# 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): June 25, 2015

# 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 June 25, 2015 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 June 25, 2015 at 8:30am ET, the Company will host a corporate business update conference call and webcast to review year-to-date accomplishments and key near-term goals. The Company also issued a press release announcing its business outlook, outlining various regulatory, clinical, business and operational milestones throughout the remainder of the year and into 2016.

#### 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 June 25, 2015.

# 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: June 25, 2015

# INDEX TO EXHIBITS

Exhibit	
Number	Description
99.1	Press Release dated June 25, 2015.



## Advaxis Provides 2015 Half-Year Review and Outlook

Multiple Clinical Milestones from 10 Clinical Studies Anticipated Through 2015 and into 2016 First-in-Human Study of ADXS-HER2 to Commence this Summer Enrollment in AstraZeneca/MedImmune MEDI 4736 Study to Commence this Summer

**PRINCETON, N.J., June 25, 2015** — <u>Advaxis, Inc.</u> (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today will hold a business update conference call at 8:30 a.m. ET highlighting year-to-date accomplishments and key near-term goals. The call is intended to provide Advaxis investors and stakeholders with a recap of the Company's achievements in the first half of 2015 and an overview of milestones anticipated throughout the remainder of the year and into 2016.

A live broadcast of the conference call will be available by direct dial at 1-888-401-4669 in the U.S. or 1-719-325-2458 outside of the U.S.; Conference Passcode 7209396, or by live webcast available online at this URL: <u>http://public.viavid.com/player/index.php?id=114962</u>.

The call will be recorded and available for playback through July 9 by dialing 1-877-870-5176 in the U.S. and 1-858-384-5517 outside of the U.S.; Replay Passcode 7209396. In addition, the webcast will be available for replay at the URL above.

"We are pleased with our accomplishments during the past six months as we continue to strengthen our proprietary immunotherapy platform," said Daniel J. O'Connor, President and CEO of Advaxis. "In addition to the significant progress in R&D, we are financially strong and now have the resources to fully execute on and expand our clinical development programs."

## **UPCOMING MILESTONES**

Advaxis anticipates the following operational milestones throughout the remainder of 2015 and into 2016.

#### *Lm* Technology<sup>™</sup> Immunotherapy Clinical Programs:

## ADXS-HPV

- Commence enrollment in the Phase 3, registration quality trial, AIM2CERV.
- Complete enrollment in Stage 2 of the ongoing GOG-0265 Phase 2 trial of ADXS-HPV in persistent or recurrent cervical cancer being conducted by the Gynecologic Oncology Group (GOG), anticipating up to 38 patients enrolled by June 30, 2016 with Final Stage 1 safety and efficacy data to be presented at an upcoming major medical meeting in 2015. Final study data (Stage 1 and 2) to be available in the first half of 2017.

- Enroll the first patient this summer in a collaborative Phase 1/2 study of ADXS-HPV in combination with AstraZeneca/MedImmune's MEDI4736 in cervical cancer and HPV-associated head and neck cancer in second half of 2015 with data available in the first half of 2016.
- Complete enrollment in Part A (dose escalation) of our Phase 1 study evaluating higher doses of ADXS-HPV immunotherapy and repeat cycles of treatment with data available from Part A in 2016.
- Complete enrollment of the Mount Sinai investigator-sponsored Phase 1/2 study of ADXS-HPV in patients with HPV-associated head and neck cancer. Data to be available in the first half of 2016.
- Commence enrollment in a Phase 2 study in patients with HPV-associated metastatic anal cancer by year's end with data available in the second half of 2016.
- Commence enrollment in the second half of 2015 on the Phase 1/2 combination study with Incyte Corporation's (Incyte) IDO-1 inhibitor.

## ADXS-PSA

• Complete enrollment in Part A (dose escalation) in the first half of 2016 in the Phase 1/2 study of ADXS-PSA as a monotherapy or in combination with Merck's anti-PD-1 therapy, Keytruda<sup>®</sup> (pembrolizumab), in metastatic, castration-resistant prostate cancer (mCRPC). Data to be available in second half of 2016.

