

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

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

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  
(State or Other Jurisdiction of  
Incorporation or Organization)

02-0563870  
(I.R.S. Employer Identification No.)

Technology Centre of New Jersey  
675 US Highway One  
North Brunswick, New Jersey  
(Address of Principal Executive Offices)

08902  
(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

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

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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  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

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

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 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).
ADX31-142	Prostate Cancer	Phase I Company sponsored (timing to be determined).
ADX31-164	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 purchase 1,431,250 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 than 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](http://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)

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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 the 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.

When Listeria enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called phagolysosomes, whose destructive enzymes kill most of the bacteria. A certain percentage of these bacteria, however, are able to break out of the phagolysosomes and enter into the cytoplasm of the cell, where they are relatively safe from the immune system. The bacteria multiply in the cell, and the Listeria is able to move to its cell surface so it can push into neighboring cells and spread.

Figs 1-7. When *Listeria* enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called phagolysosomes, whose destructive enzymes kill most of the bacteria, fragments of which are then presented to the immune system via the exogenous pathway.

Figs 8-10 A certain percentage of bacteria is able to break out of the lysosomes and enter into the cytoplasm of the cell, where they are safe from lysosomal destruction. The bacteria multiply in the cell, and the *Listeria* is able to migrate into neighboring cells and spread without entering the extracellular space. Antigen produced by these bacteria enter the Class I pathway and directly stimulate a cytotoxic T cell response.

It is the details of *Listeria* intracellular activity that are important for understanding Advaxis technology. Inside the lysosome, *Listeria* produces listeriolysin-O (“LLO”), a protein that digests a hole in the membrane of the lysosome that allows the bacteria to escape into the cytoplasm. Once in the cytoplasm, however, LLO is also capable of digesting a hole in the outer cell membrane. This would destroy the host cell, and spill the bacteria back out into the intercellular space where it would be exposed to more immune cell attacks and destruction. To prevent this, the body has evolved a mechanism for recognizing enzymes with this capability based upon their amino acid sequence. The sequence of approximately 30 amino acids in LLO and similar molecules is called the PEST sequence (for the predominant amino acids it contains) and it is used by normal cells to force the termination of proteins that need only have a short life in the cytoplasm. This PEST sequence serves as a routing tag that tells the cells to route the LLO in the cytoplasm and to the proteasome for digestion, which terminates its action and provides fragments that then go to the endoplasmic reticulum, where it is processed just like a protein antigen in the endogenous pathway to generate MHC-1 complexes.

This mechanism is used by *Listeria* to its benefit because the actions of LLO enable the bacteria to avoid digestion in the lysosome and escape to the cytosol where they can multiply and spread and then be neutralized so that it does not kill the host cell. Advaxis is using a technology that co-opts this mechanism by creating a protein that is comprised of the cancer antigen fused to a non-hemolytic portion of the LLO molecule that contains the PEST sequence. This serves to route the molecule for accelerated proteolytic degradation which accelerates both the rate of antigen breakdown and the amount of antigen fragments available for incorporation in to MHC-1 complexes; thus increasing the stimulus to activate cytotoxic T cells against a tumor specific antigen.

Other mechanisms that Advaxis vaccines employ include *Listeria*'s ability to increase the synthesis of myeloid cells such as Antigen Presenting Cells ("APC") and T cells, and to stimulate the maturation of immature myeloid cells to increase the number of available activated immune cells that underlie a cancer killing response. Immature myeloid cells actually inhibit the immune system and *Listeria* removes this inhibition within the actual tumor. Also, *Listeria* and LLO both stimulate the synthesis, release, and expression of various chemicals which stimulate a therapeutic immune response. These chemicals are called cytokines, chemokines and co-stimulatory molecules. By doing this, not only are immune cells activated to kill cancers and clear them from the body, but local environments within tumors is created that support and facilitate a therapeutic response. Finally, in a manner that appears to be unique to Advaxis vaccines, our proprietary antigen-LLO fusion proteins, when delivered by *Listeria* do not stimulate cells caused regulatory T cells ("Tregs") which are known to inhibit a therapeutic anticancer response. This does not occur when *Listeria* is engineered to deliver only a tumor specific antigen. The ability to reduce the effect of Tregs is currently under clinical investigation by other companies and is believed to be a significant mechanism of achieving a therapeutic response. *Listeria* has other effects as well, such as facilitating the transit of activated immune cells from the blood and into tumors.

