

Advaxis, Inc.
Form 8-K
July 22, 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 21, 2016**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware **000-28489** **02-0563870**
(State or Other Jurisdiction) (Commission (IRS Employer
of Incorporation) File Number) 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 21, 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 21, 2016, the Company announced that the U.S. Food and Drug Administration (“FDA”) had designated the Company’s lead immunotherapy candidate, axalimogene filolisbac (“AXAL”), as a Fast Track product for adjuvant therapy for high-risk locally advanced cervical cancer patients. The investigation of AXAL in this under-served population will be conducted in accordance with the Special Protocol Assessment recently granted by the FDA.

AXAL is a targeted immunotherapy which attacks human papillomavirus-associated cancers by altering a live strain of *Listeria monocytogenes* (*Lm*) bacteria to generate cancer fighting T cells directed against the specific cancer antigen and neutralizing factors that protect the tumor microenvironment from immunologic attack and contribute to tumor growth.

The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to help expedite development, including opportunities for frequent interactions with the FDA to discuss all aspects of development to support approval, eligibility for priority review at the time of Biologics License Application submission and early review of portions of the application before submitting a complete application.

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 21, 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 22, 2016

INDEX TO EXHIBITS

**Exhibit
Number Description**

99.1 Press Release dated July 21, 2016.

