

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

---

**FORM 8-K**

---

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **January 9, 2017**

**ADVAXIS, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-28489**  
(Commission  
File Number)

**02-0563870**  
(IRS Employer  
Identification No.)

**305 College Road East  
Princeton, New Jersey, 08540**  
(Address of Principal Executive Offices)

**(609) 452-9813**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
  - Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.
- 
-

**Item 7.01 Regulation FD Disclosure.**

A copy of the press release of Advaxis, Inc. (the “Company”) dated January 9, 2017 relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On January 9, 2017, the Company announced its business outlook for 2017, including clinical development and expanding pipeline milestones.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished as a part of this report

99.1 Press Release dated January 9, 2017.

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ADVAXIS, INC.**  
(Registrant)

By /s/ Daniel J. O'Connor  
Daniel J. O'Connor  
President and Chief Executive Officer

Date: January 9, 2017

---

INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release dated January 9, 2017.

---





## Advaxis Provides 2017 Business Outlook

**PRINCETON, N.J., January 9, 2017** — Advaxis, Inc. (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today issued its 2017 business outlook to provide an overview of anticipated events and key milestones for the coming year, as well as a look back at clinical and business highlights from 2016.

Advaxis made significant strides in its clinical development programs and expanded its pipeline with additional preclinical assets in 2016. The company's lead product candidate, axalimogene filolisbac, received Fast Track designation and a Special Protocol Assessment (SPA) for the global Phase 3 AIM2CERV study, a randomized Phase 3 study of axalimogene filolisbac following chemoradiation in patients with high-risk, locally advanced cervical cancer (HRLACC). Also in 2016, axalimogene filolisbac was classified as an advanced therapy medicinal product (ATMP) for the treatment of cervical cancer by the European Medicines Agency's (EMA) Committee for Advanced Therapies (CAT). Late in 2016, the company initiated AIM2CERV and announced positive, final data from the GOG-0265 Phase 2 trial that supports pursuing a second global Phase 3 study in a metastatic recurrent cervical cancer. Also in 2016, Advaxis entered into a collaboration with Amgen Inc. (Amgen) for the global development and commercialization of Advaxis' preclinical neoantigen technology, ADXS-NEO, to create a personalized approach to cancer treatment.

In 2016, Advaxis expanded its capabilities and added significant resources to support execution of two global registrational clinical trials and future commercialization of its immuno-oncology products. The company added close to \$100 million in capital from proceeds from the Amgen collaboration, a direct placement and a state grant. Advaxis expanded its management team in 2016 with the appointment of Chris Duke as Chief Operating Officer, and added approximately 30 more employees in key areas, as the company grew its headcount to 80 over the course of the year. In September, the company completed the buildout of its clinical manufacturing facility to produce clinical trial supplies and expanded its research laboratory facility. Also, the company began construction of its commercial manufacturing facility, all at its Princeton headquarters.

### 2017 OPERATIONAL MILESTONES

Advaxis anticipates the following development milestones in 2017:

#### Clinical Operations

##### Axalimogene Filolisbac

- Present a detailed data analysis of the completed Phase 2 GOG-0265 trial, which was conducted by the GOG Foundation, Inc. (GOG, now part of NRG Oncology), evaluating patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC), at a medical meeting in the first half of 2017. Top-line data released in 2016 showed a 12-month overall survival rate of 38 percent observed in 50 patients in the trial. This is a 52 percent improvement over the 12-month overall survival rate that was expected in the trial's patient population based on prognostic factors.
-

- Attend an end-of-Phase-2 meeting with respect to PRmCC with the U.S. Food and Drug Administration (FDA) to discuss the results of GOG-0265.
- Submit a marketing authorization application to the EMA for approval of axalimogene filolisbac to treat patients with metastatic cervical cancer in the second half of 2017.
- Open approximately 150 clinical sites for the global, 450-patient Phase 3 AIM2CERV trial in patients with HRLACC, with a trial enrollment update to be issued at a medical meeting in the first half of 2017. There are 10 active trial sites in the United States as of this week.
- Initiate a second global, registrational Phase 3 study in patients with metastatic cervical cancer in the second half of 2017.
- Present updated clinical data from the Phase 1/2 combination trial with AstraZeneca's investigational anti-PD-L1 inhibitor, durvalumab, in patients with recurrent, persistent or metastatic cervical cancer or HPV+ squamous cell cancer of the head and neck (HNSCC) at a medical meeting in the second half of 2017.
- Present additional data from the Phase 2 BrUOG trial in high-risk, locally advanced anal cancer, conducted in collaboration with Brown University's Oncology Research Group, at a medical meeting in the first half of 2017.
- Present additional data from the Phase 2 window of opportunity trial in HPV-positive head and neck cancers at a medical meeting in the first half of 2017.
- With full enrollment achieved in Stage 1 of the FAWCETT Phase 2 trial in patients with persistent or recurrent metastatic anal cancer, the company plans to present a preliminary trial update at a medical meeting in the second half of 2017.

