Ayala Pharmaceuticals Announces Closing of Merger with Biosight

October 19, 2023

REHOVOT, Israel & MONMOUTH JUNCTION, N.J., Oct. 19, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced the closing of its merger with Biosight, Ltd. ("Biosight"), pursuant to which Ayala acquired Biosight. The combined company will operate under the name Ayala Pharmaceuticals, Inc., and its shares will continue to trade on the OTCQX under Ayala's current ticker symbol ("ADXS").

"We are pleased to close the merger with Biosight which expands our product pipeline," said Ken Berlin, President & CEO. "We have added aspacytarabine (BST-236), a novel antimetabolite, which is in clinical development for AML and could potentially serve as a superior backbone therapy for unfit AML as part of combination treatment regimens. Our primary focus continues to be completing the ongoing Phase 3 RINGSIDE study evaluating AL102 in desmoid tumors and we look forward to continuing our mission of bringing innovative therapies to people with rare tumors and aggressive cancers."

Management and Organization

As previously announced, the combined company will be led by Ayala's existing senior management team, with Ken Berlin serving as President and CEO; Andres Gutierrez, MD, PhD, Executive VP and Chief Medical Officer; and Dana Gelbaum, MSc, MBA, General Manager and Chief Business Officer. Roy Golan, CPA, LLM, previously Executive VP & CFO of Biosight, has been appointed Chief Financial Officer of the combined company. The board of directors of the combined company is comprised of David Sidransky, MD (Chairman); Robert Spiegel, MD, FACP; Murray Goldberg; Vered Bisker-Leib, PhD, MBA; Roni Appel, MBA; Pini Orbach, PhD; Yuval Cabilly, PhD; and Ken Berlin, with an additional board member expected to be added at a later date.

About Ayala Pharmaceuticals, Inc.

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company primarily focused on developing and commercializing small molecule therapeutics for people living with rare tumors and aggressive cancers. The Company's lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors, and aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 segment of a pivotal study for patients with desmoid tumors (RINGSIDE). For more information, visit www.ayalapharma.com.

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Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered forward-looking statements that involve a number of risks and uncertainties, including statements regarding the future conduct of our studies and the potential efficacy and success of product candidates. 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: our ability to integrate Biosight's business successfully with ours and to achieve anticipated synergies; the possibility that other anticipated benefits of the 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; potential litigation relating to the transaction that could be instituted against us, Biosight or our respective directors; possible disruptions from the transaction that could harm our and/or Biosight's respective businesses; the ability of us and Biosight to retain, attract and hire key personnel; potential adverse reactions or changes to relationships with customers, employees, suppliers or other parties resulting from the announcement or completion of the transaction; the success and timing of clinical trials, including subject accrual, the ability to avoid and quickly resolve any clinical holds and the ability to obtain and maintain regulatory approval and/or reimbursement of product candidates for marketing; the ability to obtain the appropriate labeling of products under any regulatory approval; plans to develop and commercialize our products; our ability to continue as a going concern; our levels of available cash and our need to raise additional capital, including to support current and future planned clinical activities; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product

candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash, including to support current and planned clinical activities; uncertainties as to our ability to obtain a listing of our common stock on Nasdaq; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain our existing collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; legislative, regulatory and economic developments; 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 such other factors as are set forth in our periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in the Form 10-K for the fiscal year ended December 31, 2022 of Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and the Form 10-K for the fiscal year ended October 31, 2022 of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.) ("Ayala" or "we," "us" or "our"), and such entities' 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 October 31, 2022. Except as required by applicable law, we undertake 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.