The ability to reduce the number of Tregs within tumors appears to be as important as activating the immune system against an antigen. Advaxis live *Listeria* vaccines have many diverse salutary effects, not the least of which is the ability to reduce regulatory Tregs within tumors. Over the past few years it has become known that the reason many previous immunologic cancer treatments have failed is that although they were able to strongly activate the immune system, they were rendered ineffective by endogenous sources of immune inhibition within the tumors themselves. Tregs have the ability to turn off activated immune cells so that they no longer function within the tumor. We have published on 2 occasions that our live *Listeria* vaccines that secrete a proprietary fusion protein comprised of a non-hemolytic fragment of the *Listeria* virulence factor LLO fused to a tumor specific antigen will reduce these inhibitory cells within tumors. In this way, our vaccines not only strongly stimulate the immune system, but also modify the tumor micro-environment in a manner that allows the immune system to kill and clear tumor cells.

Advaxis live *Listeria* vaccines also have the ability to modify the function of vascular endothelial cells in a way that facilitates the trafficking of activated immune cells out of the blood and into the tumor, where they are therapeutically effective. One property of cancer is the modification of vascular cells to prevent activated immune cells from transiting into the tumor. Our vaccines appear to overcome this source of anti-tumor inhibition.

Many of the immune effector cells, such as dendritic cells, macrophages, mast cells, Langerhans cells and others are myeloid cells. Our vaccines have the ability to accelerate the synthesis and maturation of these cells, as well as their antigen specific activation, to increase the power and efficiency of the immune response.

It should also be noted that the live *Listeria* vaccines Advaxis creates are attenuated from 10,000 to 100,000 times in order that they will not cause disease themselves.

Thus, *Listeria* vaccines stimulate every immune pathway simultaneously, and in an integrated manner. It has long been recognized that cytotoxic T lymphocytes, or CTL, are the elements of the immune system that kill and clear cancer cells. The amplified CTL response to *Listeria* vaccines are arguably the strongest stimulator of CTL yet developed, but just as important is the ability Advaxis vaccines have to create a local tumor environment in which these cells can be effective. This efficacy likely results in part from the fusion of LLO to the secreted tumor antigen since many investigators have shown that LLO is a very strong source of immune stimulation independent of *Listeria*. By fusing a molecule with strong adjuvant properties to a tumor antigen, and then having it synthesized and secreted by live bacteria directly into the cytoplasm of Antigen Presenting Cells, vascular endothelium and other relevant tissues an unusually powerful and complete immune response is generated.

Recently it has been shown that Lm -LLO vaccines can cause epitope spreading. This means that these vaccines can stimulate the immune system to respond to more antigens than the one they are designed to attack. This happens when tumor cells are killed by the immune system in response to the administered vaccine and portions of those killed cells are then recognized by the immune system and they too become targets of an immune attack. This broadens the immune attack and results in a more therapeutic response.

