

September 11, 2017



Advaxis Reports Business Update and Third Quarter 2017 Results

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 provided a business update and announced its financial results for the third quarter (Q3) ended July 31, 2017.

“The board of directors selected Anthony Lombardo as interim chief executive officer in July, given his 30 years of leadership experience in the life sciences industry, including previous CEO and executive management positions in both public and private companies,” said Dr. David Sidransky, chairman of the board at Advaxis. “We’re confident in his abilities and the value he’s already helping to deliver, and he will remain in this role for the foreseeable future. Over the past two months, Lombardo has been leading an effort to conduct a review of the current Advaxis business portfolio and our future strategic direction. We have a strong scientific and clinical asset base on which to build value, and the board and the management team are aligned on the path forward to commercialization. To further strengthen the management team, our top priority is conducting a search for a chief medical officer, to ensure the effective execution of our refined clinical strategy. The board and the management team are aligned on Advaxis’ path forward.”

A Four Franchise Approach to Increasing Shareholder Value

This path forward is anchored in the company’s *Lm* Technology, a proven platform unique in its ability to safely and effectively target various cancers in multiple ways. As the field of immunotherapy continues to evolve, the flexibility of the *Lm* platform has allowed Advaxis to continue to adapt and introduce highly innovative programs.

“To fully leverage the technology’s potential and enhance the lives of more cancer patients, while also optimizing shareholder value, we’re reprioritizing programs for continued internal clinical development and implementing alternative strategies for others,” said Anthony Lombardo, interim chief executive officer at Advaxis.

Advaxis’ sharpened growth strategy centers on four clear, distinct franchises that will drive significant value creation: HPV-associated cancers, prostate cancer, neoantigen therapy and hotspot mutation therapy.

1. Franchise One: HPV- Associated Cancers

- Continue our commitment to commercializing axalimogene filolisbac:
 - Completion of the MAA submission for conditional approval in Europe is on track for year end.

- Enrollment continues in eight countries for AIM2CERV to evaluate axalimogene filolisbac as an adjuvant therapy in patients with high-risk locally advanced cervical cancer.
- Collaboration with AstraZeneca on the Phase 2 combination trial with durvalumab in cervical and head and neck cancers is ongoing and continues to enroll.
- The combination trial with ADXS-DUAL and BMS's nivolumab for the treatment of women with persistent, recurrent or metastatic cervical cancer will be initiated in 1H 2018. This program will provide a second registrational opportunity in cervical cancer.
- Given the promising early data in head and neck and anal cancers, Advaxis is actively pursuing opportunities to continue development through investigator-sponsored trials (ISTs) or other third-party approaches.

2. Franchise Two: Prostate Cancer

- Preliminary data presented at the 3rd International Cancer Immunotherapy Conference suggests that ADXS-PSA shows monotherapy activity in prostate cancer that is associated with a distinct immunologic and gene expression pattern. The ongoing trial, ADXS-PSA: Phase 1/2 Study (Keynote-046), evaluates ADXS-PSA as monotherapy and in combination with Merck's pembrolizumab. The clinical benefit in prostate cancer could be a significant value creator to expand the *Lm* platform into the prostate cancer market.
- In addition, the company is actively developing an additional product for prostate cancer, currently in preclinical testing, which could complement ADXS-PSA.

3. Franchise Three: Personalized Therapies Targeting Neoantigens

- ADXS-NEO, in partnership with Amgen Inc., has the potential to be a major step forward in personalized medicine. First patient dosed is expected in 1H 2018.
- The initial tumor types for ADXS-NEO are metastatic microsatellite stable colon, head and neck, and non-small cell lung cancers.

4. Franchise Four: Targeting Shared Hotpot Mutations and Tumor Associated Antigens

- Advancement of the proprietary ADXS-HOT preclinical program will expand *Lm* Technology into multiple products targeting several of the most common cancers.
- Advaxis expects to file INDs for the first HOT products in 2018.

As part of its portfolio refinement, the company has determined it will not pursue further clinical study of ADXS-HER2 at this time, but remains open to ISTs or licensing opportunities.

“We believe that focusing on these four franchises gives us the greatest opportunity to

increase shareholder value and have a significant impact on patients and their families,” said Lombardo. “Our excitement about the clinical potential of our *Lm* Technology is balanced by focus and fiscal discipline.”

Financial Highlights for Q3

“The company had a productive third quarter while advancing the development of its core assets,” said Sara Bonstein, chief financial officer at Advaxis. “There was increased spend in Q3 due to higher costs to support the regulatory filing of axalimogene filolisbac in Europe, and several one-time costs, which are not anticipated to recur. Our Q4 activities will focus on the execution of our core programs, and the disciplined identification and analysis of additional opportunities to leverage our *Lm* Technology platform.”

- Cash, cash equivalents and investments totaled \$89.4 million, compared to \$115.3 million as of April 30, 2017.
- \$34.2 million in disbursements include several one-time cash disbursements, among them technical operations costs associated with the European filing of axalimogene filolisbac (which is anticipated to be completed by the end of 2017) and increased clinical trial costs, together totaling approximately \$7 million. Cash disbursements are anticipated to normalize in the fourth quarter.
- Cash receivables totaled \$8.2 million, primarily from partner reimbursements, specifically \$4.5 million from Amgen in support of the ADXS-NEO program and \$3 million from Stendhal in support of the AIM2CERV program.
- Net loss was \$70.1 million (\$1.74 per share), compared to a net loss of \$51.8 million (\$1.52 per share) for the same period in 2016, largely due to increased research and development (R&D) expenses.
 - R&D expenses were \$47.8 million, compared to \$32.0 million in Q3 2016, related to an increase in clinical trial expense and technical operation support, primarily related to our HPV-franchise.
- General and administrative expenses were \$33.2 million, compared to \$20.4 million in Q3 2016; the difference is primarily attributed to stock and cash compensation expense for past employees, of which approximately \$9.5 million was a non-cash expense.
- 41 million common shares outstanding and 49.5 million shares outstanding on a fully diluted basis as of July 31, 2017.

“We continue to focus on building shareholder value and are committed to bringing clinically beneficial solutions to our patients and their families,” said Lombardo.

To learn more about Advaxis and its immunotherapy clinical programs, visit www.advaxis.com.

About Advaxis, Inc.

Advaxis, Inc., located in Princeton N.J., 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 as they access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, stimulate and 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 pre-clinical development: HPV-associated cancers, prostate cancer, neoantigen therapy and hotspot mutation therapy.

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

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2016, which is available at <http://www.sec.gov>.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law.

You are cautioned not to place undue reliance on any forward-looking statements.

This press release includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this press release and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this press release, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials, including patient accrual;
- 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 loss of key scientific or management personnel;
- 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 foreign 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; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this press release speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this press release. You should also read carefully the factors described in the “Risk Factors” section of the Company’s annual report on Form 10-K for the year ended October 31, 2016, as filed with the SEC on January 9, 2017, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate.

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