Ayala Pharmaceuticals Announces Second Quarter 2023 Financial Results and Provides Corporate Update

August 10, 2023

Successful End-of-Phase 2 meeting with FDA regarding AL102 for the treatment of desmoid tumors

Enrollment in the Phase 3 segment of RINGSIDE trial evaluating AL102 continuing globally as planned

Definitive merger agreement with Biosight, expected to close near end of Q3 2023

REHOVOT, Israel and MONMOUTH JUNCTION, N.J., Aug. 10, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced second-quarter 2023 financial results and provided a corporate update.

“We continue to make progress advancing our lead candidate AL102, which is being evaluated in the ongoing Phase 3 registration-enabling RINGSIDE for the treatment of desmoid tumors. We recently concluded an instructive and successful End-of-Phase-2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) and have confirmed that we are agreement with the FDA on key elements of the randomized Phase 3 segment of RINGSIDE,” said Ken Berlin, President and Chief Executive Officer of the Company. “The most recent data from Phase 2 of RINGSIDE presented at ASCO were encouraging and we look forward to presenting a further update at the ESMO congress in October this year. We are excited, also, to expand our clinical pipeline through the recently announced proposed merger with Biosight. The addition of Biosight’s lead asset aspacytarabine (BST-236) fits with our strategic vision and core competencies. 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.”

Second Quarter 2023 and Recent Business Highlights

- **End-of-Phase 2 meeting with FDA regarding AL102 for desmoid tumors:** Ayala confirmed that it is in agreement with the FDA on key elements of the randomized Phase 3 segment of RINGSIDE, evaluating AL102 in desmoid tumors. The FDA accepted the selection of the 1.2 mg once daily dose for Phase 3 and the completed and proposed clinical pharmacology plan. Enrollment in Phase 3 commenced in November 2022, and is continuing globally as planned, with target enrollment of 156 patients. The primary endpoint is progression free survival with secondary endpoints including objective response rates, duration of response, and patient-reported quality of life measures.

- **Updated results from Phase 2 of RINGSIDE study presented at 2023 American Society of Clinical Oncology (ASCO) annual meeting:** ASCO poster highlighted 50% partial response and 100% disease control rates in evaluable desmoid tumor patients treated with AL102 1.2 mg once daily (the selected Phase 3 dose) at a cut off date of January 3, 2023. Tumor responses, volume and T2 signal reduction were observed earlier in the 1.2 mg once daily group, with deeper and sustained treatment responses. AL102 continues to be generally well tolerated and has a manageable safety profile.

- **Definitive merger agreement with Biosight:** Ayala entered into a definitive agreement with Biosight Ltd., pursuant to which, Ayala will combine with Biosight in an all-stock transaction. Upon completion of the proposed 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”). The combined company will work to advance a portfolio of oncology assets, with a primary focus on Ayala’s AL102, and Biosight’s aspacytarabine (BST-236). The transaction is expected to close near the end of the third quarter of 2023, subject to regulatory and other conditions including approval of Biosight stockholders.

Upcoming Milestones

- **ESMO poster presentations on AL102 and AL101:** Updated results from Phase 2 of RINGSIDE evaluating AL102 in desmoid tumors and final results from the ACCURACY trial evaluating AL101 in patients with recurrent/metastatic (R/M) adenoid cystic carcinoma (ACC) have been selected for presentation at the European Society for Molecular Oncology (ESMO) Congress 2023, to be held in Madrid, Spain 20-24 October 2023.
- **Data from Phase 1 trial of ADXS-504:** ADXS-504 is being evaluated in a Phase 1 investigator-sponsored study at Columbia University in patients with biochemically recurrent (early) prostate cancer. Readout of initial clinical and PSA data are expected in 2023.
- **Gain clarity on path for future development plan for AL101 in recurrent/metastatic adenoid cystic carcinoma (R/M ACC),** expected in 2023.

Consolidated Financial Results for the Second Quarter Ended June 30, 2023

Cash position On June 30, 2023, the Company's consolidated cash and cash equivalents position was $7.1 million.

Revenue Collaboration revenue was $9 thousand in the three months ended June 30, 2023, compared with $38 thousand in the comparable period of 2022.

R&D Expenses Research and development expenses were $5.7 million for the three months ended June 30, 2023 compared to $5.6 million for the three months ended June 30, 2023.

