Advaxis, Inc.
Form 10-K
February 19, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2009

OR

¨ TRANSITION REPORT UNDER SECTION 13 OR 15 (d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-28489

ADVAXIS, INC.
(Name of Registrant in Its Charter)

Delaware	02-0563870
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
Technology Centre of New Jersey 675 US Highway One North Brunswick, New Jersey	08902
(Address of Principal Executive Offices)	(Zip Code)
(732) 545-1590 (Issuer's Telephone Number)	

Securities registered under Section 12(b) of the Exchange Act: Common Stock - $.001 par value
The Common Stock is listed on the Over-The-Counter Bulletin Board (OTC:BB)

Securities registered under Section 12(g) of the Exchange Act: [None]

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes ¨ No x

Check whether the Registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). Yes ¨ No¨

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-K contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of April 30, 2009, the aggregate market value of the voting common equity held by non-affiliates was approximately $4,529,500 based on the closing bid price of the registrant’s common stock on the Over the Counter Bulletin Board. (For purposes of determining this amount, only directors, executive officers, and 10% or greater stockholders and their respective affiliates have been deemed affiliates).

The registrant had 127,201,243 shares of Common Stock, par value $0.001 per share, issued and outstanding as of January 27, 2010.

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PART 1

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words “plan”, “intend”, “may,” “will,” “expect,” “believe”, “could,” “anticipate,” “estimate,” or “continue” or similar expressions or other v comparable terminology are intended to identify such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1: Business.

General

We are a development stage biotechnology company with the intent to develop safe and effective cancer vaccines that utilize multiple mechanisms of immunity. We are developing a live Listeria vaccine technology under license from the University of Pennsylvania (“Penn”) which secretes a protein sequence containing a tumor-specific antigen. We believe this vaccine technology is capable of stimulating the body’s immune system to process and recognize the antigen as if it were foreign, generating an immune response able to attack the cancer. We believe this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers infectious diseases and auto-immune disorders.

The discoveries that underlie this innovative technology are based upon the work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn. This technology involves the creation of genetically engineered Listeria that stimulate the innate immune system and induce an antigen-specific immune response involving both arms of the adaptive immune system. In addition, this technology supports, among other things, the immune response by altering tumors to make them more susceptible to immune attack, stimulating the development of specific blood cells that underlie a strong therapeutic immune response.

We have focused our initial development efforts upon therapeutic cancer vaccines targeting cervical cancer, its predecessor condition, CIN, Head and Neck cancer, breast cancer, prostate cancer, and other cancers. Our lead products in development are as follows:

Product	Indication	Stage
ADXS11-001	Cervical Cancer	Phase I Company sponsored & completed in 2007.
	Cervical Intraepithelial Neoplasia	Phase II Company sponsored study anticipated to commence in early 2010.
	Cervical Cancer	Phase II Company sponsored study anticipated to commence in early 2010 in India. 110 Patients with advanced cervical cancer.
	Cervical Cancer	

		Phase II The GOG of the NCI is conducting a study (timing to be determined).
	Head & Neck Cancer	Phase I The Cancer Research UK (CRUK) is conducting a study of up to 45 Patients (timing to be determined).
ADXS31-142	Prostate Cancer	Phase I Company sponsored (timing to be determined).
ADXS31-164	Breast Cancer	Phase I Company sponsored (timing to be determined).

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2009, we had an accumulated deficit of $16,603,800 and shareholders' deficiency of $15,733,328.

To date, we have outsourced many functions of drug development including manufacturing, and clinical trials management. Accordingly, the expenses of these outsourced services account for a significant amount of our accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or approved by the FDA. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies, including conducting clinical trials for our product candidates, with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

History of the Company

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were administratively dissolved on January 1, 1997 and reinstated June 18, 1998 under the name Great Expectations and Associates, Inc. In 1999, we became a reporting company under the Securities Exchange of 1934 (the “Exchange Act’). We were a publicly-traded “shell” company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004 (the “Share Exchange”), by and among Advaxis, the stockholders of Advaxis and us. As a result of such acquisition, Advaxis become our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006 our shareholders approved the reincorporation of the company from the state of Colorado to the state of Delaware by merging the Company into its wholly-owned subsidiary. As used herein, the words “Company” and "Advaxis" refer to the current Delaware corporation only unless the context references such entity prior to the June 26, 2006 reincorporation into Delaware (in which case it refers to the Colorado entity). Our principal executive offices are located at Technology Centre of NJ, 675 US Highway One, North Brunswick, NJ 08902 and our telephone number is (732) 545-1590.

