



## Advaxis Reports Second Quarter Fiscal 2019 Financial Results and Provides Pipeline Update

June 10, 2019

**Conference call to be held June 11 at 11:00 a.m. ET**

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced an update on its clinical pipeline and financial results for the fiscal second quarter ended April 30, 2019.

Key updates on the progress of the company's clinical pipeline include the following:

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- ***ADXS-NEO: Personalized, Neoantigen-Directed Therapy*** – The company is currently enrolling patients in its Phase 1 dose-escalation study to evaluate ADXS-NEO, a personalized neoantigen-directed immunotherapy designed to activate a patient's immune system in a range of cancers. The company presented safety, tolerability and immune correlative data from this study at the American Association of Cancer Research ("AACR") Annual Meeting in March, and updated findings were presented at the Frontiers in Cancer Immunotherapy Conference at the New York Academy of Sciences ("NYAS") in May. The study's preliminary data demonstrated anti-tumor immune activation, including T-cell responses to neoantigens and antigen spreading, within one week after the first dose. In addition, data from two microsatellite-stable ("MSS") colorectal cancer patients dosed with ADXS-NEO at  $1 \times 10^8$  CFU demonstrated increased CD8+ T-cell infiltration in the tumor microenvironment after three doses of ADXS-NEO. Metastatic MSS colorectal cancer is considered to be a "cold" tumor type and typically exhibits little CD8+ T-cell infiltration and resistance to immunotherapy, yet both MSS patients had their "cold" tumors successfully transition into "hot" tumors with ADXS-NEO therapy. Further, two patients (one treated at  $1 \times 10^9$  and one at  $1 \times 10^8$  CFU) achieved stable disease in the study per RECIST 1.1 criteria.
- ***ADXS-HOT: Cancer Type-Focused Hotspot/Off-the-Shelf Neoantigen-Directed Therapies*** – ADXS-HOT is a program consisting of over 10 different cancer-type specific immunotherapy constructs, which target hotspot mutations, cancer testis antigens and oncofetal antigens. The first drug candidate from this program, ADXS-503, is designed to treat most types of non-small cell lung cancer and is in a Phase 1/2 clinical trial. One site is currently activated and enrolling patients with a second site anticipated to be activated by the end of June. The study will determine the recommended dose, safety, tolerability and immune and clinical activity of ADXS-503 administered alone and in combination with a checkpoint inhibitor. Preliminary data from this Phase 1/2 study are anticipated in the second half of 2019. The company plans to file INDs on two additional HOT constructs within the next nine months.
- ***ADXS-PSA: Prostate Cancer*** – The company presented updated clinical and biomarker data at the AACR Annual Meeting in April on its Phase 1/2 KEYNOTE-046 study of ADXS-PSA, alone and in combination with KEYTRUDA®, Merck's anti-PD-1 therapy, for patients with metastatic castration-resistant prostate cancer ("mCRPC"). In addition, updated findings presented at the Frontiers in Cancer Immunotherapy Conference at the NYAS in May demonstrated clinical activity and prolonged overall survival in MSS mCRPC patients, who typically are not expected to respond to treatment of a checkpoint inhibitor.
- ***ADXS-HPV: Cervical Cancer*** – In May, the U.S. Food and Drug Administration ("FDA") lifted its partial clinical hold on the Phase 3 AIM2CERV study evaluating ADXS-HPV ("AXAL") for the treatment of patients with high-risk, locally advanced cervical cancer. The company is in discussions with the FDA to allow for an earlier interim analysis for efficacy under proposed revisions to the AIM2CERV protocol.

### Management Commentary

"We are very encouraged by the early and promising data from our first neoantigen-directed immunotherapy, ADXS-NEO," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Based on these results, we continue to believe neoantigen-directed immunotherapies can become an important addition to the cancer treatment paradigm due to the unique presentation of neoantigens in cancer cells. The results from our ADXS-NEO program have shown the ability to have an impact within the tumor microenvironment in metastatic colorectal cancer, which historically has been a tumor type that is refractory to immunotherapy. We look forward to starting Part B of the study with ADXS-NEO in combination with a checkpoint inhibitor in the third quarter of this year."

"We have used the valuable insight we have gained from our ADXS-NEO platform to further advance our ADXS-HOT drug constructs. We are in discussions with a leading academic institution to finalize an investigator-sponsored trial evaluating ADXS-HOT in patients with prostate cancer, and anticipate the IND for this construct will be filed later this year." He added, "In order to ensure we have the appropriate resources to fund our programs,

we have taken cost-control measures over the past year. These efforts have resulted in a reduction to our cash burn of more than 50% for the first six months of fiscal year 2019 versus the comparable period last year.” He concluded, “We are actively reviewing our plans to finance the areas of the business where we feel there is a strong likelihood of us achieving our mission of improving the lives of people with cancer and their loved ones.”