Thus, what makes Advaxis live *Listeria* vaccines so effective are a combination of effects that stimulate multiple arms of the immune system simultaneously in a manner that generates an integrated physiologic response conducive to the killing and clearing of tumor cells. These mechanisms include:

1. Very strong innate immune response
2. Stimulates inordinately strong killer Tregs response
3. Stimulates helper Tregs
4. Stimulates release of and/or up-regulates immuno-stimulatory cytokines, chemokines, co-stimulatory molecules
5. Adjuvant activity creates a local tumor environment that supports anti-tumor efficacy
6. Minimizes inhibitory Tregs and inhibitory cytokines and shifts to Th-17 pathway
7. Stimulates the development and maturation of all Antigen Presenting Cells and effector Tregs & reduces immature myeloid cells
8. Eliminates sources of endogenous inhibition present within tumors that suppress activated immune cells and prevent them from working within tumors
9. Effecting non-immune systems that support the immune response, like the vascular system, the marrow, and the maturation of cells in the blood stream
10. Enables epitope spreading to increase the number of antigens attacked by the immune system.

## Research and Development Program

### Overview

We use genetically engineered and highly attenuated *Listeria monocytogenes* as a therapeutic agent. We start with an attenuated strain of *Listeria*, and then add to this bacterium multiple copies of a plasmid that encodes a fusion protein sequence that includes a fragment of the LLO molecule joined to the tumor antigen of interest. This protein is secreted



by the Listeria inside the antigen processing cells, and other cells that Listeria infects which then results in the immune response as discussed above.

We can use different tumor, infectious disease, or other antigens in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, ADX11-001 uses a HPV derived antigen that is present in cervical cancers. ADXS31-162 uses Her2/neu, an antigen found in many breast cancer and melanoma cells, to induce an immune response that should be useful in treating these conditions. See “Item 1. Description of Business -Research and Development Programs.

## Partnerships and Agreements

### University of Pennsylvania

On July 1, 2002 we entered into a 20-year exclusive worldwide license, with Penn with respect to the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology in the area of innate immunity, or the immune response attributable to immune cells, including dendritic cells, macrophages and natural killer cells that respond to pathogens non-specifically. This agreement has been amended from time to time and has been amended and restated as of February 13, 2007.

This license, unless sooner terminated in accordance with its terms, terminates upon the later (a) expiration of the last to expire Penn patent rights; or (b) twenty years after the effective date of the license. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to raise capital and pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our common stock which currently represents approximately 3.27% of our common stock outstanding on a fully-diluted basis. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of \$525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which we are not expecting to begin paying within the next five years). In addition, under the license, we are obligated to pay an annual maintenance fee on December 31, in 2008, 2009, 2010, 2011 and 2012 and each December 31st thereafter for the remainder of the term of the agreement of \$50,000, \$70,000, \$100,000, \$100,000 and \$100,000, respectively until the first commercial sale of a Penn licensed product. Overall the amended and restated agreement payment terms reflect lower near term requirements but the savings are offset by higher long term milestone payments for the initiation of a Phase III clinical trial and the regulatory approval for the first Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Furthermore, upon the achievement of the first sale of a product in certain fields, Penn will be entitled to certain milestone payments, as follows: \$2.5 million will be due for first commercial sale of the first product in the cancer field. In addition, \$1.0 million will be due upon the date of first commercial sale of a product in each of the secondary strategic fields sold.

As a result of our payment obligations under the license, assuming we have net sales in the aggregate amount of \$100.0 million from our cancer products, our total payments to Penn over the next ten years could reach an aggregate of \$5.4 million. If over the next 10 years our net sales total an aggregate amount of only \$10.0 million from our cancer products, total payments to Penn could be \$4.4 million.

Pursuant to an option contained in our existing license agreement with Penn, as amended, we have been in negotiations with Penn since March 2007 to further amend and restate the terms of the license agreement to acquire the rights to use an additional 12 docket or more (patentable research agents) under Penn's ownership which, as of October 31, 2009, have generated approximately 35 additional patent applications for Listeria and LLO-based vaccine docket. "Docket number" or "case number" refers to a subject on which a patent application or applications are filed. A docket number or case number can contain several applications, which are usually related applications. Related applications are sometimes assigned to more than one docket number, for example if the inventor list is not identical. As a condition to our exercising this option and entering into an amendment, we must, among other things, pay Penn a mutually agreeable option exercise fee and reimburse Penn for all of its historically accrued patent and licensing