On July 28, 2005 we began trading on the Over-The-Counter Bulletin Board (OTC:BB) under the ticker symbol ADXS.

Recent Developments

Preferred Equity Financing

On January 11, 2010, the Company issued and sold 145 shares of non-convertible, redeemable Series A preferred stock to Optimus Life Sciences Capital Partners LLC (“Optimus”) pursuant to the terms of a Preferred Stock Purchase Agreement between the Company and Optimus dated September 24, 2009 (the “ Purchase Agreement ”). The Company received net proceeds of $1,320,000 from this transaction. The aggregate purchase price for the Series A preferred stock was $1.45 million (less $130,000 representing an administrative fee and the balance of a commitment fee due and owing to Optimus under the Purchase Agreement). Under the terms of the Purchase Agreement, Optimus remains obligated, from time to time until September 24, 2012, to purchase up to an additional 355 shares of Series A preferred stock at a purchase price of $10,000 per share upon notice from the Company to Optimus, and subject to the satisfaction of certain conditions, as set forth in the Purchase Agreement.

In connection with the foregoing transaction, an affiliate of Optimus was granted 33,750,000 warrants on September 24, 2009 at an exercise price of $0.20 to be exercised and priced upon the draw down date of each tranche. On January 11, 2010, the draw down date of the first tranche, Optimus exercised warrants to purchase 11,563,000 shares of common stock at an adjusted exercise price of $0.17 per share. The Company and Optimus agreed to waive certain terms and conditions in the Purchase Agreement and the warrant in order to permit the affiliate of Optimus to exercise the warrants at such adjusted exercise price prior to the closing of the purchase of the Preferred Stock and acquire beneficial ownership of more than 4.99% of the Company’s common stock on the date of exercise. As permitted by the terms of such warrants, the aggregate exercise price of $1,965,710 received by the Company is payable pursuant to a four year full recourse promissory note bearing interest at the rate of 2% per year.

As a result of anti-dilution protection provisions contained in certain of the Company’s outstanding warrants, the Company has (i) reduced the exercise price from $0.20 per share to $0.17 per share with respect to an aggregate of approximately 62.0 million warrant shares to purchase the Company’s Common Stock and (ii) correspondingly adjusted the amount of warrant shares issuable pursuant to certain warrants such that approximately 11.0 million additional warrant shares are issuable at $0.17 per share.

Recent Bridge Financings

From November 1, 2009 through February 16, 2010, we issued to certain accredited investors (i) junior unsecured convertible promissory notes in the aggregate principal face amount of $673,529, for an aggregate net purchase price of $572,500 and (ii) warrants to purchase1,431,250 shares of our common stock at an exercise price of $0.20 (prior to anti-dilution adjustments) per share, subject to adjustments upon the occurrence of certain events. Each of these bridge notes were issued with an original issue discount of 15% (OID) and are convertible into shares of our common stock. The maturity dates of these notes range between April 16 and July 30, 2010. The indebtedness represented by the bridge notes is expressly subordinate to our currently outstanding senior secured indebtedness (including the June 2009 bridge notes), as well as any future senior indebtedness of any kind. We will not make any payments to the holders of these bridge notes until the earlier of the repayment in full or conversion of the senior indebtedness.

During January and February 2010, the Company repaid $834,852 of the $1,131,353 in face value of our June 2009 bridge notes. In addition, holders of the remaining $296,501 of our June 2009 bridge notes agreed to extend the maturity dates from December 31, 2009 to periods into February and March 2010. The Company has agreed to issue additional consideration, including warrants to June 2009 bridge note holders, all of which have agreed to extend the maturity period beyond December 31, 2009.

On February 15, 2010, we agreed to amend the terms of the Moore Notes such that (i) Mr. Moore may elect, at his option, to receive accumulated interest thereon on or after March 17, 2010 (which we expect will amount to approximately $130,000), (ii) we will begin to make monthly installment payments of $100,000 on the outstanding principal amount beginning on April 15, 2010; provided, however, that the balance of the principal will be repaid in full on consummation of our next equity financing resulting in gross proceeds to us of at least $6.0 million and (iii) we will retain $200,000 of the repayment amount for investment in our next equity financing.

