# Ayala Pharmaceuticals and Biosight Enter into Definitive Merger Agreement

July 27, 2023

*Combined company to operate as Ayala Pharmaceuticals, Inc.*

*Merger to add a clinical stage oncology asset to Ayala's portfolio with data anticipated in the first half of 2024*

REHOVOT and TEL AVIV, Israel and MONMOUTH JUNCTION, N.J., July 27, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a publicly-traded clinical-stage oncology company, and Biosight Ltd., a privately-held pharmaceutical company developing innovative therapeutics for hematological malignancies and disorders, today announced they have entered into a definitive merger agreement pursuant to which Ayala will combine with Biosight in an all-stock transaction. Upon completion of the merger, the combined company will operate under the name Ayala Pharmaceuticals, Inc., and will continue to trade on the OTCQX under Ayala's current ticker symbol ("ADXS"). Certain of the current Biosight shareholders have agreed to support the proposed transaction.

The combined company will work to advance a portfolio of oncology assets, with a primary focus on Ayala's AL102, a once-daily, potent, selective, oral gamma-secretase inhibitor (GSI) and Biosight's Aspacytarabine (BST-236). AL102 is currently being evaluated in the registrational RINGSIDE study in desmoid tumors. There are currently no FDA-approved therapies for the treatment of unresectable, recurrent or progressive desmoid tumors. Data from the Phase 2 portion of RINGSIDE were presented at the recent American Society of Clinical Oncology Annual Meeting demonstrating AL102's activity against progressing desmoid tumors. These data showed 50% partial response and 100% disease control rates in evaluable desmoid tumor patients treated with AL102 in the 1.2 mg once daily arm, the dosing regimen being tested in the ongoing Phase 3 study. The majority of the patients from Phase 2 have continued on study and are now in the open label extension of the Phase 3 portion of RINGSIDE. Ayala expects to present updated data on these patients at a medical conference later this year.

"The addition of Biosight's lead asset aspacytarabine (BST-236) fits with our strategic vision and core competencies and provides us with additional avenues towards key clinical catalysts," said Ken Berlin, President and CEO of Ayala. "Along with the merger, we have plans to strengthen our balance sheet and execute our clinical plans, with the goal of creating sustainable value for patients and shareholders."

Pini Orbach, PhD, Chairman of Biosight, commented, "The Ayala team shares our commitment to bringing innovative treatments to cancer patients in need and we are excited to enter into this merger. Leveraging the combined capabilities and resources of both organizations will provide a truly unique opportunity to build a leading, publicly-traded oncology company with advanced and diverse clinical stage assets. I would like to express my deepest appreciation to the entire Biosight team, and I am proud of their excellent work and dedication in advancing aspacytarabine and our pipeline."

**About the Merger**

Under the terms of the merger agreement, upon completion of the merger, ownership of the combined company will be split, with 55% ownership going to Biosight stockholders and 45% going to Ayala stockholders. The merger agreement has been unanimously approved by the Board of Directors of each company, by all directors entitled to vote. The transaction is expected to close prior to the end of the third quarter of 2023, subject to regulatory and other conditions including approval of Biosight stockholders.

**Management and Organization**

Effective as of the closing of the merger, the combined company will be led by Ayala's existing senior management team, with Ken Berlin serving as President and CEO. Additionally, the Board of Directors is expected to consist of nine members, including four designated by Ayala and four designated by Biosight, as well as Mr. Berlin.

**Advisors**

Morgan, Lewis & Bockius LLP and Meitar are serving as legal counsel to Ayala. Goodwin Procter LLP and Horn & Co. Law Offices are serving as legal counsel to Biosight.

**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 and is also developing proprietary *Lm*-based antigen delivery products for patients suffering from more common cancers. The Company's lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors; ADXS-504, a *Lm*-based therapy for early-stage prostate cancer; and the intravenous gamma secretase inhibitor, AL101, for adenoid cystic carcinoma. 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.

**About AL102**

AL102 is an investigational small molecule gamma secretase inhibitor (GSI) that is designed to potently and selectively inhibit Notch 1, 2, 3 and 4, and is currently being evaluated in the Phase 2/3 RINGSIDE clinical studies in patients with progressing desmoid tumors. AL102 is designed to inhibit the expression of Notch gene targets by blocking the final cleavage step by the gamma secretase required for Notch activation. Ayala obtained an exclusive, worldwide license to develop and commercialize AL102 from Bristol-Myers Squibb Company in November 2017. AL102 was granted U.S.

FDA Fast Track Designation for the treatment of desmoid tumors.

**About Biosight Ltd.**

Biosight is a private clinical stage biotech company developing innovative therapeutics for hematological malignancies and disorders. Biosight's lead product, aspacytarabine (BST-236), is an innovative proprietary anti-metabolite designed to address unmet medical needs by enabling high-dose chemotherapy with reduced systemic toxicity. For additional information, please visit www.biosight-pharma.com.

**About Aspacytarabine (BST-236)**

Aspacytarabine (BST-236) is being developed to serve as a superior novel backbone for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) therapy, either as a single agent or in combination with other therapies, including targeted therapy agents. Results from a recently completed Phase 2b study evaluating aspacytarabine as a single-agent first-line AML therapy demonstrate safety and impressive single-agent activity. Additional studies are ongoing to evaluate aspacytarabine in combination with venetoclax as a first-line treatment of AML, as well as a second line monotherapy for patients with relapsed or refractory MDS or AML. Aspacytarabine has been granted FDA Fast Track Designation for first-line treatment of AML patients unfit for standard chemotherapy, and Orphan Drug designations from the FDA and EMA in AML, as well as Orphan Drug designation in MDS from the FDA.

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**Cautionary Statement Regarding Forward-Looking Statements**

This communication relates to the proposed transaction pursuant to the Agreement and Plan of Merger and Reorganization dated as of July 26, 2023, by and among Ayala Pharmaceuticals, Inc.("Ayala"), Advaxis Israel Ltd. and Biosight Ltd. ("Biosight"). This communication includes express or implied forward-looking statements about the proposed transaction between Ayala and Biosight and the operations of the combined company 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: 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; uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Ayala and Biosight to consummate the proposed transaction; the ability of Ayala and Biosight to integrate their businesses successfully and to achieve anticipated synergies; 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; potential litigation relating to the proposed transaction that could be instituted against Ayala, Biosight or their respective directors; possible disruptions from the proposed transaction that could harm Ayala's and/or Biosight's respective businesses; the ability of Ayala 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 proposed transaction; potential business uncertainty, including changes to existing business relationships, during the pendency of the proposed transaction that could affect Ayala's or Biosight's financial performance; certain restrictions during the pendency of the proposed transaction that may impact Ayala's or Biosight's ability to pursue certain business opportunities or strategic transactions; 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.