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): April 5, 2021

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36138	02-0563870
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey	08852
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (609) 452-9813

(Former name or former address, if changed since last report.)

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 Capital Market
Preferred Stock Purchase Rights	-	Nasdaq Capital 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 April 5, 2021, Advaxis, Inc. (the "Company") issued a press release announcing an agreement with Columbia University Irving Medical Center to fund a Phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated April 5, 2021

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.

April 6, 2021

ADVAXIS, INC.

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer, Interim Chief Financial Officer

Advaxis Announces Agreement with Columbia University Irving Medical Center to Fund Phase 1 Study of ADXS-504 for the Treatment of Early Prostate Cancer

Initiation of Phase 1 study in biochemically recurrent prostate cancer anticipated in Q2

PRINCETON, N.J. – April 5, 2021 – Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced an agreement with Columbia University Irving Medical Center to fund a Phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study, expected to begin in Q2 2021, will be the first clinical evaluation of ADXS-504, Advaxis' off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer. Mark Stein, M.D., associate professor of medicine in the Division of Hematology/Oncology at Columbia University Vagelos College of Physicians and Surgeons, will be the study's principal investigator.

The Phase 1 open-label study will evaluate the safety and tolerability of ADXS-504 monotherapy, administered via infusion, in 9-18 patients with biochemically recurrent prostate cancer, i.e., those with elevation of prostate-specific antigen (PSA) in the blood after radical prostatectomy or radical radiotherapy (external beam or brachytherapy) and who are not currently receiving androgen ablation therapy. The study will also evaluate preliminary clinical and immune responses following treatment with ADXS-504 monotherapy.

Nearly 248,530 men in the United States will be diagnosed with prostate cancer in 2021, and approximately 34,130 will die from this disease. Many more men with prostate cancer will experience rising prostate-specific antigen (PSA) levels following local therapy with radical radiotherapy or prostatectomy, a condition known as biochemical recurrence (BCR). BCR is not typically associated with imminent death, and biochemical progression may occur over a prolonged period. Clinicians treating men with BCR thus face a difficult set of decisions in attempting to delay the onset of metastatic disease and death while avoiding over-treating patients whose disease may never affect their overall survival or quality of life.

"Currently, men with biochemically recurrent prostate cancer are either monitored for a period of time without intervention or may be started on medicine to decrease the level of testosterone in the body, which can have significant side effects," said Dr. Stein. "Therefore, we need new approaches to stimulate the body's immune system to control the prostate cancer. Given the encouraging results from a Phase 2 study of ADXS-PSA, which targets a single-antigen, in combination with KEYTRUDA®, in men with advanced prostate cancer, and emerging signals of potential clinical activity of the Company's multi-antigen technology in non-small cell lung cancer, we are excited to have the opportunity to explore the potential of ADXS-504 immunotherapy as a novel treatment modality for biochemically recurrent prostate cancer."

ADXS-504 is a novel *Lm*-based immunotherapy, bioengineered to elicit T cell responses against 24 tumor antigens that include 14 peptide antigens derived from frequently occurring and commonly shared hotspot mutations in patients with prostate cancer and 10 peptide antigens derived from sequence-optimized tumor-associated antigens (TAAs) that are differentially expressed or overexpressed in prostate cancer. ADXS-504 is designed to express multiple tumor antigen targets to which patients may generate a broad set of effector T cells for tumor control. Similar to Advaxis' other *Lm*-based immunotherapies, ADXS-504 is expected to induce an innate immune response followed by the adaptive response and modification of the immunosuppressive tumor microenvironment (TME) by reducing regulatory T cells (Tregs) and myeloid-derived suppressor cell (MDSC) frequencies in the TME.

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis said, "We are pleased to be working with Columbia University Irving Medical Center to conduct the first clinical evaluation of ADXS-504 in earlier stages of prostate cancer where drug constructs of this type could potentially control micrometastasis efficiently. The strategic decision to transition the ADXS-504 to an investigator-sponsored study at Columbia will provide access to world-class expertise and has the potential to accelerate patient recruitment in order to expedite our clinical progress. We are encouraged by our momentum and look forward to continued progress across our ADXS-HOT program, which also includes ongoing studies in NSCLC in the first line setting and in patients who have progressed on pembrolizumab."

About Advaxis

Advaxis, Inc. is a clinical-stage biotechnology company focused on the 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.

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. 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. Such risks include, but are not limited to: the success and timing of the Company's clinical trials, including patient accrual; the Company's ability to develop and commercialize its products; the Company's ability to identify license and collaboration partners and to maintain existing relationships; the Company's available cash and its ability to obtain additional funding; and any outcomes from the Company's review of strategic transactions. 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, as amended, and its periodic reports on Form 10-Q and Form 8-K. 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 whether as a result of new information, future events or otherwise, except as otherwise required by law.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

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