Other Developments

On February 9, 2010 the Company announced that Cancer Research UK (CRUK), the UK philanthropy dedicated to cancer research, has agreed to fund the cost of a clinical trial to investigate the use of ADXS11-001, Advaxis' lead human papilloma virus (HPV)-directed vaccine candidate, for the treatment of head and neck cancer. This sponsored-clinical trial will investigate the safety and efficacy of ADXS11-001 in head and neck cancer patients who have previously failed treatment with surgery, radiotherapy and chemotherapy – alone or in combination. Advaxis will provide the vaccines with all other associated costs to be funded by CRUK. The study is to be conducted at Aintree Hospital at the University of Liverpool, Royal Marsden Hospital in London, and Cardiff Hospital at the University of Wales. Patient enrollment is slated for the latter part 2010. At such time, enrollment officials anticipate recruiting a maximum of forty-five (45) patients.

Effective as of January 5, 2010, Mark Rosenblum, 56, was hired as Senior Vice President, Chief Financial Officer and Secretary of the Company. Since April 2005 Mr. Rosenblum was the Chief Financial Officer of Hemobiotech, Inc. (OTC BB: HMBT.OB), a company primarily engaged in the commercialization of human blood substitute technology licensed from Texas Tech University. From 2003 until 2005, he acted as a consultant to various distribution and manufacturing companies. From 1985 through 2003, Mr. Rosenblum was employed by Wellman, Inc., a public chemical manufacturing company and held positions as its Corporate Controller, Vice President and Chief Accounting Officer. Mr. Rosenblum's base compensation is $225,000 per annum, with a discretionary bonus of up to 30% of his base compensation awarded annually in March beginning in 2011. In addition, on January 5, 2010 Mr. Rosenblum was granted options to purchase 1,000,000 shares of the Company's Common Stock with an exercise price equal to the closing bid price on the date of grant. One third of these options vested on the date of grant, one third vests on the first anniversary of the date of grant, and one third vests on the second anniversary of the date of grant. Mr. Rosenblum may be eligible for additional option grants in one year.

On December 15, 2009, the Company announced its Phase II Trial Collaboration with the National Cancer Institute Gynecologic Oncology Group to Study ADXS11-001 in Sixty-Patient Study. The Company will collaborate with the Gynecologic Oncology Group (GOG), a collaborative research group of the National Cancer Institute (NCI), in a multicenter, Phase II clinical trial of the Company's lead drug candidate, ADXS11-001 in the treatment of advanced cervix cancer in women who have failed prior cytotoxic therapy. This Phase II trial will be conducted by GOG investigators and largely underwritten by the NCI. The study's patient population – a very sick and rapidly progressive patient population that was treated in Advaxis Phase I trial of ADXS11-001. Under this agreement Advaxis is responsible for covering the costs of translational research and has agreed to pay a total of $8,003 per patient, with the bulk of the costs of this study underwritten by NCI.

The Company received $278,978 from the New Jersey Economic Development Authority. Under the State of New Jersey Program for small business we received this cash amount on January 15, 2010 from the sale of our State Net

Operating Losses (“NOL”) through December 31, 2008 and our research tax credit for fiscal years 2007 and 2008.

Between February and December of 2009 the US, Japanese, and European patent offices have approved patents for a newly developed strain of Listeria that uses a novel method of attenuation. This strain is attenuated by deleting genes that are responsible for making a protein that is essential for the bacterial cell wall, and by engineering back the ability to make this protein at a reduced level. In developing this strain the objective was to improve upon the useful properties of Listeria while reducing potential disease causing properties of the bacterium, and in preliminary testing this strain of Lm appears to be more immunogenic and less virulent that prior vaccine strains.

On December 15, 2009 the survival of the patients in Advaxis Phase I trial of the agent were determined at the scheduled three month interval. Two patients were still alive out of the 13 patients who were available for efficacy analysis. At that time these patients had survived for 1,104 and 1,053 days after their initial dose. One patient who had been alive at the prior assessment had passed away after 1,064 days. This Phase I safety study was not designed to assess efficacy, however the response rate was greater than that associated with historical controls and the long survival of these patients is noteworthy.

