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

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**FORM 8-K**

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

**001-36138**  
(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.

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.

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## 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](http://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:

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Advaxis, Inc., dated February 13, 2018.</a>

**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*

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Sara Bonstein  
Executive Vice President and Chief Financial Officer

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# ADVAXIS

## IMMUNOTHERAPIES

### Advaxis Submits Conditional Marketing Authorization Application for Axalimogene Filolisbac for the Second-Line Treatment of Metastatic Cervical Cancer in European Union

- Advaxis reaches important regulatory milestone for axalimogene filolisbac with submission of Conditional MAA to treat metastatic cervical cancer in patients who progress beyond first-line therapy
- The MAA submission is centered around the encouraging results from the GOG-0265 study
- Each year, more than 24,000 women in Europe die from metastatic cervical cancer<sup>1</sup>

**PRINCETON, N.J. (February 13, 2018)** – Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of cancer immunotherapies has submitted a conditional Marketing Authorization Application (MAA) to the European Medicines Agency (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 submission of the MAA represents a significant regulatory milestone for Advaxis and the ongoing development of our *Lm* Technology Platform,” stated Anthony Lombardo, interim Chief Executive Officer of Advaxis. “The submission is based on the improvement in 12-month survival rates observed in the Phase 2 GOG-0265 study. We feel that these data support axalimogene filolisbac as a potential therapeutic option for patients living with PRmCC who are in desperate need of new treatment options beyond first-line therapy,” added Lombardo.

The MAA submission is 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%.<sup>2</sup> More than 50% of treated women in this study had previously received multiple prior lines of therapy including treatment with bevacizumab and subsequently experienced progression of their disease.<sup>2</sup>

“Despite the availability of preventative measures, metastatic cervical cancer continues to be a major public health concern associated with high mortality rates within Europe,” said Mansoor Mirza, M.D., Chief Oncologist at the Copenhagen University Hospital in Denmark and Medical Director of the Nordic Society of Gynaecological Oncology (NSGO). “The results from GOG-0265 are encouraging and could represent a meaningful step forward in the care of women suffering from PRmCC, which has seen very little innovation in almost 30 years.”

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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 strategic decision to harmonize all trials to axalimogene filolisbac is based on its clinical profile to date in over 250 patients, and its demonstration of similar activity in both HPV 16 and 18 subtypes in GOG-0265. The company believes that harmonizing to a single product candidate for all HPV-related programs will streamline developmental, regulatory and commercialization strategies.

### **About Axalimogene Filolisbac**

Axalimogene filolisbac is a targeted *Listeria monocytogenes (Lm)*-based investigational immunotherapy that attacks HPV-associated cancers by altering a live strain of *Lm* bacteria to generate cancer-fighting T cells against cancer antigens while neutralizing the tumor's natural protections that guard the tumor microenvironment from immunologic attack.

Axalimogene filolisbac has already achieved multiple regulatory milestones, including classification as an EMA advanced therapy-medicinal product for the treatment of cervical cancer, receipt of the U.S. Food and Drug Administration (FDA) Fast Track Designation as an adjuvant therapy for treating high-risk, locally advanced cervical cancer (HRLACC), receipt of a Special Protocol Assessment agreement with the FDA for the Phase 3 AIM2CERV trial, and orphan drug designations in three HPV-associated indications (PRmCC, head and neck, and anal cancer). In addition, axalimogene filolisbac will be studied in combination with nivolumab in the ADVANCE trial, a potential registrational trial for patients with PRmCC, which is planned to begin in 2018.

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

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes (Lm)* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy, and are designed to access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, activate the immune system with the equivalent of multiple adjuvants and simultaneously reduce tumor protection in the tumor microenvironment to enable the T cells to eliminate tumors. Advaxis has four franchises in various stages of clinical and near-clinical development: HPV-associated cancers, individualized neoantigen immunotherapy, cancer-specific hotspot mutation immunotherapies and prostate cancer.

To learn more about Advaxis, visit [www.advaxis.com](http://www.advaxis.com) and connect on Twitter, LinkedIn, Facebook, and YouTube.

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## References

1. Ferlay J, et al. *Eur J Cancer* 2013;49:1374-403.
2. Huh W, et al. Presented at the Annual Meeting on Women's Cancer. March 12-15, 2017.

## Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' 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 Advaxis' proprietary immunotherapies. 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, 2017, which is available at [www.sec.gov](http://www.sec.gov).

Any forward-looking statements set forth in this press release speak only as of the date of this press release. 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.

## CONTACTS:

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