expenses relating to these patents (dockets), including their legal and filing fees. As of October 31, 2009, such expenses totaled approximately \$548,105. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn over the form of payment and expect to reach a conclusion at the close of our next financial raise. If we fail to acquire a license to use the additional dockets and patent applications, our patent position may be materially and adversely affected. In addition, as of October 31, 2009, approximately \$328,820 in fees and expense are due and owing to Penn by us under our existing license agreement and other related agreements. While we consider our relationship with Penn to be good, we are in frequent communications over payment of past due invoices and other payables due to our lack of cash. If we fail to reach a mutual agreement, Penn may issue a default notice and we will have 60 days to cure the breach or be subject to the termination of the agreement.

Strategically we intend to enter into sponsored research agreements with Dr. Paterson and Penn to generate new intellectual property and to exploit all existing intellectual property covered by the license.

Penn is not involved in the management of our company or in our decisions with respect to exploitation of the patent portfolio, except that Dr. Paterson is the Chairperson of our Scientific Advisory Board.

Dr. Yvonne Paterson

Dr. Paterson is a Professor in the Department of Microbiology at Penn and the inventor of our licensed technology. She has been an invited speaker at national and international health field conferences and leading academic institutions. She has served on many federal advisory boards, such as the NIH expert panel to review primate centers, the Office of AIDS Research Planning Fiscal Workshop, and the Allergy and Immunology NIH Study Section. She has written over one hundred publications in immunology (including a recently published book) with emphasis during the last several years on the areas of HIV, AIDS and cancer research. Her instruction and mentorship has trained over forty post-doctoral and doctoral students in the fields of Biochemistry and Immunology. She was recently elected a fellow of the American Association for the Advancement of Science.

Dr. Paterson is currently the principal investigator on several grants from the federal government and charitable trusts and the program director of training grants. Her research interests are broad, but her laboratory has been focused for the past ten years on developing novel approaches for prophylactic vaccines against infectious disease and immunotherapeutic approaches to cancer. The approach of the laboratory is based on a long-standing interest in the properties of proteins that render them immunogenic and how such immunogenicity may be modulated within the body.

**Consulting Agreement.** On January 28, 2005 we entered into a consulting agreement with Dr. Paterson, which expired on January 31, 2009. We are currently in the process of establishing a revised agreement to continue to have access to Dr. Paterson's consulting services for one full day per week. There can be no assurance that we will be able to enter into a new agreement with Dr. Paterson. Dr. Paterson has advised us on an exclusive basis on various issues related to our technology, manufacturing issues, establishing our lab, knowledge transfer, and our long-term research and development program. Pursuant to the expired agreement, Dr. Paterson received \$7,000 per month. Upon the closing of an additional \$9.0 million in equity capital, Dr. Paterson's rates would have increased to \$9,000 per month. Also, under the prior Agreement, on February 1, 2005, she received options to purchase 400,000 shares of our common stock at an exercise price of \$0.287 per share which are now fully vested. In total she holds 704,365 shares of our common stock and 569,048 fully vested options to purchase shares of our common stock.

We intend to enter into additional sponsored research agreements with Penn in the future with respect to research and development on our product candidates.

We believe that Dr. Paterson's continuing research will serve as a source of ongoing findings and data that both supports and strengthen the existing patents. We further believe that her work will expand the claims of the patent portfolio (potentially including adding claims for new tumor specific antigens, the utilization of new vectors to deliver antigens, and applying the technology to new disease conditions) and create the infrastructure for the future filing of new patents.

Dr. Paterson is also the Chairman of our Scientific Advisory Board.