Our Website

We maintain a website at www.advaxis.com which contains descriptions of our technology, our drugs and the trial status of each drug.

Strategy

During the next 24 months, we intend to strategically focus on developing sufficient human clinical data on ADXS11-001, our first Listeria construct, to demonstrate the effectiveness of this technology. This technology is based on attenuated Listeria that secretes an antigen LLO fusion protein that can be an effective platform for multiple therapies against cancer and infectious disease. Overall our clinical trial plans outlined below are contingent on our ability to raise additional capital or enter into partnerships. In the U.S., we plan on initiating the single blind, placebo controlled Phase II clinical trial of ADXS11-001 with three dosage arms in CIN, a pre cancerous indication. Following the conclusion of the first arm, we expect to generate an interim assessment of efficacy approximately 18 months following the start of the single blind, placebo controlled Phase II Clinical Trial of ADXS11-001

In parallel with the CIN trial, we also intend to start trials in the development of ADXS11-001, both in the U.S. and abroad, as a treatment of late stage cervical cancer in women who have progressed after receiving cytotoxic therapy and head and neck cancer. We intend to hold our first Phase II trial in the therapeutic area of cervical cancer in India. In order to run a second trial in this patient population we are in advanced discussions with the Gynecologic Oncology Group, which we refer to as the GOG which receives support from the National Cancer Institute, which we refer to as the NCI. We anticipate that this trial, with the same patient population as those studied in our first Phase I trial, will be underwritten, in part, by the NCI. Therefore, this Phase II multi-center study in their network in cervical cancer, is expected to result in a cost savings to us of approximately $2.5 million to $3.0 million in trial expenses. Furthermore, once the above trials are underway, we expect to enter our prostate construct ADXS31-142 (formerly called Lovaxin P) into human clinical trials as funds or partnerships are secured.

In order to implement our strategy, we will require substantial additional investment in the near future. Our failure to raise capital or pursue partnering opportunities will materially and adversely affect both our ability to commence or continue the clinical trials described above and our business, financial condition and results of operations, and could force us to significantly curtail or cease operations. Further, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing over and above the preferred stock financing on acceptable terms or secure funds from new partners.

Given our expertise to genetically modify a host of Listeria vaccines, our longer term strategy will be to license the commercial development of ADXS11-001 for the indications of CIN and cervical cancer. On a global basis, these indications are extremely large and will require one or more significant partners. We do not intend to engage in commercial development beyond Phase II without entering into one or more partnerships or a license agreement.

We intend to continue to devote a substantial portion of our resources to the continued pre-clinical development and optimization of our technology so as to develop it to its full potential and to find appropriate new drug candidates. These activities may require significant financial resources, as well as areas of expertise beyond those readily available. In order to provide additional resources and capital, we may enter into research, collaborative or commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including major international pharmaceutical companies or universities.

Background

Cancer

Despite tremendous advances in science, cancer remains a major health problem, and for many it continues to be the most feared of diseases. Although age-adjusted mortality rates for all cancer fell during the 1990’s, particularly for the major cancer sites (lung, colorectal, breast, and prostate), mortality rates are still increasing in certain sites such as liver and non-Hodgkin’s lymphoma. In 2004, the last year for which we have reliable numbers, 1,437,180 cases of invasive cancer were diagnosed according to the American Cancer Society, and 565,650 patients are expected to die

from cancer annually.

Cancer is the second largest cause of death in the United States, exceeded only by heart disease. The cost of treating cancer patients in 2007 is estimated to be $219.2 billion in healthcare costs and another $18.2 billion in indirect costs resulting from morbidity and lost productivity (source: Facts & Figures 2008, American Cancer Society). The NIH estimates the overall cost for cancer in the year 2005 at $209.9 billion: $74.06 billion for direct medical costs, $17.5 billion for indirect morbidity costs (loss of productivity due to illness) and, $118.4 billion for indirect mortality costs (cost of lost productivity due to premature death). (Source: cancer facts & figures 2006, American Cancer Society). The incidence of newly diagnosed cervical cancer in the US in 2007 was 11,070 (ibid) and numbers for newly diagnosed CIN are approximately about 250,000 patients per year based on 3.5 million abnormal Pap smears (source: Jones HW, Cancer 1995:76:1914-18; Jones BA and Davey, Arch Pathol Lab Med 2000; 124:672-81)

