

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

January 5, 2009
(Date of Earliest Event Reported)

Advaxis, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

00028489
(Commission
File Number)

02-0563870
(IRS Employer
Identification No.)

Technology Centre of New Jersey
675 Rt. 1, Suite B113
North Brunswick, N.J. 08902
(Address of principal executive offices)

(732) 545-1590 (Registrant's telephone number, including area code)

(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))
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Item 8.01 Other Events

On January 6, 2009, Advaxis, Inc issued a press release regarding its Phase II Clinical Trial "Hold" Lifted.

A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by this reference.

Item 9.01 Financial Statements and Exhibits

99.1 Advaxis, Inc. press release, dated January 6, 2009

SIGNATURE

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

Dated: January 6, 2009

Advaxis, Inc.

By: /s/ Thomas A. Moore

Name: Thomas A. Moore

Title: Chief Executive Officer



ADVAXIS' PHASE II CLINICAL TRIAL "HOLD" LIFTED

U.S. FDA Approves Investigational New Drug Application for Phase II for Cervical Intraepithelial Neoplasia Grade 2/3 Clinical Trial

North Brunswick, NJ – January 6, 2009 – Advaxis Inc (OTCBB: ADXS), a biotechnology company, received permission from the U. S. Food and Drug Administration (FDA) to test its lead drug candidate, Lovaxin C, in patients with grade 2/3 cervical intraepithelial neoplasia (CIN). With this approval of the Investigational New Drug (IND) application for Lovaxin C, the FDA "HOLD" on Advaxis' clinical program has been lifted.

Advaxis submitted its IND application to the FDA in May 2008, which outlined the proposed protocol for a Phase II clinical trial safety study targeting CIN – a precursor condition to cervical cancer, commonly diagnosed by PAP smears. The proposed trial, unlike Advaxis' Phase I cervical cancer trial, will target the disease at a much earlier stage of development and recruit CIN patients living in the U. S. that are otherwise healthy. Due to the different patient population, the FDA requested more information to support the safety of Lovaxin-C and the methods used in its manufacture, which prompted the clinical trial "HOLD."

Regarding the FDA's acceptance of the Company's IND application, Advaxis' Executive Director of Product Development, Dr. Christine Chansky, MD, JD, said, "Advaxis' clinical and scientific team comprehensively responded to the FDA's questions. There were well over 700 pages of documentation submitted, which included results from our Phase I clinical trial study as well as animal research conducted specifically for the response. It was a great job by the team and a fine start to our regulatory relationship with the FDA. The FDA has requested additional information regarding our manufacturing processes as they develop, which we will provide as the processes are validated."

Addressing the CIN trial's expectations, Advaxis' Executive VP of Science & Operations Dr. John Rothman commented, "This study is a blinded, randomized and placebo-controlled trial of sufficient size; to build upon the promising results of our Phase I study in metastatic cervical cancer patients. In this study however, we are treating healthier women with stronger immune systems and with much less disease burden. We believe that this work will provide us with meaningful support that our live, Listeria-based drug delivery system can safely resolve CIN before it becomes invasive cervical cancer, and without the adverse events that currently attend surgical treatment." The Company anticipates commencing the trial in the second or third quarter of 2009.

CIN is a cervical condition caused by the sexually transmitted human papilloma virus ("HPV"), which can lead to invasive cervical cancer, if not diagnosed properly and left untreated. Recently developed vaccines can prevent disease if administered before HPV is contracted but do not treat the disease, and cannot be used to treat women who have already been exposed to HPV. Today, the accepted treatment protocol for late stage CIN is surgery, which is performed to preclude invasive cancer. Surgical treatment of CIN is associated with various adverse events and may render the cervix incompetent to come to a full term pregnancy.

“The FDA’s approval of Advaxis’ IND application to conduct the first US based clinical trial of a live *Listeria monocytogenes* vaccine that secretes an LLO-tumor specific antigen fusion is a major milestone for the Company as well as for the entire field of immunotherapy,” commented Advaxis Inc.’s Chairman and CEO, Thomas A. Moore. “Our technology enables the delivery of a tumor specific antigen fused to the highly adjuvant Listeria protein, Listeriolysin O (“LLO”), which has a very powerful, anti-tumor effect. Although we have an active clinical program in invasive cervical cancer planned, the safety and efficacy results in the CIN indication will enable us to pursue a U. S. market of about 250,000 patients per year; 50 times the market size of cervical cancer.”

About Advaxis, Incorporated

Based in North Brunswick, New Jersey, Advaxis is developing proprietary *Listeria monocytogenes* (“Lm”) cancer vaccines based on technology developed by Dr. Yvonne Paterson, Professor of Microbiology at the University of Pennsylvania and Chairperson of Advaxis’ Scientific Advisory Board. Advaxis is developing attenuated live Listeria-based vaccines that deliver engineered tumor antigens, which safely stimulate multiple simultaneous immunological mechanisms to fight cancer.

Advaxis’ lead Listeria vaccine candidate, Lovaxin-C, targets human papilloma virus (“HPV”)-associated cancers such as cervical and head and neck. Current Lm vaccines in development target prostate, breast, ovarian and other cancers. Recently, Advaxis completed a Phase I clinical trial of Lovaxin-C. A Phase II clinical trial is planned for patients with cervical intraepithelial neoplasia (“CIN”). The Lm platform also has applications in the fields of infectious disease and autoimmune disorders.

For further information on the Company, please visit: www.advaxis.com.

About the Lovaxin-C Vaccine

Advaxis’ technology platform uses modified *Listeria monocytogenes* to deliver a tumor-specific antigen fusion protein. Bioengineered Listeria that are attenuated and secrete Advaxis’ proprietary fusion protein, have the ability to generate a robust immune response, break immune tolerance to cancer and produce an unusually strong and effective multi-level therapeutic immune response to existing cancer and other diseases.

Advaxis’ Listeria-based technology is based on over a decade worth of work by Dr. Yvonne Paterson in her laboratory at the University of Pennsylvania. The Company’s proprietary antigen fusion protein technology, stimulates innate immunity, both arms of the adaptive cellular immune system, suppresses regulatory T-cells that inhibit many vaccines in the function of activated tumor-killing cells and has other anti-tumor effects.

Unlike prophylactic vaccines, Lovaxin-C was designed to treat women who have already developed cervical cancer as a result of contracting an HPV infection, which is the most prevalent sexually transmitted disease in the US. Current products on the market are ineffective in treating HPV-infected women.

For further information on Lovaxin-C, please visit: www.advaxis.com/lc.htm.

Forward-Looking Statements

Certain statements contained in this press release are forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward looking statements 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 deal with the Company's current plans, intentions, beliefs and expectations and statements of future economic performance. Forward-looking statements involve known and unknown risks and uncertainties that may cause the Company's actual results in future periods to differ materially from what is currently anticipated. Factors that could cause or contribute to such differences include those discussed from time to time in reports filed by the Company with the Securities and Exchange Commission. The Company cannot guarantee its future results, levels of activity, performance or achievements.

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