



Advaxis Announces Prioritization of Product Portfolio and Reports Fiscal 2018 Second Quarter Financial Results

June 7, 2018

Annual cash burn will be reduced to approximately \$50 million from approximately \$80 million through a combination of portfolio rationalization and headcount reduction

Conference call begins today at 11:00 a.m. Eastern time

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 a new prioritization of its product portfolio, as well as financial results and business highlights for the three months ended April 30, 2018.

The product portfolio review was conducted under the leadership of recently appointed President and CEO Ken Berlin, along with the full Advaxis executive team including recently named Chief Medical Officer Andres Gutierrez, M.D., Ph.D. The process reflects a commitment to allocate capital to programs that meet three criteria: (i) commercially attractive applications for the company's *Lm* technology platform, (ii) the opportunity for the *Lm* platform to meaningfully impact cancer care, and (iii) a rapid and cost-effective route to generate clinical and immunological response data to demonstrate proof of concept. Each portfolio program was reviewed to determine whether Advaxis can create more value by developing the program internally or externally.

Advaxis has decided to reduce internal investment in axalimogene filolisbac (AXAL) and will seek partnership opportunities for AXAL in most human papillomavirus (HPV)-associated cancers, including cervical cancer. If the company is unable to secure a partner within a limited period of time, Advaxis will wind down the ongoing AIM2CERV trial in high-risk locally advanced cervical cancer, and will not conduct the ADVANCE PD-1 combination trial in metastatic cervical cancer, which has not yet been initiated. Advaxis has determined to focus future development efforts for AXAL on HPV-positive head-and-neck cancer through cost-effective clinical studies that are currently being explored.

Data were presented on the ADXS-PSA combination trial with KEYTRUDA® on June 2nd at ASCO 2018. These data, while early, have proven worthy of further evaluation and the company will continue to follow patients for the next six to nine months in order to determine the path forward.

Advaxis has also decided to increase internal investment in the ADXS-NEO and ADXS-HOT programs, both of which target neoantigens, a potentially transformational, next-generation approach to treating cancer.

Both the ADXS-NEO and the ADXS-HOT programs aim to instruct T cells to selectively attack neoantigens and, in the case of ADXS-HOT, against other tumor-associated antigens, with the goal of controlling tumor growth and prolonging life. Advaxis' proprietary *Lm* platform uniquely positions the company in the development of advanced T cell therapeutics compared with other approaches. This belief is based on, among other things, data derived from more than 530 patients treated with AXAL and other product candidates, showing a manageable safety profile, induction of immune responses and clinical activity.

Clinical Hold Update

In March 2018 the company received notification from the U.S. Food and Drug Administration (FDA) that its Investigational New Drug (IND) application for its Phase 1/2 combination study of AXAL with durvalumab for the treatment of patients with advanced, recurrent or refractory HPV-associated cervical cancer and HPV-associated head-and-neck cancer was placed on clinical hold due to the death of a trial subject that involved pulmonary toxicity occurring after nine months of therapy.

As announced at the time, Advaxis began working closely with the site investigator, its partner AstraZeneca and the FDA to review this event in detail and to resolve this clinical hold. Several external experts from prominent institutions were also consulted in the process.

Advaxis plans to submit a response to the FDA shortly, and expects to receive a response from the Agency within 30 days after the submission.

Management Commentary

"Everything we are striving to accomplish depends on focus and optimal allocation of resources, and is designed to maximize shareholder value. We are dedicating more resources to the HOT program because these assets scored very high when we conducted our portfolio review," said Mr. Berlin. "This program, along with our NEO program which is partnered with Amgen, hold great potential in the exciting and fast-developing field of neoantigens and have application across multiple tumor types in high-value indications. Therefore, it is important for us to allocate increased resources to realize the potential of these programs and to allow for more rapid advancement in this competitive field."

"Our new approach is based on a simple reality: While we are fortunate to have a robust product pipeline, we cannot continue to pursue all programs

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with our current level of resources. We continue to believe in HPV as a target, and are evaluating cost-effective studies for AXAL in head-and-neck cancer. We hope to secure a partner to continue the development of AXAL in cervical cancer," he added.

"In addition, we are pleased to have completed the buildout of our executive leadership team with yesterday's announcement that Molly Henderson has joined Advaxis as Executive Vice President and Chief Financial Officer," he continued. "Coupled with the addition of Executive Vice President and Chief Medical Officer Dr. Andres Gutierrez, we now have the team in place to drive the company forward."

Corporate Restructuring and Impact on Operating Expenses

As part of the change in strategic direction, Advaxis will implement a reduction in force, effective today, to align staffing levels with development priorities. The workforce reduction involves the elimination of approximately 24% of the company's workforce. Advaxis will take a one-time charge in the fiscal third quarter related to this restructuring of approximately \$905,000. The elimination of these positions in conjunction with reductions in clinical expenditures will significantly lower operating expenses, allowing the company to focus on priority programs.

Reflecting the product portfolio prioritization and workforce reduction, Advaxis expects that its annual cash burn will be approximately \$50 million, down 38% from its prior annual cash burn of approximately \$80 million.

Financial Highlights for Second Quarter Fiscal Year 2018

The net loss for the second quarter ended April 30, 2018 was \$13.4 million or \$0.27 per share based on 49.9 million shares outstanding. This compares with a net loss for the second quarter of fiscal year 2017 of \$20.5 million or \$0.51 per share based on 40.3 million shares outstanding.

Research and development expenses for the second quarter of fiscal year 2018 were \$10.8 million, compared with \$16.3 million for the second 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 was filed in February 2018.

General and administrative expenses for the second quarter of fiscal year 2018 were \$4.5 million, compared with \$7.8 million for the second quarter of fiscal year 2017. The decrease was largely attributable to the elimination of non-cash stock-based compensation paid to consultants.

Balance Sheet Highlights

As of April 30, 2018, the company had \$58.8 million in cash, restricted cash, cash equivalents and short-term investment securities on its balance sheet. The company has completed a thorough analysis of operating expenses and its research and development programs. As a result, the company has announced a workforce reduction effective June 7, 2018, and is in the process of making further cost-reduction decisions regarding select ongoing clinical trials. Based upon these actions, the company believes its cash position as of today is sufficient to fund operations for at least one year.

Conference Call and Webcast Information

Advaxis' senior management will host a conference call to review the content of this news release and answer questions. The conference call and live audio webcast will begin today at 11:00 a.m. Eastern time.

To access the conference call please dial (domestic) (844) 348-6133 or (631) 485-4564 (international) and refer to conference ID 8975538. A live and archived audio webcast of the call will be available on the Company's website at ir.advaxis.com/events-presentations.

For those unable to participate in the live conference call or webcast, a digital recording will be available beginning two hours after the conference call ends. To access the recording, dial (855) 859-2056 or (404) 537-3406 and provide the operator with the conference ID: 8975538. In addition, the audio webcast will be archived on the Company's website for a period of time at ir.advaxis.com/events-presentations.

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 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 patient accrual; our ability to release the clinical hold 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.

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