#### The Sage Group

We are party to a consulting agreement with The Sage Group, a health-care strategy consultant assisting us with a program to commercialize our vaccines. The initial agreement was entered into in January 2009 and subsequently amended on July 22, 2009. Pursuant to the terms of agreement, as amended, we have agreed to pay Sage (i) \$5,000 per month (which we began paying in January 2009) until an aggregate of \$120,000 has been paid to Sage under the consulting agreement and (ii) a 5% commission for certain transactions if completed in the first 24 months of the term of the agreement, reduced to 2% if completed in the 12 months thereafter. The Sage Group has been paid approximately \$20,600 through October 31, 2009.

#### Dr. David Filer

On January 7, 2005 we entered a consulting agreement with Dr. David Filer, a biotech consultant. The Agreement provides that Dr. Filer spend three days per month assisting us with our development efforts, reviewing our scientific technical and business data and materials and introducing us to industry analysts, institutional investor collaborators and strategic partners. In addition, Dr. Filer received options to purchase 40,000 shares of common stock which are fully vested. As of October 1, 2007 we entered into a new two year agreement at a monthly fee of \$5,000 including 1,500,000 warrants exercisable at \$0.20 per warrant (prior to anti-dilution adjustments) as consideration for his assistance in the raise on October 17, 2007 as well as his advisory services and assistance. This agreement expired on September 30, 2009 and has not been renewed.

University of California

On March 14, 2004 we entered into a nonexclusive license and bailment agreement with the Regents of the University of California (“UCLA”) to commercially develop products using the XFL7 strain of *Listeria monocytogenes* in humans and animals. The agreement is effective for a period of 15 years and is renewable by mutual consent of the parties. Advaxis paid UCLA an initial licensee fee and continues to pay an annual maintenance fee of \$1,000 for use of the *Listeria*. We may not sell products using the XFL7 strain *Listeria* other than agreed upon products or sublicense the rights granted under the license agreement without the prior written consent of UCLA.

Cobra Biomanufacturing PLC (“Cobra”)

In July 2003, we entered into an agreement with Cobra for the purpose of manufacturing our cervical cancer vaccine ADX11-001. Cobra has extensive experience in manufacturing gene therapy products for investigational studies. Cobra is a full service manufacturing organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotech industry. These services include the Good Manufacturing Practices (“GMP”) manufacturing of DNA, recombinant protein, viruses, mammalian cell products and cell banking. Cobra’s manufacturing plan for us involves several manufacturing stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase I trial. The agreement to manufacture expired in December 2005 upon the delivery and completion of stability testing of the GMP material for the Phase I trial. Cobra has agreed to surrender the right to \$300,000 of its existing fees for manufacturing in exchange for future royalties from the sales of ADX11-001 at the rate of 1.5% of net sales, with royalty payments not to exceed \$1,950,000.

In November 2005, in order to secure production of ADXS11-001 on a long-term basis as well as other drug candidates which we are developing, we entered into a Strategic Collaboration and Long-Term Vaccine Supply Agreement for Listeria Cancer Vaccines, under which Cobra will manufacture experimental and commercial supplies of our Listeria cancer vaccines, beginning with ADXS11-001. This agreement leaves the existing agreement in place with respect to the studies contemplated therein, and supersedes a prior agreement and provides for mutual exclusivity, priority of supply, collaboration on regulatory issues, research and development of manufacturing processes that have already resulted in new intellectual property owned by Advaxis, and the long-term supply of live Listeria based vaccines on a discounted basis.

In October 20, 2007 we entered into a production agreement with Cobra to manufacture our Phase II clinical materials using a new methodology now required by the United Kingdom, and likely to be required by other regulatory bodies in the future. The contract was for £274,500 plus consumables and as of October 31, 2008 we have recorded \$543,620 in full excluding consumables. In addition, we entered into a contract for £47,250 to fill the Listeria in vials and as of October 31, 2008, we have recorded \$107,793 in full payment. In 2009 we also have several other small contracts to cover, testing, stability and storage of our clinical supplies.

