

Advaxis, Inc.
Form DEFA14A
February 11, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

SCHEDULE 14A

(Rule 14a-101)

**Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934**

(Amendment No.)

Filed by the Registrant ☒ [X]
Filed by a Party other than the Registrant ☐ []

Check the appropriate box:

☐ [] Preliminary Proxy Statement
☐ [] **Confidential, For Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
☐ [] Definitive Proxy Statement
☒ [X] Definitive Additional Materials
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Advaxis, Inc.

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

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(3) Filing Party:

(4) Date Filed:

305 College Road East

Princeton, New Jersey 08540

February 11, 2016

Dear Fellow Stockholders:

Advaxis' goal is to make a meaningful contribution to the treatment of cancer by developing immunotherapies to provide patients in need with beneficial, cost-effective, innovative cancer immunotherapies. To achieve this goal, we are building a highly integrated biopharmaceutical operation, with products developed and manufactured in-house, licensed and partnered.

In 2015, Advaxis made great strides financially, clinically and operationally. We completed three successful rounds of financing, raising more than \$100M in capital. In addition, building on our innovative *Lm* Technology™, a proprietary versatile platform that alters the tumor microenvironment by increasing tumor fighting cells and decreasing tumor protecting cells, we are evaluating the clinical safety and efficacy of three investigational immunotherapies: axalimogene filolisbac (formerly, ADXS-HPV) in HPV-associated cancers, ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, including osteosarcoma, esophageal and gastric cancer.

As we move forward in 2016, Advaxis anticipates achieving a significant number of clinical development-related value-enhancing milestones. With our lead program, axalimogene filolisbac, which is currently being evaluated in several clinical trials for HPV-associated cancers, we are focused on initiating enrollment in a Phase 3 trial for the treatment of high-risk, locally advanced cervical cancer (the "AIM2CERV" study) in mid-2016. In addition, we plan to complete enrollment in stage 2 of the GOG-0265 Phase 2 study in patients with persistent or recurrent cervical cancer. Positive preliminary data from that study were reported in September at the 2015 American Gynecological & Obstetrical Society Annual Meeting. That data showed that axalimogene filolisbac surpassed historical survival rates in a refractory and heterogeneous patient population. We also expect to present, in the first half of 2016, data from a Phase 1/2 window of opportunity trial in HPV-positive head and neck cancer at a major medical meeting. In the second half of the year, we intend to complete enrollment in the combination Phase 1/2 study started in 2015 with MedImmune's durvalumab, an anti-PD-L1 immune checkpoint inhibitor, for the treatment of cervical cancer.

Similarly, we anticipate strong progress in 2016 with ADXS-PSA, which is our clinical program focused on targeting the prostate-specific antigen (PSA) associated with prostate cancer. Enrollment should be completed by the end of the year in the Phase 1/2 study in combination with Merck's Keytruda® (pembrolizumab), an anti-PD-1 immune checkpoint inhibitor, for the treatment of advanced, metastatic castrate-resistant prostate cancer. This comes on the heels of the successful completion in 2015 of dose escalation cohorts 1 and 2. Importantly, as a result of our work in prostate cancer research, we are proud to have been recognized by the Movember Foundation and the Prostate Cancer Foundation who each awarded grants of \$1 million to Advaxis for two research projects in metastatic, treatment-resistant prostate cancer with ADXS-PSA.

With respect to ADXS-HER2, which targets human epidermal growth factor receptor 2 (HER2) expressing cancers, we anticipate completing enrollment of the Phase 1b dose-escalation study in patients with HER2-driven malignancies in the first half of 2016. We will fully enroll Part A, which is designed to establish safe dosing levels in preparation for the expansion phase of the study. Once an optimal dose is identified from Part A, enrollment in a Part B expansion phase will commence in the second half of 2016. Also, our canine program with ADXS-HER2 deserves recognition for its achievements and work to advance the care of pets. In 2016, our partner for this program, Aratana Therapeutics (NASDAQ:PETX) anticipates conditional approval from the U.S. Department of Agriculture (USDA) of ADXS-HER2 and thereafter intends to initiate commercialization (under the name AT-014) for the treatment of canine osteosarcoma.

In addition, Advaxis' *Lm* Technology™ is uniquely positioned to take advantage of recent advances in genome sequencing and has the bandwidth to potentially target all of a patient's immunogenic cancer neo-epitopes, reducing and/or eliminating the need to use predictive algorithms. Our *Lm* Technology™ may enable the development of truly individualized immunotherapies that can be manufactured in a cost-effective and timely manner. We anticipate making strong headway with our personalized cancer immunotherapy neo-epitope program in 2016. MINE™ (My Immunotherapy Neo-Epitopes), a collaboration with Memorial Sloan Kettering Cancer Center and potentially other centers of excellence, will progress toward the filing of an Investigational New Drug submission in 2016. MINE™ utilizes Advaxis' *Lm* Technology™ to develop neo-epitope immunotherapies based on an individual patient's tumor. We believe this program has significant potential and we look forward to further advances with this work in 2016 and beyond.

Advaxis plans to expand its manufacturing, testing, and product development capabilities through the completion of a new pilot plant, GMP manufacturing suites, research and development labs, and quality control labs at its Princeton, N.J. site. These new capabilities will allow the company to accelerate execution of pipeline related projects, strengthen its supply chain, and continue to ensure reliable and cost competitive supply of its clinical products.

Finally, in order to further leverage the versatility of our *Lm* Technology™ platform, Advaxis has developed, and begun executing on, a global partnering strategy focused on identifying additional collaborations with biopharmaceutical industry leaders and recognized cancer centers of excellence. To this end, we are pleased to have formed important relationships with both Stendhal in Latin America and Knight Therapeutics in Canada.

For a full list of our 2016 anticipated milestones, please visit our website and review our 2016 Business Outlook Press Release.

In closing, Advaxis is dedicated to providing new, innovative cancer therapies to the patients who need them. The company's senior leadership has demonstrated its commitment to this corporate mission through voluntary and frequent out-of-pocket purchases of Advaxis stock at market price. We believe in the potential of our *Lm* Technology™ platform and are committed to addressing unmet medical needs and creating shareholder value for our investors.

Sincerely,

Daniel J. O'Connor
President and Chief Executive Officer