#### ADXS-PSA

- Complete initial dosing of Part B of the Phase 1/2 trial evaluating ADXS-PSA in combination with KEYTRUDA<sup>®</sup> (pembrolizumab) in advanced, metastatic castration-resistant prostate cancer (mCRPC) and present preliminary data at a medical meeting in 2017.
  - Initiate and complete enrollment of the expansion cohort by year-end 2017.

#### ADXS-HER2

- Initiate a study in pediatric osteosarcoma in collaboration with the Children's Oncology Group in 2017.
-

## **Expanding Pipeline**

### **ADXS-NEO Collaboration with Amgen**

- Submit an Investigational New Drug (IND) application to the FDA in early 2017.
- Initiate the first-in-human ADXS-NEO clinical trial.
- Accelerate the discovery of personalized cancer immunotherapies derived from neoantigens as part of the TESLA (Tumor neoantigEn SeLection Alliance) with the Parker Institute for Cancer Immunotherapy and the Cancer Research Institute.

### **ADXS-HOT**

- Prepare and file an IND with the FDA for ADXS-HOT constructs that target tumor driver genes, so-called hotspot mutations or public mutations, found in various cancer types in the second half of 2017.

## **Enhanced Manufacturing and Research Capabilities**

- Increase capacity to include in-house clinical and commercial manufacturing capabilities, initially to manufacture clinical supplies for the ADXS-NEO program in 2017.
- Reduce lead times and improve overall supply chain by operationalizing several technology transfers with its partners and by installing new innovative technologies.

## **Corporate Development**

- Pursue research, clinical and commercial partnerships to optimize the cancer immunotherapy portfolio, including to enable development of lead asset, axalimogene filolisbac, in combination with other novel cancer therapies and to support its registration and potential commercialization in the EU.
- Explore the application of detoxified Listeriolysin O (dtLLO) technology and optimize the research and development as an adjuvant molecule in the development of vaccines.

## **2016 REVIEW**

Advaxis achieved several regulatory, clinical, business and operational milestones in 2016:

### **Clinical Milestones**

#### **Axalimogene Filolisbac**

- June: Presented preliminary data at American Society of Clinical Oncology (ASCO) from stage 1 of the Phase 2 GOG-0265 clinical study showing a 6-month survival rate of 38.5 percent in 26 patients, which exceeds prior historical GOG trials in this patient population. Of particular note, a patient from this stage experienced a complete response following three doses which remains ongoing.
-



- June: Dosed the first patient in the first stage of the Phase 2 FAWCETT trial in patients with persistent or recurrent metastatic anal cancer.
- July: Reached an agreement with the FDA under the SPA process for the Phase 3 AIM2CERV trial.
- July: Received classification as an ATMP for the treatment of cervical cancer by the EMA's CAT and received Fast Track Designation from the FDA for high-risk, locally advanced cervical cancer.
- October: Entered Phase 3 with initiation of AIM2CERV evaluating axalimogene filolisbac as an adjuvant therapy following chemotherapy and radiation.
- October: Announced updated data from the Phase 2 GOG-0265 clinical study which showed a patient with recurrent cervical cancer achieved a durable complete response, as well as a 12-month overall survival rate of 38 percent across all study subjects (n=50), surpassing historical 12-month survival rates in GOG studies which have never exceeded 30 percent.
- November: As presented at the Society for Immunotherapy of Cancer annual meeting, a patient with cervical cancer participating in the combination trial with AstraZeneca's durvalumab achieved a complete response, and two patients with HNSCC achieved stable disease.
- April: The window of opportunity trial, as presented at American Association for Cancer Research annual meeting, showed increased systemic HPV-reactive T-cell responses in patients with late-stage HPV-positive oropharyngeal cancer, allowing for the trial to advance to the second stage, being conducted at the Icahn School of Medicine at Mount Sinai.

#### ADXS-PSA

- April: Finalized the part A dose-escalation cohort of the Phase 1/2 KEYNOTE-046 combination trial with Merck, which evaluated maximum tolerability of ADXS-PSA in patients with previously treated mCRPC.
- October: Initiated the combination portion evaluating ADXS-PSA in combination with KEYTRUDA.