#### Vibalogics GtmbH

In April of 2008 we entered into a series of agreements with Vibalogics GmbH in Cuxhaven Germany to provide fill and finish services for our final clinical materials that were made for the scheduled clinical trials described above. These agreements describe all of the fill and finish operations as well as the specific tests that have to be performed in order to release the clinical materials for human use.

#### LVEP Management, LLC (“LVEP”)

The Company entered into a consulting agreement with LVEP dated as of January 19, 2005, and amended on April 15, 2005, and October 31, 2005, pursuant to which Mr. Roni Appel served as Chief Executive Officer, Chief Financial Officer and Secretary of the Company and was compensated by consulting fees paid to LVEP. Pursuant to an amendment dated December 15, 2006 (“effective date”) Mr. Appel resigned as President and Chief Executive Officer and Secretary of the Company on the effective date, but remains as a board member and consultant to the Company.

On February 11, 2008 the Company and LVEP agreed to satisfy the balances of the LVEP Agreement with cash payments of \$130,000 and \$20,000 in the Company’s common stock (153,846 shares). The cash payment was made on February 12, 2008 and the shares were issued on April 4, 2008 and recorded at the market value of \$14,615.

#### Pharm-Olam International Ltd. (“POI”)

In April 2005, we entered into a consulting agreement with POI, whereby POI is to execute and manage our Phase I clinical trial in ADXS11-001 for a fee of \$430,000 plus reimbursement of certain expenses. As of October 31, 2009 the Company has an outstanding balance due POI of \$219,131.

#### Biologics Consulting Group, Inc. (“BCG”)

On June 1, 2006 we entered into an agreement with Biologics Consulting Group, Inc., which we refer to as BCG, and effective June 1, 2008, we entered into an amendment No. 2 to provide biologics regulatory consulting services to us, on an as needed basis, in support of the IND submission to the FDA and other related services. The tasks to be performed under this Agreement will be agreed to in advance by us and BCG. The term of the amendment No. 2 is from June 1, 2006 to June 1, 2010. In April 2009 we entered into Amendment No. 2 which set June 1, 2008 as the effective date and amended the term from June 1, 2006 through June 1, 2010.

Numoda Corporation

On June 19, 2009 we entered into a Master Agreement and on July 8, 2009 we entered into a Project Agreement with Numoda, a leading clinical trial and logistics management company, to oversee Phase II clinical activity with ADXS11-001 for the treatment of invasive cervical cancer and CIN. Numoda will be responsible for integrating oversight and logistical functions with the clinical research organizations, contract laboratories, academic laboratories and statistical groups involved. The scope of this agreement covers over three years and is estimated to cost \$8.0 million for both trials.

## Patents and Licenses

Dr. Paterson and Penn have invested significant resources and time in developing a broad base of intellectual property around the cancer vaccine platform technology to which on July 1, 2002 we entered into a 20-year exclusive worldwide license and a right to grant sublicenses pursuant to our license agreement with Penn. As of October 31, 2009 Penn has 24 issued and 15 pending patents in the U.S. and other large countries including Japan, and the European Union, through the Patent Cooperation Treaty system pursuant to which we have an exclusive license to exploit the patents. Penn holds 35 additional patents and patent applications in foreign countries. We are negotiating to license these patents as part of our Seconded Amended and Restated Agreement with Penn. We believe that these patents will allow us to take a lead in the U.S. in the field of Listeria -based therapy.

In 2001, an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642. These patent rights are included in the patent rights licensed by Advaxis from Penn. It is contemplated by GlaxoSmithKline plc, which we refer to as GSK, Penn and us that the issue will be resolved through: (1) a correction of inventorship to add certain GSK inventors, (2) where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and (3) a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above.

Pursuant to our existing license with Penn, we had an option to license from Penn any new future invention conceived by either Dr. Yvonne Paterson or by Dr. Fred Frankel in the vaccine area that expired on June 17, 2009. Under our license agreement with Penn, we expanded our intellectual property base and gained access to inventions. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn to obtain additional patent licenses. Further, our previous consulting agreement with Dr. Paterson provided, among other things, that, to the extent that Dr. Paterson's consulting work resulted in new inventions, such inventions were assigned to Penn, and we have access to those inventions under existing license agreements to be negotiated. This agreement is currently being revised.