### **Fiscal Second Quarter Financial Results**

Research and development expenses for the second quarter of fiscal year 2019 were \$6.0 million, compared with \$10.4 million for the second quarter of fiscal year 2018. The \$4.4 million decrease was primarily attributable to cost controls initiated in the second half of fiscal year 2018. In addition, there was a decrease in clinical trial expenses resulting from the partial clinical hold on AIM2CERV and the winding down of several older studies, partially offset by an increase in expenses related to the startup costs associated with the commencement of the Phase 1/2 ADXS-HOT clinical trial.

General and administrative expenses for the second quarter of fiscal year 2019 decreased 37% to \$3.1 million from \$4.9 million for the second quarter of fiscal year 2018. The \$1.8 million decrease was primarily attributable to a reduction in headcount and in professional and consulting fees related to external strategy and program assessment work performed in fiscal 2018.

Revenue decreased approximately \$0.5 million to \$1.2 million for the second quarter of fiscal 2019 from \$1.7 million for the second quarter of 2018 due to the termination of the collaboration agreement with Amgen effective February 2019. Net loss for the second quarter of fiscal year 2019 was \$9.4 million or \$1.59 per share, compared with a net loss for the second quarter of fiscal year 2018 of \$13.4 million or \$4.03 per share.

Net cash used during the six months ended April 30, 2019 was \$11.4 million. As of April 30, 2019, Advaxis had cash and cash equivalents of \$33.7 million, which includes \$9.0 million in net proceeds from a public offering completed in April.

### **Conference Call**

The company will host a business update call on Tuesday, June 11, 2019 at 11:00 a.m. ET. During the call, Advaxis' senior management will review the company's clinical development programs and fiscal second quarter financial results, and provide a general business update.

The conference call and live audio webcast information is as follows:

WHEN: Tuesday, June 11, 2019 at 11:00 a.m. ET  
DOMESTIC DIAL-IN: (844) 348-6133  
INTERNATIONAL DIAL-IN: (631) 485-4564  
CONFERENCE ID: 6199489  
WEBCAST: [ir.advaxis.com/events-presentations](http://ir.advaxis.com/events-presentations)

For those unable to participate in the live conference call or webcast, a digital recording will be available beginning June 11, 2019 two hours after the completion of the call. To access the recording, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the operator with the conference ID: 6199489. In addition, an audio webcast will be archived on the Company's website for a period of time at [www.advaxis.com](http://www.advaxis.com).

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

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, 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. Advaxis has four programs in various stages of clinical development: ADXS-NEO, a personalized neoantigen-directed therapy in principle for any solid tumor; ADXS-503 for non-small cell lung cancer, from its ADXS-HOT off-the-shelf neoantigen-directed program, ADXS-PSA for prostate cancer and ADXS-HPV for cervical cancer.

To learn more about Advaxis, visit [www.advaxis.com](http://www.advaxis.com) and connect on Twitter, LinkedIn, Facebook and YouTube.

### **Advaxis Forward-Looking Statement**

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success and timing of our clinical trials, including subject accrual; our ability to avoid any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; 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; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; 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 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; and, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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[Financial tables follow]

**Advaxis, Inc.**

**Selected Balance Sheet Data  
(In thousands)**

	April 30, 2019 (Unaudited)	October 31, 2018
Cash and cash equivalents	\$ 33,706	\$ 44,141
Restricted cash	\$ -	\$ 977
Total assets	\$ 49,771	\$ 62,267
Total stockholders' equity	\$ 43,170	\$ 24,051

**STATEMENTS OF OPERATIONS**

**(unaudited, in thousands, except share and per share data)**

	Three Months Ended April 30,		Six Months Ended April 30,	
	2019	2018	2019	2018
Revenue	\$ 1,188	\$ 1,747	\$ 20,877	\$ 3,803
Operating expenses *				
Research and development expenses	5,969	10,368	12,675	27,119
General and administrative expenses	3,092	4,932	5,759	10,785
Total operating expenses	9,061	15,300	18,434	37,904
(Loss) income from operations	(7,873)	(13,553)	2,443	(34,101)
Interest income, net	113	151	259	291
Net changes in fair value of derivative liabilities	(14)	-	2,395	-
Loss on shares issued in settlement of warrants	(1,607)	-	(1,607)	-
Other expense	(2)	(6)	(56)	(90)
Net (loss) income	\$ (9,383)	\$ (13,408)	\$ 3,434	\$ (33,900)
Net (loss) income per common share				
Basic	\$ (1.59)	\$ (4.03)	\$ 0.65	\$ (11.16)
Diluted	\$ (1.59)	\$ (4.03)	\$ 0.20	\$ (11.16)
Weighted average number of common shares outstanding				
Basic	5,900,449	3,324,320	5,259,677	3,038,439
Diluted	5,900,449	3,324,320	5,282,772	3,038,439
* Includes stock-based compensation as follows:				
Research and development	\$ 258	\$ 526	\$ 581	\$ 1,799
General and administrative	221	699	520	2,235
	\$ 479	\$ 1,225	\$ 1,101	\$ 4,034

**CONTACT:**

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