G&A Expenses General and administrative expenses were $2.7 million for the three months ended June 30, 2023 compared to $2.3 million for the three months ended June 30, 2023.

Net Loss The net loss for the three months ended June 30, 2023 was approximately $8.7 million or ($1.82) per share based on approximately 4.8 million weighted average shares outstanding. This compares with a net loss for the three months ended June 30, 2022 of approximately $8.1 million or ($2.83) per share based on approximately 2.9 million weighted average shares outstanding.

For further details on the Company's financial results, including results for the six-month period ended June 30, 2023, refer to our quarterly report on Form 10-Q for the quarter ended June 30,2023, filed with the Securities and Exchange Commission.

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). On July 26, 2023 Ayala entered into a definitive merger agreement with Biosight Ltd., a privately-held pharmaceutical company developing innovative therapeutics for hematological malignancies and disorders, pursuant to which Ayala will combine with Biosight in an all-stock transaction. 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. 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: the risk that the conditions to the closing of the proposed transaction with Biosight are not satisfied, including the failure to timely or at all obtain the approval of the Biosight stockholders 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 Biosight and us to consummate the proposed transaction; the ability of Ayala and us to integrate our 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 us, Biosight or our respective directors; possible disruptions from the proposed 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 proposed transaction; potential business uncertainty, including changes to existing business relationships, during the pendency of the proposed transaction that could affect our or Biosight's financial performance; certain restrictions during the pendency of the proposed transaction that may impact our 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.

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

	June 30, 2023	December 31, 2022
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,079	$ 2,408
Short-term restricted bank deposits	106	110
Trade receivables	-	234
Prepaid expenses and other current assets	2,371	436
Total current assets	9,556	3,188
LONG-TERM ASSETS:		
Deferred issuance costs		1,953
Operating lease right of use asset	1,390	1,462
Intangible assets, net	115	-
Property and equipment, net	882	960
Other assets	$ 208	$ 206
Total long-term assets	2,595	4,581
Total assets	**$ 12,151**	**$ 7,769**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade payable	$ 4,420	$ 4,080
Operating lease liabilities	542	419
Accrued expenses	1,905	551
Accrued payroll and employee benefits	1,401	994
Other accounts payable	159	169
Total current liabilities	8,427	6,213
LONG TERM LIABILITIES:		
Long-term warrant liability	67	-
Uncertain tax position	1,648	1,323
Long-term operating lease liabilities	1,000	1,332
Total long-term liabilities	**$** 2,715	$ 2,655
STOCKHOLDERS' EQUITY:		
Common Stock of $0.001 par value per share; 170,000,000 and 37,480,000 shares authorized on June 30, 2023 and on December 31, 2022, respectively; 4,838,321 and 2,775,906 shares issued and on June 30, 2023 and December 31, 2022, respectively; * 4,779,826 and 2,695,067 shares outstanding at June 30, 2023 and December 31, 2022, respectively.	$ 5	$ 3
Additional paid-in capital*	166,218	148,052
Accumulated deficit	(165,214)	(149,154
Total stockholders' equity	1,009	(1,099
Total liabilities and stockholders' equity	**$** 12,151	**$ 7,769**

See accompanying notes to unaudited condensed consolidated financial statements in Form 10Q.

* Common Stock, additional paid-in capital and per share data have been retroactively adjusted for the impact of the merger, see note 1. 1

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues from licensing agreement and others	$ 9	$ 38	$ 13	$ 496
Cost of services	(9)	(38)	(13)	(406)
Gross profit	—	—	—	90
Operating expenses:				
Research and development	5,723	5,580	12,988	13,083
General and administrative	2,763	2,272	7,367	4,705
Operating loss	(8,486)	(7,852)	(20,355)	(17,698)
Financial (loss) Income, net	(86)	(42)	215	40
Loss before income tax	(8,572)	(7,894)	(20,140)	(17,658)
Taxes on income	(127)	(214)	4,080	(403)
Net loss	(8,699)	(8,108)	(16,060)	(18,061)
Net Loss per share attributable to common stockholders, basic and diluted	$ (1.82)	$ (2.83)	$ (3.51)	$ (6.30)
Weighted average common shares outstanding, basic and diluted*	**4,776,344**	**2,869,612**	**4,580,661**	**2,868,499**