

**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): January 7, 2020

ADVAXIS, INC.

(Exact name of registrant as specified in its 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 (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	ADXS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01 Other Events.

On January 7, 2020, Advaxis, Inc. (the “Company”) issued a press release announcing that the United States Food and Drug Administration has cleared the Investigational New Drug for the initiation of a Phase 1 clinical study of ADXS-504. The Company’s press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Advaxis, Inc. dated January 7, 2020.

SIGNATURE

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.

January 7, 2020

ADVAXIS, INC.

By: /s/ Molly Henderson

Name: Molly Henderson

Title: Executive Vice President and Chief Financial Officer

Advaxis Announces FDA Clearance of IND for ADXS-504 for Treatment of Prostate Cancer

ADXS-504 is the Company's second drug product candidate from the HOT program to receive IND clearance from FDA

PRINCETON, N.J. – January 7, 2020 – Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for the initiation of a Phase 1 clinical study of ADXS-504, the Company's ADXS-HOT candidate for prostate cancer. ADXS-HOT is the Company's off-the-shelf neoantigen clinical program targeting hotspot mutations that currently includes over ten cancer-type specific drug constructs in various stages of development.

"With encouraging proof-of-concept data within our neoantigen program, we believe the ADXS-HOT program has potential to provide off-the-shelf, neoantigen targeted immunotherapies to a broad patient population," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "We are proud of the progress we have made to date with our HOT program, which includes advancing the clinical development of ADXS-503, our candidate for non-small cell lung cancer, while also seeking to launch our next clinical program, ADXS-504, in prostate cancer. We look forward to presenting immunogenicity and safety data from the first cohort from our lung program later this quarter."

About Advaxis, Inc.

Advaxis, Inc. is a clinical-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 T cells to eliminate tumors.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the expected clinical development of the Company's drug product candidates. These and other risks are discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on December 20, 2019, and its periodic reports on Form 10-Q and Form 8-K. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

Contact:

Tim McCarthy, LifeSci Advisors, LLC
212.915.2564
tim@lifesciadvisors.com