US Cancer Rates (2009 Estimated)

Percent of US deaths due to cancer in 2006

Immune System and Normal Antigen Processing

Living creatures, including humans, are continually confronted with potentially infectious agents. The immune system has evolved multiple mechanisms that allow the body to recognize these agents as foreign, and to target a variety of immunological responses, including innate, antibody, and cellular immunity that mobilize the body's natural defenses against these foreign agents and will eliminate them.

Innate Immunity:

Innate immunity is the first step in the recognition of a foreign antigen, and underlies an adaptive (antigen specific) response by lymphocytes. This non-specific ingestion Phagocytosis by these cells results in their activation and the release of various soluble mediators of immune response such as cytokines, chemokines and co-stimulatory molecules.

Exogenous pathway of Adaptive Immunity (Class II pathway):

Proteins and foreign molecules ingested by Antigen Processing Cells ("APC") are broken down inside digestive vacuoles into small pieces, called peptides, and the pieces are combined with proteins called Class 2 MHC (for Major Histocompatibility Complex) in a part of the cell called the endoplasmic reticulum. The MHC-peptide, termed and MHC-2 complex from the Class 2 (or exogenous) pathway, is then pushed out to the cell surface where it interacts with certain classes of lymphocytes (CD4+) such as helper T-cells that produce induce a proliferation of stimulate B-cells, which produce antibodies, or helper T cells that assist in the maturation of cytotoxic T-lymphocytes. This system is called the exogenous pathway, since it is the prototypical response to an exogenous antigen like bacteria. (Listeria generated MHC-2 responses are directed at the activation of helper T cell activation, as Listeria tends not to stimulate antibody formation.)

Endogenous pathway of Adaptive Immunity (Class I pathway):

There exists another adaptive immune pathway, called the endogenous pathway. In this system, when one of the body's cells begins to create unusual proteins within the cytoplasm (as opposed to within he digestive phagosome), the protein is broken up into peptides in the cytoplasm and directed into the endoplasmic reticulum, where it is incorporated into an MHC-1 protein and trafficked to the cell surface. This signal then calls effector cells of the cellular immune system, especially CD8+ cytotoxic T-lymphocytes, to come and kill the cell. The endogenous pathway is primarily for elimination of virus-infected or cancerous cells.

Listeria based vaccines are unique for many reasons, one of which is that unlike viral vectors, DNA or peptide antigens or other vaccines, Listeria stimulates all of the above mechanisms of immune action. Our technology allows the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by utilizing a number of biologic characteristics of the Listeria bacteria and Advaxis proprietary antigen-fusion protein technology to stimulate multiple therapeutic immune mechanisms simultaneously in an integrated and coordinated manner.

Mechanism of Action

Listeria is a bacterium well known to medical science because it can cause an infection in humans. Listeria is a pathogen that causes food poisoning, typically in the very old, the very young, people who are either immunocompromised or who eat a large quantity of the microbe as can occur in spoiled dairy products. It is not laterally transmitted from person to person, and is a common microbe in our environment. Most people ingest Listeria without being aware of it, but in high quantities or in immune suppressed people Listeria can cause various clinical conditions, including sepsis, meningitis and placental infections in pregnant women. Fortunately, many common antibiotics can kill and sterilize Listeria.

Because Listeria is a live bacterium it stimulates the innate immune system, thereby priming the adaptive immune system to better respond to the specific antigens that the Listeria carries, which viruses and other vectors do not do. This is a non-specific stimulation of the overall immune system that results when certain classes of pathogens such as bacteria (but not viruses) are detected. It provides some level of immune protection and also serves to prime the elements of adaptive immunity to respond in a stronger way to the specific antigenic stimulus. Listeria stimulates a strong innate response which engenders a strong adaptive response.

Antigen Presenting Cells (APC) are the scavengers' in the body that circulate looking for foreign invaders. When they find one, they ingest it, break it down, and provide the fragments as molecular targets for the immune system to attack. In this way they are the cells that direct a specific immune response, and Listeria has the ability to infect them.