Our approach to the intellectual property portfolio is to create significant offensive and defensive patent protection for every product and technology platform that we develop. We work closely with our patent counsel to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines.

We are aware of a private company, Anza Therapeutics, Inc (formerly Cerus Corporation), which, is no longer in existence, but had been developing Listeria vaccines. We believe that through our exclusive license with Penn we have earliest known and dominant patent position in the U.S. for the use of recombinant Listeria monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. We successfully defended our intellectual property by contesting a challenge made by Anza to our patent position in Europe on a claim not available in the U.S. The EPO Board of Appeals in Munich, Germany has ruled in favor of The Trustees of Penn and its exclusive licensee Advaxis and reversed a patent ruling that revoked a technology patent that had resulted from an opposition filed by Anza. The ruling of the EPO Board of Appeals is final and can not be appealed. The granted claims, the subject matter of which was discovered by Dr. Yvonne Paterson, scientific founder of Advaxis, are directed to the method of preparation and composition of matter of recombinant bacteria expressing tumor antigens for treatment of patients with cancer.

Based on searches of publicly available databases, we do not believe that Anza or any other third party owns any published Listeria patents or has any issued patent claims that might materially and adversely affect our ability to operate our business as currently contemplated in the field of recombinant Listeria monocytogenes. Additionally, our proprietary position that is the issued patents and licenses for pending applications restricts anyone from using plasmid based Listeria constructs, or those that are bioengineered to deliver antigens fused to LLO, ActA, or



fragments of LLO or ActA. On January 7, 2009 we made the decision to discontinue our use of the Trademark Lovaxin and write-off of our intangible assets for trademarks resulting in an asset impairment of \$91,453 as of October 31, 2008. We developed a classic coding system for our constructs. The rationale for this decision stemmed from several legal challenges to the Lovaxin name over the last two years and certain rules in Title 21 of the Code of Federal Regulations which do not allow companies to use names that are assigned to drugs in development after marketing approval. We will therefore focus company resources on product development and not the defense the Lovaxin name.

On May 26, 2009, the United States Patent and Trademark Office (“PTO”) approved our patent application “Compositions and Methods for Enhancing the Immunogenicity of Antigens.” This patent application covers the use of *Listeria monocytogenes* (Lm) protein ActA and fragments of this protein for use in the creation of antigen fusion proteins. This intellectual property protects a unique strain of *Listeria monocytogenes* for use as a vaccine vector.

On February 10, 2009 the U.S. PTO issued patent 7,488,487 “Methods of Inducing Immune response Through the Administration of Auxotrophic Attenuated DAT/DAL Double Mutant *Listeria* Strains”, assigned to Penn and licensed to us. This intellectual property protects a unique strain of *Listeria monocytogenes* for use as a vaccine vector. This new strain of *Listeria* is an improvement over the strain currently in clinical testing as it is more attenuated, more immunogenic, and does not have an antibiotic resistance gene inserted. We believe that this technology will make our product more effective and easier to obtain FDA regulatory approval.

## Governmental Regulation

### The Drug Development Process

The Food and Drug Administration (“FDA”) requires that pharmaceutical and certain other therapeutic products undergo significant clinical experimentation and clinical testing prior to their marketing or introduction to the general public. Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or is conducted on behalf of these companies by contract research organizations.

The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. Below, we describe the principal framework in which clinical studies are conducted, as well as describe a number of the parties involved in these studies.

Protocols. Before commencing human clinical studies, the sponsor of a new drug must typically receive governmental and institutional approval. In the U.S., Federal approval is obtained by submitting an IND to the FDA and amending it for each new proposed study. The clinical research plan is known in the industry as a protocol. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

- Who must be recruited as qualified participants and who is to be excluded;
- how often, and how to administer the drug and at what dose(s);
- what tests to perform on the participants; and
- what evaluations are to be made and how the data will be assessed.

