Advaxis, Inc.
Form 8-K
February 13, 2009
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 134

February 12, 2009
(Date of Earliest Event Reported)

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

Delaware	00028489	02-0563870
(State or other jurisdiction of incorporation)	(Commission File Number)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

On February 12, 2009, we provided a letter to our shareholders as follows:

Dear Fellow Shareholders,

I am pleased to announce that we will hold our Annual Stockholder meeting at 10:00 a.m. on April 22, 2009, at the New Jersey Centre of Technology, 675 Route 1, North Brunswick, New Jersey in the Multipurpose room. The Notice of Annual Meeting of Stockholders of Advaxis, Inc. along with the date of record and proxy materials will be forthcoming this month.

Here's an overall perspective of our key accomplishments over the past two years and our goals and strategies for the next few years. To achieve these goals we must be successful in obtaining financings in a very difficult market and/or commercial partnerships.

The past two years have yielded some extraordinary achievements for your company. I could not be more proud of the extremely talented and dedicated team that we have assembled. The commercialization of Dr. Yvonne Paterson's extraordinary insight to redirect a powerful, natural immune reaction to fight cancer and infectious disease has deserved our very best efforts. True scientific breakthroughs are almost always slow to be fully appreciated. We are all delighted that, Dr. Paterson was recently elected a fellow of the American Academy for the Advancement of Science based in part on her innovative science that is the core of our company.

Our company has achieved the following milestones:

- completed a fifteen patient Phase I trial in advanced cervical cancer that demonstrated that our human papilloma virus (HPV) construct, ADXS11-001, formerly called Lovaxin C, was safely administered and may show initial signs of efficacy

- developed a construct for prostate cancer, ADXS31-142, formerly called Lovaxin P, which demonstrated even stronger preclinical results than ADXS11-001

- raised $9.40 million in a common stock and warrant financing, while unwinding a potentially troublesome financing behind convertible debt

    - awarded $922,000 in non-dilutive financing through the NJ Economic Development Agency

    - developed methodologies pairing two different antigens in our attenuated, live Listeria bacteria; thereby, simultaneously addressing multiple targets and making more effective treatments possible

- filed an Investigational New Drug (IND) application with the Food and Drug Administration (FDA), which included a protocol for a new clinical program combating cervical intraepithelial neoplasia (CIN) and received agreement to the IND and Phase II trial in this new indication

- successfully reversed an adverse patent ruling by the European Patent Commission that would have facilitated European competition

    - secured early agreements to three (3) potential very low cost clinical trials of our ADXS11-001 immunotherapy in cervical, and head and neck cancer in the US and UK

For a lean organization of only 9 people, this is a reasonably productive set of accomplishments. We are excited to proceed to the next phase of human research on ADXS11-001 (Lovaxin C).

Our objective is to develop sufficient human clinical data on this first live listeria construct to demonstrate further that attenuated listeria plus the LLO fusion protein can be an effective platform for multiple therapies against cancer. Success with ADXS11-001 would demonstrate that Advaxis could be one of the world's leading immunotherapy companies.

Our goals over the next few years are to:

1. Initiate the ADXS11-001 Phase II single blind, placebo controlled trial in pre cancerous CIN by June 2009. At the conclusion of the first of three dosage arms, we plan to generate interim efficacy results by December 2010 and complete the final two arms of the trial by December 2011. This will require additional financing by May 2009.

2. Apply for US orphan drug designation for ADXS11-001 in the treatment of cervical cancer by early March 2009 and initiate a clinical program for this indication. We expect a response 60 days after submission, At least one trial sponsored by the Gynecological Oncology Group (The National Cancer Institute) is anticipated to begin in 2009. We also anticipate starting studies in countries outside North American and Europe where advanced cervical cancer remains a major unmet medical need. This is anticipated to be cheaper than our CIN program, with more funding required by Fall 2009.

