

Advaxis, Inc.
Form 8-K
July 06, 2016

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): **July 6, 2016**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware **000-28489** **02-0563870**

(State or Other Jurisdiction of Incorporation) (Commission File Number) (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 July 6, 2016 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 July 6, 2016, the Company announced that it reached an agreement with the U.S. Food and Drug Administration (the “FDA”), under the Special Protocol Assessment (the “SPA”) process, for the Phase 3 AIM2CERV trial evaluating the Company’s lead *Lm* immunotherapy candidate, axalimogene filolisbac (“AXAL”), in patients with high-risk, locally advanced cervical cancer. AIM2CERV is a multinational, randomized, controlled clinical trial.

A successfully concluded SPA provides an agreement with FDA’s review division that a pivotal trial design, conduct, and planning analysis adequately address the scientific and regulatory objectives in support of a regulatory submission for drug approval. Final marketing approval depends upon the efficacy results, safety profile and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical trial.

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 July 6, 2016.

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: July 6, 2016

INDEX TO EXHIBITS

| Exhibit Number | Description |
|---------------------------|-----------------------------------|
| 99.1 | Press Release dated July 6, 2016. |

