

Advaxis, Inc.
Form 8-K
February 15, 2018

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): **February 13, 2018**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-36138	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.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

A copy of the press release of the Company, dated February 13, 2018, relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information provided pursuant to this Item 7.01, including Exhibit 99.1, is “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or of Sections 11 and 12(a)(2) of the Securities Act, and shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On February 13, 2018, the Company issued a press release announcing the submission of a conditional Marketing Authorization Application (“MAA”) to the European Medicines Agency (the “EMA”) for the Company’s lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of persistent, recurrent or metastatic carcinoma of the cervix (“PRmCC”).

The MAA submission was built around data from the GOG-0265 study which examined overall survival rates in 50 women and showed a 12-month overall survival rate (primary efficacy endpoint) of 38% (n=19/50) in women with PRmCC, representing a 55% improvement over an expected, model-predicted, 12-month survival rate of 24.5%. In the GOG-0256 study, axalimogene filolisbac was generally well-tolerated with mostly Grade 1 and 2 flu-like adverse events associated with cytokine release which were managed with standard medical care. This safety profile is consistent with the ongoing clinical experience of axalimogene filolisbac across all clinical trials. The EMA will evaluate the totality of the data, including results from GOG-0265 as well as supportive data from other clinical trials evaluating axalimogene filolisbac. In parallel with the MAA review process, the Company will continue assessing partnership opportunities for the potential commercialization of axalimogene filolisbac in Europe.

The Company has also decided to align and simplify its strategy by using axalimogene filolisbac exclusively in all ongoing and planned HPV-related cancer clinical trials, including the upcoming ADVANCE trial, previously planned with ADXS-DUAL. The Company believes that harmonizing to a single product candidate for all HPV-related programs will streamline developmental, regulatory and commercialization strategies.

Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements regarding the Company's ability and strategies to develop and commercialize cancer immunotherapies, timing of planned clinical trials and regulatory milestones, potential partnership opportunities and the safety and efficacy of the Company's proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in the Company's SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2017, which is available at www.sec.gov. Any forward-looking statements set forth in this report speak only as of the date of this report. 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. Information contained on the Company's website does not constitute part of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
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99.1	<u>Press release issued by Advaxis, Inc., dated February 13, 2018.</u>
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SIGNATURES

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

ADVAXIS, INC.

(Registrant)

Date: February 15, 2018

By: */s/ Sara Bonstein*

Sara Bonstein

Executive Vice President and Chief Financial Officer

