Advaxis Reports Fiscal 2018 Third Quarter Business Highlights and Financial Results

September 10, 2018

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 business highlights and financial results for the fiscal year 2018 third quarter, ended July 31, 2018.

"We are encouraged by the momentum achieved with both of our neoantigen-focused programs during our third fiscal quarter and continue on our path of achieving our goal of having five neoantigen-based product candidates in clinical evaluation by the end of 2019"

Recent key accomplishments include:

- Dosing of the first patient in the Company's Phase 1 trial with ADXS-NEO, a personalized immunotherapy approach targeting neoantigens identified by sequencing a patient's own cancer cells, partnered with Amgen.
- U.S. Food and Drug Administration (FDA) allowance of the Company's Investigational New Drug (IND) application for its first ADXS-HOT drug candidate, ADXS-503, for non-small cell lung cancer. ADXS-HOT is an off-the-shelf cancer-type specific immunotherapy approach that leverages the Company's proprietary *Lm* technology platform to target hotspot mutations and other tumor-associated antigens that commonly occur in specific cancer types.
- Selecting prostate and bladder cancers as the second and third ADXS-HOT drug candidates to take into the clinic.
- Granting of a license to OS Therapies for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma, a rare and aggressive tumor that forms in the bone.
- Pricing of its public offering of common stock and warrants. The planned underwritten public offering is expected to result in gross proceeds of approximately $20 million and close on or around September 11, 2018.

Management Commentary

"We are encouraged by the momentum achieved with both of our neoantigen-focused programs during our third fiscal quarter and continue on our path of achieving our goal of having five neoantigen-based product candidates in clinical evaluation by the end of 2019," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "We believe in the powerful impact neoantigens may have on the cancer treatment paradigm. Several of the unique attributes of our *Lm* platform including the capacity of our vector to contain a large number of neoantigens in each single drug construct, as well as the vector's ability to generate strong T-cell responses to neoantigens as demonstrated in previously reported studies, provide us with an opportunity to lead in this potentially revolutionary field of cancer treatment.

"ADXS-NEO, partnered with Amgen, takes a personalized approach to therapy and has the potential to make an important contribution among underserved cancer patient populations with few or no treatment options," he added. "Similarly, the IND allowance by the FDA of our ADXS-HOT drug candidate for non-small cell lung cancer enables us to finalize our Phase 1 trial design and dose our first patient by the end of the year. The ADXS-HOT program, in general, is focused on shared hotspot mutations and other cancer antigens commonly found in cancers with large patient populations such as non-small cell lung cancer and prostate cancer."

"We are also excited about the licensing transaction executed with OS Therapies to evaluate our HER-2 therapy for the treatment of human osteosarcoma. This is a product candidate we believe in, although it falls outside our neoantigen focus. The transaction supports continued clinical development by a team of experts exclusively focused on finding new treatments for osteosarcoma and allows us to remain dedicated to our corporate strategy," he added.

Financial Results for Third Quarter Fiscal Year 2018

The net loss for the third quarter ended July 31, 2018 was $14.0 million or $0.27 per share. This compares with a net loss for the third quarter of fiscal year 2017 of $32.6 million or $0.80 per share. The $18.6 million reduction in the net loss compared to prior year was primarily a result of the significant reduction in spending in research, development and administrative areas.

Research and development expenses for the third quarter of fiscal year 2018 were $10.8 million, compared with $17.8 million for the third quarter of fiscal year 2017. The decrease is primarily attributable to a decrease in laboratory costs, drug manufacturing process validation and drug stability studies supporting the MAA, which we withdrew in July 2018.

General and administrative expenses for the third quarter of fiscal year 2018 were $4.5 million, compared with $18.0 million for the third quarter of fiscal year 2017. The decrease is primarily attributable to a decrease in stock-based compensation of approximately $11.4 million related to the resignation of the Company's Chief Financial Officer and Chief Executive Officer in April 2018 and July 2017, respectively, two Board members who did not seek re-election in March 2018, a reduction in headcount and the elimination of stock-based compensation paid to consultants.

Balance Sheet Highlights

As of July 31, 2018, the Company had approximately $40.4 million in cash, restricted cash and cash equivalents on its balance sheet. The Company is anticipating closing on an underwritten public offering of its common stock and warrants on or around September 11, 2018 which is expected to result in gross proceeds of approximately $20 million to the Company.

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 the T cells to eliminate tumors. Advaxis has four franchises in various stages of clinical and preclinical development: HPV-associated cancers, neoantigen therapy, hotspot/cancer antigens and prostate cancer.

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

Advaxis Forward-Looking Statements

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 patient accrual; our ability to resolve any clinical holds and reduce the impact to our trials; 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; 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 ability of our product candidates to successfully perform in clinical trials; our ability to initiate trials, enroll our trials, obtain and maintain approval of our product candidates; 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.

Advaxis, Inc.
Selected Consolidated Balance Sheet Data
(Unaudited, in thousands)

	July 31, 2018	October 31, 2017
Cash and cash equivalents	$ 39,434	$ 23,900
Restricted cash	$ 977	$ 587
Short-term investment securities	$ -	$ 46,398
Total assets	$ 61,059	$ 93,642
Total stockholders' equity	$ 33,331	$ 54,260

Advaxis, Inc.
Condensed Statements of Operations
(unaudited, in thousands, except per share information)

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2018	2017	2018	2017
Revenue	$ 1,131	$ 3,052	$ 4,934	$ 10,268
Operating expenses *				
Research and development expenses	10,800	17,794	38,703	47,750
General and administrative expenses	4,495	17,995	14,495	33,101
Total operating expenses	15,295	35,789	53,198	80,851
Loss from operations	(14,164)	(32,737)	(48,264)	(70,583)

Other expense	147	112	397	459
Net loss before benefit for income taxes	(14,017)	(32,625)	(47,867)	(70,124)
Income tax expense	-	-	50	50
Net loss	$ (14,017)	$ (32,625)	$ (47,917)	$ (70,174)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.80)	$ (1.00)	$ (1.74)
Weighted average number of common shares outstanding, basic and diluted	52,668,919	40,609,794	47,966,672	40,315,356
* Includes stock-based compensation as follows				
Research and development	$ 543	$ 1,517	$ 2,342	$ 4,271
General and administrative	1,409	12,853	3,645	20,423
	$ 1,952	$ 14,370	$ 5,987	$ 24,694

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