#### ADXS-HER2

- Enroll the first patient in a Phase 1 first-in-human trial of ADXS-HER2 in metastatic HER2 expressing solid tumors in the second half of 2015 with data to be available in the second half of 2016.
- Initiate a clinical study of ADXS-HER2 in pediatric osteosarcoma in partnership with the Children's Oncology Group (COG) in 2016.
- Secure conditional license for ADXS-HER2 (also known as AT-014) for the treatment of canine osteosarcoma from the U.S. Department of Agriculture in 2016.

#### **Business:**

- Advaxis continues to seek partnerships for its *Listeria monocytogenes* (*Lm*) Technology that will enable additional research in combination with other cancer therapies and novel immunotherapies. Advaxis currently retains full commercial rights to its programs.
- Advaxis continues to explore options for retaining a Latin American partner for ADXS-HPV to collaborate on co-development and registration in this important region.

## FIRST HALF 2015 REVIEW

Since issuing its previous business update in January 2015, Advaxis achieved several regulatory, clinical, business and operational milestones during the first half of 2015.

#### *Lm* Technology<sup>™</sup> Immunotherapy Clinical Programs:

ADXS-HPV

• GOG's Phase 2 Study of ADXS-HPV for the Treatment of Persistent or Recurrent Cervical Cancer Achieved Stage 1 Safety and Efficacy Criteria; GOG Began Enrolling Patients in Stage 2 of the Study

On January 28, Advaxis announced that GOG-0265 Phase 2 open-label clinical study of ADXS-HPV in patients with persistent or recurrent cervical cancer with documented disease progression being conducted by the GOG, has completed its first stage and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. The GOG began enrolling patients in Stage 2 of the ongoing Phase 2 trial and expects the study to be fully enrolled by the end of 2015.

• Advaxis and GOG to Collaborate on Phase 3 Study of ADXS-HPV in High Risk, Locally Advanced Cervical Cancer; Filed a SPA

On January 7, Advaxis announced a clinical trial collaboration agreement with the GOG for a planned Phase 3 study evaluating the safety and efficacy of ADXS-HPV in high-risk, locally advanced cervical cancer. On June 15, Advaxis announced the submission of a Special Protocol Assessment (SPA) request to the U.S. Food and Drug Administration (FDA) for the Phase 3 study and plans to initiate the study by the end of 2015, depending on the length of the SPA process.

• Advaxis Treated First Patient in Phase 1/2 Study of ADXS-HPV for Recurrent Cervical Cancer

On March 19, Advaxis announced that the first patient was dosed in a Phase 1/2 clinical trial evaluating higher doses and repeat cycles of ADXS-HPV in persistent, metastatic or recurrent cervical cancer, based on encouraging survival data seen previously with a lower dose in this patient population.

• FDA Cleared IND for Phase 2 Study of ADXS-HPV and Incyte's epacadostat for HPV-Associated Early Stage Cervical Cancer

On June 1, Advaxis announced the clearance of the Investigational New Drug (IND) application by the FDA to conduct a Phase 2 study of ADXS-HPV alone or in combination with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat, for the treatment of early stage HPV-associated cervical cancer. The trial is expected to begin patient enrollment in the second half of 2015.

• Advaxis and RTOG Foundation to Collaborate on a Pivotal Phase 2/3 Study of ADXS-HPV in Anal Cancer

On April 6, Advaxis announced entering into a clinical trial collaboration agreement with the Radiation Therapy Oncology Group (RTOG) Foundation to evaluate the safety and efficacy of ADXS-HPV in a pivotal Phase 2/3 anal cancer trial, which will be run by NRG Oncology.

• Preliminary Data from a Phase 1/2 Study of ADXS-HPV in HPV-Associated Anal Cancer Presented at the 2015 IANS Scientific Meeting

On March 16, Advaxis announced that preliminary data from an ongoing Brown University Oncology Research Group investigator-sponsored Phase 1/2 clinical study investigating ADXS-HPV in combination with chemoradiation in HPV-associated locally advanced anal cancer were presented at the International Anal Neoplasia Society (IANS) 2015 Scientific Meeting. Based upon these preliminary data, this study has the potential to transition to a Phase 2/3 registration quality study to be conducted by RTOG.