#### ADXS-HER2

- May: As published in Clinical Cancer Research, in a dose-escalation study of ADXS-HER2 in canine osteosarcoma, antigen-specific T-cell responses were seen within 6 months of immunotherapy administration.
  - April: FDA granted Fast Track designation for ADXS-HER2 for patients with newly diagnosed, non-metastatic, surgically-resectable osteosarcoma.
-

## **Expanding Pipeline**

### **ADXS-NEO**

- January: Established a five-year exclusive supply agreement with Synthetic Genomics, Inc. to manufacture the synthetic DNA used in ADXS-NEO.
- August: Advaxis entered into a **global collaboration** with Amgen to develop and commercialize ADXS-NEO. Under the collaboration agreement, Advaxis will lead the clinical development of ADXS-NEO through proof-of-concept, retain manufacturing responsibilities, and receive development, regulatory and sales milestone payments of up to \$475 million. Amgen received worldwide rights to develop and commercialize ADXS-NEO.
- December: Advaxis joined the TESLA (Tumor neoantigen Selection Alliance) collaboration with the Parker Institute for Cancer Immunotherapy and the Cancer Research Institute, along with 30 leading academia and industry partners, to further cancer neoantigen research.

## **Business & Operations**

Advaxis achieved the following operational milestones in 2016:

- Over the course of 2016, Advaxis expanded its leadership team, deepening its clinical operations, manufacturing and business development functions:
    - Christopher Duke, Senior Vice President and Chief Operating Officer.
    - Ranya Dajani, Vice President, Corporate Development
  - January: Established a Scientific Advisory Board, including Antoni Ribas, M.D., Ph.D., Jedd Wolchok, M.D., Ph.D., Nancy Freitag, Ph.D., Marc Lecuit, M.D., Ph.D.
  - January: Added two more patents to its growing patent portfolio; European Patent No. 1804831 expands the composition of matter claims covering HER-2 tumor antigens, and U.S. Patent No. 9,226,958 expands the use of the Company's Lm Technology™ beyond oncology, specifically to induce an immune response in parasitically infected patients.
  - February: **Bradley Monk**, co-primary investigator of the GOG-0265 Phase 2 study, joined Advaxis as the company's Lead Cervical Cancer Advisor to head the development of Advaxis' Lm Technology platform and lead the AIM2CERV program.
  - February: Agreement established with Especificos **Stendhal** SA de CV ("Stendhal") to co-develop and commercialize axalimogene filolisbac in Latin America.
  - February: Daniel O'Connor, president and chief executive officer of Advaxis, was appointed to the **Board of Trustees of BioNJ**.
  - April: Advaxis became the first biotechnology company to receive the Vision of Hope Award from the Sarcoma Foundation of America for its ADXS-HER2 osteosarcoma immunotherapy platform.
  - August: Advaxis secured **\$30 million in direct placement financing** from healthcare institutional specialist investors.
-

- September: Advaxis unveiled its state-of-the-art laboratory and manufacturing facility to develop immuno-oncology therapeutics in Princeton, N.J. where Governor Chris Christie led the ribbon-cutting event.
- October: Advaxis received \$2.5M through the New Jersey Economic Development Authority's (NJEDA) New Jersey Technology Business Tax Certificate Transfer (NOL) program.

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

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary **Lm** Technology. The **Lm** Technology, using bioengineered live attenuated *Listeria monocytogenes (Lm)* bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead **Lm** Technology immunotherapy, axalimogene filolisbac, targets HPV-associated cancers and is in clinical trials for three potential indications: Phase 3 in invasive cervical cancer, Phase 2 in head and neck cancer, and Phase 2 in anal cancer. The FDA has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for HRLACC patients and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. Axalimogene filolisbac has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development. In addition, Advaxis and Amgen are developing ADXS-NEO, a preclinical investigational cancer immunotherapy treatment designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor, with plans to enter the clinic in 2017.

For additional information on Advaxis, visit [www.advaxis.com](http://www.advaxis.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#) and [Google+](#).

---

## **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 immunotherapy, axalimogene filolisbac. 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.

KEYTRUDA<sup>®</sup> is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, N.J., USA.

### **CONTACTS:**

#### **Company:**

[Advaxis, Inc.](#)

Ranya Dajani, Vice President, Corporate Development

[dajani@advaxis.com](mailto:dajani@advaxis.com)

609.250.7559

#### **Media Contact:**

[JPA Health Communications](#)

David Connolly

[dconnolly@jpa.com](mailto:dconnolly@jpa.com)

617.945.9316

---

