Advaxis Reports 3rd Quarter Ended July 31, 2021 Financial Results and Provides a Business Update

September 10, 2021

Entered definitive merger agreement with Biosight Ltd. to advance pipeline of clinical-stage oncology programs for solid tumors and hematological malignancies

Initiated Phase 1 clinical trial of ADXS-504 for the treatment of early prostate cancer

ADXS-503 Phase 1/2 data presented at ASCO demonstrate disease control rate of 44% with durable clinical benefit observed beyond one year in patients with disease progression on KEYTRUDA®

MONMOUTH JUNCTION, N.J., Sept. 10, 2021 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announces its financial results for the third quarter ended July 31, 2021 and provides a business update.

Third Quarter Ended July 31, 2021 Financial Results and Recent Key Accomplishments:

- Entered into a definitive merger agreement with Biosight Ltd. The proposed merger will create a public company, operating as Biosight Therapeutics, to advance a pipeline of clinical-stage oncology programs including Biosight's lead product, aspacytarabine (BST-236). The combined company is expected to have approximately $50 million in cash, cash equivalents and marketable securities at closing. Following the closing, which is expected to occur in the 4th calendar quarter of 2021, Advaxis will be renamed Biosight Therapeutics and is expected to trade on the Nasdaq Capital Market under the ticker symbol "BSTX".
- The combined company anticipates the following milestones across the combined pipeline over the next 12-18 months:
    - Topline results in 65 patients from the ongoing Phase 2 trial of aspacytarabine, which has completed enrolment, as first-line therapy in acute myeloid leukemia (AML) patients who are unfit for standard chemotherapy
        - Recent data presented at 2021 American Society of Clinical Oncology (ASCO) Annual Meeting showed that aspacytarabine alone achieved complete remission (CR) rates of 39% across all evaluable patients (n=46) with 63% of cases analyzed to date with negative minimal residual disease (MRD(-)) and median duration of response not yet reached at 12 months. Altogether these results are encouraging considering the high-risk factors in this population at baseline;
    - Initial results from the Phase 2 trial of aspacytarabine in collaboration with the European cooperative group, Groupe Francophone des Myélodysplasies (GFM) in patients with relapsed/refractory AML and higher-risk Myelodysplastic Syndrome (MDS);
    - Initiation in the U.S. of a second, Phase 2 trial of aspacytarabine in patients with relapsed/refractory AML and higher-risk MDS;
    - Results from the ongoing Phase 1/2 trial with ADXS-503 in combination with pembrolizumab in non-small cell lung cancer; and
    - Initial results from the Phase 1 trial of ADXS-504 in biochemically recurrent prostate cancer
- Initiated Phase 1 clinical trial of ADXS-504 being conducted at Columbia University Irving Medical Center for the treatment of biochemically recurrent prostate cancer, expanding the off-the-shelf ADXS-HOT program to a second indication
- Presented updated clinical data from Part B of the ongoing Phase 1/2 trial of ADXS-503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in non-small cell lung cancer (NSCLC) at the 2021 ASCO Annual Meeting; data presented from the Part B arm of this study, demonstrate a disease control rate of 44%, with durable clinical benefit observed including a partial response (PR) and stable disease (SD) sustained for over a year, and another observed SD lasting over 6 months. An additional SD was maintained for approximately 4 months. Translational and biomarker results demonstrate on-mechanism immune activation tied to clinical benefit
- Presented data from Part B of the ongoing Phase 1/2 study of ADXS-503 in combination with KEYTRUDA® (pembrolizumab) at the Non-Small Cell Lung Cancer Drug Development Summit
- Announced Nasdaq extension, to November 22, 2021, to regain compliance with the $1.00 minimum bid price rule and complete merger transaction with Biosight, Ltd.
- Cash balance at July 31, 2021 of $45.3 million

Management Commentary

“We are thrilled by the transformative potential of our proposed merger with Biosight and believe the opportunity to build a diversified clinical pipeline with both early and late-stage oncology assets will benefit both patients and our stockholders,” said Kenneth A. Berlin, President, Chief Executive Officer and Interim Chief Financial Officer of Advaxis. “We expect that the coming months will provide data readouts from our expanded off-the-shelf neoantigen program in both NSCLC and prostate cancer which will build upon our strong foundation of data show consistent clinical benefit, the potential to enhance and/or restore responsiveness to checkpoint inhibitors and on-mechanism innate and adaptive immune system stimulation. These results, in combination with key data readouts from Biosight’s ongoing studies evaluating aspacytarabine in AML and MDS, will elucidate the promise of the combined clinical pipeline across both solid tumors and hematological malignancies and disorders. We look forward to continued progress in the clinic and expect to provide updated guidance regarding the proposed merger before year end.”