#### ADXS-PSA

 Advaxis and Merck Initiated Enrollment in the Phase 1/2 Study of ADXS-PSA in Combination with Anti-PD-1 Therapy KEYTRUDA, in Advanced Prostate Cancer

On April 8, Advaxis and Merck announced enrollment has commenced in the Phase 1/2 KEYNOTE-046 clinical trial evaluating ADXS-PSA as a monotherapy and in combination with Merck's anti-PD-1 therapy, KEYTRUDA (pembrolizumab), in previously treated mCRPC.

## ADXS-HER2

• FDA Accepted IND for First-in-Human Trial of ADXS-HER2; Advaxis to Initiate Phase 1b Study in Patients with Metastatic HER2 Expressing Solid Tumors

On January 22, Advaxis announced the FDA cleared its IND to conduct a Phase 1b clinical study evaluating the safety and tolerability of ADXS-HER2 as a monotherapy in patients with metastatic HER2 expressing solid tumors. The clinical trial will be the first-in-human study of ADXS-HER2 and is expected to begin patient enrollment in the summer of 2015.

• Preliminary Data from Phase 1 Study of ADXS-HER2 in Canine Osteosarcoma Presented at the 2015 AACR Meeting

On April 20, preliminary data from one clinical and two preclinical studies demonstrating the survival outcomes and anti-tumor effects of Advaxis's *Lm* Technology immunotherapies in various settings were presented at the American Association for Cancer Research (AACR) Annual Meeting 2015. Data from the ongoing Phase 1 clinical study of ADXS-HER2 in combination with palliative radiation suggested that ADXS-HER2 delayed tumor progression and prolonged overall survival in 10 pet dogs with spontaneous osteosarcoma that were not candidates for primary tumor removal (amputation). The commercial rights to the veterinary indications for ADXS-HER2 have been licensed to Aratana Therapeutics.

## **Business & Operations:**

Advaxis Completed Two Successful Rounds of Financing

Advaxis has raised approximately \$140 million in fewer than two years and has approximately \$100 million in cash on the balance sheet.

• Advaxis Completed Leadership Hires In Core Business Functions

Advaxis's new hires secured leadership positions in manufacturing, regulatory affairs and clinical operations. The industry experience and caliber of these executives highlights that Advaxis has become a company able to attract premier staff from the industry.

• Advaxis and Sorrento Formed a Collaboration to Evaluate Combinations of Advaxis's Lm Technology Product Candidates and Sorrento's Immunomodulatory Antibodies

Advaxis entered into a non-exclusive research and clinical trial collaboration agreement with Sorrento Therapeutics, Inc. (Sorrento) to evaluate combinations of the company's immunotherapy candidates, including ADXS-HPV, ADXS-PSA and ADXS-HER2, with Sorrento's fully human antibodies targeting immune checkpoints, including GITR, OX40, LAG-3 and TIM-3.

• Advaxis Formed a Clinical Trial Collaboration With Incyte to Evaluate Investigational Combination of Two Novel Cancer Immunotherapies for Early Stage Cervical Cancer

Advaxis established an agreement with Incyte to investigate the combination of ADXS-HPV together with Incyte's investigational IDO1 inhibitor, epacadostat. The recently accepted IND for the Phase 2 study evaluating ADXS-HPV as a monotherapy and in combination with epacadostat in patients with early stage HPV-associated cervical cancers is expected to start in the second half of 2015.

#### 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<sup>TM</sup>. The Lm Technology, using bioengineered live attenuated Listeria monocytogenes bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T-cells directed against a cancer antigen and neutralize Tregs and myeloid-derived suppressor cells (MDSCs), that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's lead Lm Technology immunotherapy, ADXS-HPV, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted Advaxis orphan drug designation for each of these three indications. For additional information on Advaxis, visit <u>www.advaxis.com</u> and connect on <u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u>, <u>YouTube</u> and <u>Google+</u>.

## **Forward-Looking Statements**

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies;statements regarding our initiation and completion of enrollment of patients for our studies related to ADXS-HPV, ADXS-PSA and ADXS-HER2, statements regarding preliminary data related to our studies and whether such data is predictive of future clinical trials, and the safety and efficacy of Advaxis's proprietary immunotherapy, ADXS-HPV. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis's SEC filings, including but not limited to its report on Form 10-K for the fiscal year ended October 31, 2014, which is available at <a href="http://www.sec.gov">http://www.sec.gov</a>. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

# **CONTACTS:**

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