3. Once the above two programs are underway, we will enter our prostate construct ADXS31-142 (formerly called Lovaxin P) into human clinical trials if sufficient funds or partnerships are secured.

We plan to out license the commercial development of ADXS11-001 for the indications of CIN and cervical cancer. Funds, if obtained, will provide the financial platform to develop the preclinical and clinical development of prostate construct, breast cancer construct, and combination constructs which combine specific tumor antigens and anti-angiogenesis antigens into a single "combination" listeria vector.

Our plans might lead to several questions on your part which I would like to address here:

"Why the new designation of ADXS11-001 for Lovaxin C?" Over the past two years, we have seen legal challenges to the Lovaxin name. Because the FDA will not permit us to use "Lovaxin" after marketing approval, (marketing brand names have to be completely new), we will focus company resources to product development and not defending the Lovaxin name.

"Why we are excited about conducting a phase II study in CIN?" The market is very large with an unmet need for non-surgical treatment that may be superior at a reduced cost. In the US, there are 250,000 cases of CIN, annually. In the US there are the broad scale use of pap smears (about 74% of women) identifies CIN, the pre-invasive stage of cervical cancer. Our therapy could, if successful, avoid surgery and the frequent complication of an "incompetent cervix" which reduces the ability to carry unborn children to term.

"Why pursue an orphan drug indication in cervical cancer?" While cervical cancer is the number one killer of women under the age of 45 worldwide, there are only about 5,000 new cases reported in the US annually. This provides the opportunity to designate cervical cancer as an orphan drug indication. In the US, therapies that treat commonly serious diseases that affect less than 200,000 patients are eligible for designation as orphan drugs. About 50% of applicants for orphan drug status are granted this status, which confers several advantages: (1) shortened FDA communication cycles; (2) direct FDA guidance on clinical design; (3) seven year marketing exclusivity once approved, and (4) eligibility for clinical grants through the FDA. Our aim will be to utilize our orphan drug status (if we are successful) to develop a clinical plan with FDA for combined phase II/III studies designed to get approval for use in advanced cervical cancer as quickly as possible. In theory, we could see approval in as little as 3-3 ½ years, although this is dependent on FDA agreement to clinical plans which we have not yet submitted.

With adequate funding, we believe we can conduct trials simultaneously in the US and in markets where cervical cancer is a leading source of mortality with the effective use of contact resource organizations that specialize in cancer trials globally. The potential market size in the rest of world dwarfs the CIN indication in the US and EU. With our inexpensive manufacturing cost, we believe we could market successfully, assuming of course that our clinical trial data meets the requisite standards for safety and efficacy.

“Is immunotherapy getting any traction scientifically today?” We are encouraged to see immunotherapies as the next wave in cancer, moving towards approval in the US and abroad. Immunotherapy deals between biotech and large pharmaceutical companies continue to be made at an increasing pace. In the last two years almost a dozen deals have been included, some at a total value of $500M, or more. To move Advaxis forward in this, we have contracted the Sage Group, a highly experienced and respected licensing facilitation team to present our technology to a range of midsize and large size pharmaceutical companies.

We are looking forward to our meeting on April 22, 2009 to further update our progress.

I remain a substantial investor in this company beyond my investment of $400,000 in the October 17, 2007 financing and have recently advanced $500,000 in personal funds to keep this company moving forward in these difficult times. The Advaxis team and I are more confident than ever that this technology will has the potential to meet unmet needs in cancer treatment at a low cost with improved quality of life.

Kind regards,

Thomas A. Moore,
Chairman and Chief Executive Officer

This report contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including the risks described in our annual report on Form 10-KSB and other reports we file with the Securities and Exchange Commission. Although we believe the expectations reflected in the forward-looking statements are reasonable, they relate only to events as of the date on which the statements are made. We do not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in our expectations, except as required by law.

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: February 13, 2009

Advaxis, Inc.

By:	/s/ Thomas A. Moore
Name:	Thomas A. Moore
Title:	Chief Executive Officer