



## Ayala Pharmaceuticals and Advaxis Enter into Merger Agreement

October 19, 2022

*Merger brings U.S. management and presence, cash to develop compelling late-stage asset*

*Lead candidate AL102 being evaluated in ongoing Phase 2/3 RINGSIDE study, a potential registration trial in desmoid tumors*

*Ayala and Advaxis stockholders will respectively own approximately 62.5% and 37.5%*

*Combined Company to Seek Uplisting to Nasdaq*

*Conference Call and Webcast today at 8:00am ET*

REHOVOT, Israel and WILMINGTON, Del. and MONMOUTH JUNCTION, N.J., Oct. 19, 2022 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA) (Ayala), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers and Advaxis, Inc. (OTCQX: ADXS) (Advaxis), a biotechnology company devoted to the discovery, development and commercialization of immunotherapies based on a technology which uses engineered *Listeria monocytogenes*, today announced that they have entered into a definitive merger agreement. The merger would result in a combined company that will focus predominantly on the development and commercialization of Ayala's lead program AL102 for the treatment of desmoid tumors and Advaxis's candidate ADXS-504 in development for prostate cancer.

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis, said, "Advaxis took a thorough approach in our quest to find the right partner with the right products. This merger is expected to enhance Advaxis's portfolio of clinical assets, with Ayala's proprietary gamma secretase inhibitors that are being developed as targeted therapies for rare and aggressive tumors. Ayala's lead candidate, AL102, is currently being investigated in the Phase 2/3 RINGSIDE study in desmoid tumors, which we believe will accelerate the stage of product development for the combined company dramatically. We are particularly excited about very promising interim data from RINGSIDE, which showed that AL102 monotherapy had meaningful anti-tumor activity with tumor shrinkage in the majority of patients that appeared to be deepening over time. The combined management team has extensive commercial and R&D experience, and we believe we have the cash to advance the combined portfolio through key milestones in 2023, including longer-term data from Part A of RINGSIDE, clarity on the registration path for AL101 in recurrent/metastatic adenoid cystic carcinoma (ACC) and initial clinical and PSA data from the Phase 1 trial of ADXS-504 in prostate cancer. We believe that this transaction will also help drive our efforts to return to a Nasdaq listing and enhance our ability to access capital."

Roni Mamluk, Ph.D., President and Chief Executive Officer of Ayala commented, "We are pleased to announce the proposed merger with Advaxis, which is expected to provide our pipeline and AL102 with additional financial resources as well as additional infrastructure in the U.S. The two companies have a shared mission to develop innovative therapies to improve the lives of patients with cancer and I believe we have found a good partner to advance our pipeline and create value for our stakeholders."

### **Additional Transaction Details**

Subject to the terms and conditions of the merger agreement, at the closing of the merger, each outstanding share of Ayala common stock will be converted into the right to receive shares of common stock of Advaxis based on the exchange ratio set forth in the merger agreement. Upon completion of the merger, 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. Advaxis will, at the effective time of the merger, assume the outstanding restricted stock units and stock options of Ayala, subject to the terms of the merger agreement. No fractional shares will be issued in connection with the merger and Advaxis will pay cash in lieu of any such fractional shares. The merger is intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Consummation of the merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Ayala. At the closing of the merger, Ayala will be delisted from The Nasdaq Global Market. The combined company's common stock is expected to begin trading on the OTCQX at the effective time of the merger, subject to Advaxis' planned efforts to have the stock of the combined company listed on Nasdaq, as to which no assurances can be made.

### **Management and Board of Directors**

At the effective time of the merger, the executive officers of the combined company will include Mr. Kenneth A. Berlin, President, Chief Executive Officer and Director; Andres Gutierrez, M.D., Ph.D., current Chief Medical Officer of Advaxis; and Igor Gitelman, Interim Chief Financial Officer of Advaxis. Roni Mamluk, Ph.D., Founder and Chief Executive Officer of Ayala, and Yossi Maimon, Chief Financial Officer of Ayala will resign their positions and will help with the transition. Gary Gordon, M.D., Chief Medical Officer of Ayala, will also resign his position but is expected to continue in an advisory role for a period of time. The board of directors of the combined company is expected to consist of seven members: two designated by Advaxis, four designated by Ayala, and Mr. Berlin.

### **Conference Call and Webcast**

There will be a conference call and webcast at 8:00 a.m. Eastern Time today, Wednesday, October 19, 2022, with Advaxis and Ayala to discuss the merger and respond to questions.

Investors Dial: 1-877-407-9716  
Int'l Investors Dial: 1-201-493-6779  
Investors in Israel Dial: 1 809 406 247  
Conference ID: 13733948

Webcast: [Webcast Link](#)

The webcast will also be archived for a period of 90 days on the Investor Relations web pages of Advaxis (<https://www.advaxis.com/events-and-presentations>) and Ayala (<https://ir.avalapharma.com/news-events/events-presentations>).

#### **About Ayala Pharmaceuticals, Inc.**

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.avalapharma.com](http://www.avalapharma.com).

#### **About Advaxis, Inc.**

Advaxis, Inc. is a clinical-stage biotechnology company focused on the development and commercialization of proprietary Lm-based antigen delivery products. These off-the-shelf immunotherapies are a significant advancement in immunotherapy as they integrate multiple functions into a single therapy by directing antigen presenting cells to stimulate T-cells and other components of the immune system, while reducing tumor protection in the tumor microenvironment, facilitating the elimination of tumors. The company has two programs in the clinic: ADXS-503 for late-stage lung cancer and ADXS-504 for early-stage prostate cancer. To learn more about Advaxis, visit [www.advaxis.com](http://www.advaxis.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 Securities and Exchange Commission ("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](http://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](mailto:ir@advaxis.com). Copies of the documents filed with the SEC by Ayala will also be available free of charge at <https://ir.avalapharma.com/financial-information/sec-filings> or by contacting Ayala's investor relations department by email at [jallaire@lifesciadvisors.com](mailto: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.

#### **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 Pharmaceuticals, Inc. ("Ayala") and Advaxis, Inc. ("Advaxis"), the ability to consummate the proposed transaction, and the ability to list the common stock of the combined company on Nasdaq. 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, the ability of each of Ayala and Advaxis to consummate the proposed transaction, and the ability of the combined company to meet the requirements to list its common stock on Nasdaq; (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 (xiv) 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 and Advaxis can give no assurance that the conditions to the proposed transaction will be satisfied. Except as required by applicable law, Ayala and Advaxis 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.