company's common stock is expected to begin trading on the OTCQX, subject to Advaxis's planned efforts to have the stock of the combined company listed on Nasdaq, as to which no assurances can be made. The merger is expected to close by the end of Q1 2023, subject to approval by Ayala's shareholders and the satisfaction of customary closing conditions.
- **On October 6, the Company hosted a key opinion leader (KOL) webinar on the unmet medical needs and evolving treatment landscape of desmoid tumors:** The webinar featured presentations by Professors Bernd Kasper, MD, Ph.D., from the Mannheim University Medical Center, and Robin Jones, MD, from The Royal Marsden Hospital and Institute of Cancer Research. A replay of the webinar, including slides, can be found here.
- **Positive interim data from Part A of the Phase 2/3 RINGSIDE study of AL102 in desmoid tumors presented at ESMO:** Data showed efficacy across all cohorts, with early responses that deepened over time. The first confirmed partial response (PR) was achieved at week 16 and 3 additional unconfirmed PRs over the follow-up period. AL102 was well tolerated at all three dosing regimens with no dose-limiting toxicities and no Grade 4/5 adverse events. Part B, the Phase 3 portion of RINGSIDE, is open for enrollment with a selected dose of 1.2mg once daily.
- **Fast Track designation granted for AL102:** In September, the U.S. FDA granted Fast Track designation for AL102 for the treatment of progressing desmoid tumors. The designation holds important advantages that may expedite the development and regulatory review of AL102.

Upcoming Milestones

- **Continue enrollment in Phase 3 of the RINGSIDE trial**: Part B, the Phase 3 portion of the RINGSIDE trial, is a double-blind placebo-controlled study enrolling up to 156 patients with progressive desmoid disease, randomized between AL102 or placebo. The primary endpoint is Progression Free Survival with secondary endpoints including objective response rates, duration of response, and patient-reported quality of life measures.

- **A poster featuring the interim data from Part A of RINGSIDE has been selected for presentation at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting**, taking place November 16-19 in Vancouver, Canada.
- **Gain clarity from U.S FDA on the registration path for AL101 in recurrent/metastatic adenoid cystic carcinoma (R/M ACC),** expected in early 2023
- **Expected closing of merger with Advaxis,** by the end of Q1 2023, subject to approval by Ayala's shareholders and the satisfaction of customary closing conditions
- **Present longer-term data from Part A of RINGSIDE with AL102,** expected in mid-2023

Third-Quarter 2022 Financial Results

Cash Position: Cash and cash equivalents were $11.2 million as of September 30, 2022.

Collaboration Revenue: Collaboration revenue was $91 thousand for the third quarter of 2022, as compared to $625 thousand for the corresponding quarter in 2021.

R&D Expenses: Research and development expenses were $7.2 million for the third quarter of 2022, compared to $7.4 million for the corresponding quarter in 2021.

G&A Expenses: General and administrative expenses were $2.9 million for the third quarter of 2022, compared to $2.2 million for the third quarter of 2021.

Net Loss: Net loss was $10.2 million for the third quarter of 2022, resulting in basic and diluted net loss per share of $0.66. This compares with a net loss of $9.8 million for the third quarter of 2021 or basic and diluted net loss per share of $0.68 for that quarter.

For further details on the company's financial results, refer to our Quarterly Report on Form 10-Q for the three months ended September 30, 2022, filed with the Securities and Exchange Commission ("SEC") on November 3, 2022.

About Ayala Pharmaceuticals

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers. Ayala's approach is focused on predicting, identifying and addressing tumorigenic drivers of cancer through a combination of its bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors, including adenoid cystic carcinoma (ACC) and desmoid tumors. AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 portion of a pivotal study for patients with desmoid tumors (RINGSIDE). AL101 has received Fast Track Designation and Orphan Drug Designation from the U.S. FDA and is currently in a Phase 2 clinical trial for patients with ACC (ACCURACY) bearing Notch activating mutations. For more information, visit www.ayalapharma.com.