Third Quarter Ended July 31, 2021 Financial Results

Research and development expenses for the third quarter of fiscal year 2021 were $1.70 million, compared with $3.46 million for the third quarter of fiscal year 2020. The decrease of $1.76 million was primarily attributable to the substantial reduction in costs associated with the winding down of clinical studies that have been discontinued.

General and administrative expenses for the three months ended July 31, 2021 were at $2.68 million, compared to $2.38 million in the same three-month period in fiscal 2020. The increase of $0.3 million primarily relates to increases in legal and consulting fees, and were partially offset by decreases in rent and utilities, personnel costs, and charges related to the abandonment of non-strategic intellectual property.

As of July 31, 2021, the Company had approximately $45.3 million in cash and cash equivalents.

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 immunotherapies are based on a platform technology that utilizes live attenuated Listeria monocytogenes (*Lm*) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable T cells to eliminate tumors.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

Important Information about the Merger and Where to Find It

This press release contains information that relates to a proposed transaction between the Company and Biosight Ltd. (“Biosight”) pursuant to the Agreement and Plan of Merger and Reorganization, dated July 4, 2021 by and among the Company, Biosight and other parties referenced therein (the “Merger Agreement”). This press release does not constitute an offer to sell or exchange or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed Merger, the Company filed a registration statement on Form S-4 with the Securities and Exchange Commission (the “SEC”) on August 25, 2021, which includes a proxy statement, information statement and prospectus (the “Registration Statement”). This communication is not a substitute for the Registration Statement or for any other document that the Company may file with the SEC or send to the Company’s stockholders in connection with the proposed transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF THE COMPANY ARE URGED TO READ THE REGISTRATION STATEMENT AND OTHER DOCUMENTS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE COMPANY, BIOSIGHT, THE MERGER AND RELATED MATTERS. Investors and security holders may obtain free copies of the Registration Statement (when available) and other documents filed with the SEC by the Company through the website maintained by the SEC at http://www.sec.gov. The documents filed by the Company with the SEC also may be obtained free of charge at the Company’s website at www.advaxis.com or by written request to the Company at 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ, Attention: Igor Gitelman, VP of Finance and Chief Accounting Officer.

Participants in the Solicitation

The Company and Biosight and their respective directors and executive officers may be considered participants in the solicitation of proxies with respect to the proposed transaction. Information regarding such directors and executive officers, including a description of their interests, by security holdings or otherwise, in the proposed transaction will be set forth in the Registration Statement other relevant materials to be filed with the SEC regarding the proposed transaction. Stockholders, potential investors and other interested persons should read the Registration Statement carefully before making any voting or investment decisions. These documents, when available, can be obtained free of charge as described in the preceding paragraph.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the risk that the proposed transaction may not be completed in a timely manner or at all, which may adversely affect the Company’s business and the price of the common stock of the Company; the failure of either party to satisfy any of the conditions to the consummation of the proposed transaction, including the adoption of the Merger Agreement by the Company’s stockholders and the receipt of certain governmental and regulatory approvals; uncertainties as to the timing of the consummation of the proposed transaction; the occurrence of any event, change or other circumstance that could give rise to the termination of the Merger Agreement; the effect of the announcement or pendency of the proposed transaction on the Company’s business relationships, operating results and business generally; risks that the proposed transaction disrupts current plans and operations and the potential difficulties in employee retention as a result of the proposed transaction; risks related to diverting management’s attention from the Company’s ongoing business operations; the outcome of any legal proceedings that may be instituted against the Company related to the Merger Agreement or the proposed transaction; unexpected costs, charges or expenses resulting from the proposed transaction; the Company’s history of net operating losses and uncertainty regarding its ability to achieve profitability; expected clinical development of the Company’s drug product candidates, statements about the Company’s balance sheet position, including the sufficiency of the Company’s cash and cash equivalents to fund its obligations into the future, and statements related to the goals, plans and expectations for the Company’s ongoing clinical studies. These and other risks are

discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on January 22, 2021, and its periodic reports on Form 10-Q and Form 8-K. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

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ADVAXIS, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

	July 31, 2021 (Unaudited)	October 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 45,257	$ 25,178
Deferred expenses	1,047	1,808
Prepaid expenses and other current assets	1,138	865
Total current assets	47,442	27,851
Property and equipment (net of accumulated depreciation)	278	2,393
Intangible assets (net of accumulated amortization)	3,291	3,261
Operating right-of-use asset (net of accumulated amortization)	-	4,839
Other assets	11	182
Total assets	$ 51,022	$ 38,526
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 454	$ 410
Accrued expenses	2,206	1,737
Common stock warrant liability	4,085	17
Current portion of operating lease liability	-	962
Deferred revenue	-	165
Total current liabilities	6,745	3,291
Operating lease liability, net of current portion	-	5,055
Total liabilities	6,745	8,346
Commitments and contingencies – Note 9		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; Series B Preferred stock; 0 shares issued and outstanding at July 31, 2021 and October 31, 2020. Liquidation preference of $0 at July 31, 2021 and October 31, 2020	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 145,638,459 and 78,074,023 shares issued and outstanding at July 31, 2021 and October 31, 2020	146	78
Additional paid-in capital	467,287	440,840
Accumulated deficit	(423,156)	(410,738)
Total stockholders' equity	44,277	30,180
Total liabilities and stockholders' equity	$ 51,022	$ 38,526

ADVAXIS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except share and per share data)

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2021	2020	2021	2020
Revenue	$ 250	$ -	$ 3,240	$ 253
Operating expenses:				
Research and development expenses	1,703	3,458	8,616	12,239
General and administrative expenses	2,678	2,384	9,038	8,063
Total operating expenses	4,381	5,842	17,654	20,302
Loss from operations	(4,131)	(5,842)	(14,414)	(20,049)
Other income (expense):				
Interest income, net	1	7	3	108
Net changes in fair value of derivative liabilities	846	7	1,814	(16)
Other (expense) income	-	(1)	229	(2)
Net loss before income taxes	(3,284)	(5,829)	(12,368)	(19,959)
Income tax expense	50	-	50	50
Net loss	$ (3,334)	$ (5,829)	$ (12,418)	$ (20,009)
Net loss per common share, basic and diluted	$ (0.02)	$ (0.09)	$ (0.10)	$ (0.35)
Weighted average number of common shares, basic and diluted	145,638,459	61,634,031	123,514,178	57,963,228

ADVAXIS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine Months Ended July 31,	
	2021	2020
OPERATING ACTIVITIES		
Net loss	$ (12,418)	$ (20,009)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	511	708
Employee stock purchase plan expense	-	1
(Gain) loss on change in value of warrants	(1,814)	16
Loss on disposal of property and equipment	1,530	-
Abandonment of intangible assets	90	892
Depreciation expense	366	683
Amortization expense of intangible assets	203	263
Amortization of right-of-use asset	327	553
Net gain on write-off of right-of-use asset and lease liability	(1,116)	-
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and deferred expenses	488	977
Other assets	171	1
Accounts payable and accrued expenses	513	(2,251)
Deferred revenue	(165)	50
Operating lease liabilities	(389)	(606)
Net cash used in operating activities	(11,703)	(18,722)
INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	219	-
Cost of intangible assets	(323)	(421)
Net cash used in investing activities	(104)	(421)

FINANCING ACTIVITIES		
Net proceeds of issuance of common stock and warrants	28,115	10,621
Warrant exercises	3,771	-
Proceeds from employee stock purchase plan	-	5
Employee tax withholdings paid on equity awards	-	(2)
Tax shares sold to pay for employee tax withholdings on equity awards	-	2
Net cash provided by financing activities	31,886	10,626
Net increase (decrease) in cash and cash equivalents	20,079	(8,517)
Cash and cash equivalents at beginning of period	25,178	32,363
Cash and cash equivalents at end of period	$ 45,257	$ 23,846
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for taxes	$ 50	$ 50
SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES		
Warrant liability reclassified into equity	-	2
Amounts accrued for offering costs	-	37
Commitment fee shares issued for equity line	-	644

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Source: Advaxis, Inc.