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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 intends to file with the SEC a registration statement on Form S-4 that will include a proxy statement of Ayala and that will constitute 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 (when available) 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, will be 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements relating to the completion of the our merger with Advaxis and the anticipated impact of the merger, the timing of our communications with the FDA, our development of AL101 and AL102, 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, our participation at scientific or medical conferences, the sufficiency of cash to fund operations, and the anticipated impact of COVID-19, on our business. These forward-looking statements are based on management's current expectations. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the announcement and pendency of the Merger (as defined herein) could have an adverse effect on our business; failure to consummate the Merger within the expected timeframe or at all could have a material adverse impact on our business, financial condition and results of operations; certain provisions of the Merger Agreement (as defined herein) may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement; failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations; if we do not successfully consummate the Merger with Advaxis (as defined herein), our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation; our directors and executive officers have interests in the Merger that are different from our stockholders, and that may influence them to support or approve the Merger without regard to our stockholders' interests; if the Merger is not completed, our stock price may fluctuate significantly; the announcement and pendency of the Merger, whether or not consummated, adversely affected the trading price of our common stock and may continue to adversely affect the trading price of our common stock; the failure to successfully integrate the businesses and operations of Ayala and Advaxis in the expected time frame may adversely affect the combined company's future results; 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; we have identified conditions and events that raise substantial doubt about 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 carry forwards 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; even if we obtain FDA approval 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 AL102, 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; any future collaborations will be, important to our business. If we are unable to maintain our existing collaboration or enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected; 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; and risks related to our operations in Israel could materially adversely impact our business, financial condition and results of operations.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended September 30, 2022 filed with the U.S. Securities and Exchange Commission (SEC) on November 3, 2022 and our other filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	September 30, 2022 (Unaudited)	December 31, 2021
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 11,195	$ 36,982
Short-term Restricted Bank Deposits	110	122
Trade Receivables	129	—
Prepaid Expenses and other Current Assets	1,598	2,636
Total Current Assets	13,032	39,740
LONG-TERM ASSETS:		
Other Assets	$ 229	$ 267
Property and Equipment, Net	999	1,120
Total Long-Term Assets	1,228	1,387
Total Assets	**$ 14,260**	**$ 41,127**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 2,326	$ 3,214
Other Accounts Payables	3,379	3,258
Total Current Liabilities	5,705	6,472
LONG TERM LIABILITIES:		
Long-term Rent Liability	396	497
Total Long-Term Liabilities	$ 396	$ 497
STOCKHOLDERS' STOCKHOLDERS' EQUITY:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at December 31, 2021 and September 30, 2022; 14,820,727 and 14,080,383 shares issued at September 30, 2022 and December 31, 2021, respectively; 14,301,984 and 13,956,035 shares outstanding at September 30, 2022 and December 31, 2021, Respectively	$ 139	$ 139
Additional Paid-in Capital	147,586	145,160
Accumulated Deficit	(139,566)	(111,141)
Total Stockholders' Equity	8,159	34,158
Total Liabilities and Stockholders' Equity	**$ 14,260**	**$ 41,127**

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues from licensing agreement	$ 91	$ 625	$ 587	$ 2,360
Cost of services	(91)	(625)	(497)	(2,360)
Gross profit	—	—	90	—
Operating expenses:				
Research and development	7,196	7,368	20,279	22,414
General and administrative	2,885	2,198	7,586	7,037
Operating loss	(10,081)	(9,566)	(27,775)	(29,451)
Financial Income (Loss), net	(1)	(63)	(141)	(177)
Loss before income tax	(10,082)	(9,629)	(27,916)	(29,628)
Taxes on income	(106)	(167)	(509)	(577)
Net loss	(10,188)	(9,796)	(28,425)	(30,205)
Net Loss per share, basic and diluted	$ (0.66)	$ (0.68)	$ (1.85)	$ (2.14)
Weighted average common shares outstanding, basic and diluted	**15,482,809**	**14,483,629**	**15,365,342**	**14,130,993**