Institutional Review Board (Ethics Committee). An institutional review board is an independent committee of professionals and lay persons which reviews clinical research studies involving human beings and is required to adhere to guidelines issued by the FDA. The institutional review board does not report to the FDA and its members are not appointed by the FDA, but its records are audited by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board is convened by the institution where the protocol will be conducted and its role is to protect the rights of the participants in the clinical studies. It must approve the protocols to be used, and then oversees the conduct of the study, including: the communications which we or the contract research organization conducting the study at that specific site proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

Clinical Trials. Human clinical studies or testing of a potential product prior to Federal approval are generally done in three stages known as Phase I, Phase II, and Phase III testing. The names of the phases are derived from the CFR 21 that regulates the FDA. Generally, there are multiple studies conducted in each phase.

Phase I. Phase I studies involve testing a drug or product on a limited number of participants. Phase I studies determine a drug’s basic safety and how the drug is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year. Typically, cancer therapeutics are initially tested on very late stage cancer patients.

Phase II. Phase II trials involve large numbers of participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to three years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to review the substance in Phase III studies. It is during Phase II that everything that goes into a Phase III test is determined.

Phase III. Phase III studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to six years. Phase III studies are conducted at multiple locations or sites. Like the other phases, Phase III requires the site to keep detailed records of data collected and procedures performed.

New Drug Approval. The results of the clinical trials are submitted to the FDA as part of an NDA or BLA. Following the completion of Phase III studies, assuming the sponsor of a potential product in the U.S. believes it has sufficient information to support the safety and effectiveness of its product, it submits an NDA or BLA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all preclinical and clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging, labeling and testing the product. The FDA's review of an application can take a few months to many years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the U.S., subject to any conditions imposed by the FDA.

The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials.

On November 21, 1997, former President Clinton signed into law the FDA Modernization Act. That act codified the FDA's policy of granting "Fast Track" approval for cancer therapies and other therapies intended to treat serious or life threatening diseases and that demonstrate the potential to address unmet medical needs. The Fast Track program emphasizes close, early communications between the FDA and the sponsor to improve the efficiency of preclinical and clinical development, and to reach agreement on the design of the major clinical efficacy studies that will be needed to support approval. Under the Fast Track program, a sponsor also has the option to submit and receive review of parts of the NDA or BLA on a rolling schedule approved by FDA, which expedites the review process.

The FDA's Guidelines for Industry Fast Track Development Programs require that a clinical development program must continue to meet the criteria for Fast Track designation for an application to be reviewed under the Fast Track Program. Previously, the FDA approved cancer therapies primarily based on patient survival rates or data on improved quality of life. While the FDA could consider evidence of partial tumor shrinkage, which is often part of the data relied on for approval, such information alone was usually insufficient to warrant approval of a cancer therapy, except in limited situations. Under the FDA's new policy, which became effective on February 19, 1998, Fast Track designation ordinarily allows a product to be considered for accelerated approval through the use of surrogate endpoints to demonstrate effectiveness. As a result of these provisions, the FDA has broadened authority to consider evidence of partial tumor shrinkage or other surrogate endpoints of clinical benefit for approval. This new policy is intended to facilitate the study of cancer therapies and shorten the total time for marketing approvals. Under accelerated approval, the manufacturer must continue with the clinical testing of the product after marketing approval to validate that the surrogate endpoint did predict meaningful clinical benefit. To the extent applicable we intend to take advantage of the Fast Track programs to obtain accelerated approval on our future products, however, it is too early to tell what effect, if any, these provisions may have on the approval of our product candidates.

#### Other Regulations

Various Federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movements, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, are used in connection with our research or applicable to our activities. They include, among others, the U.S. Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation. The extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted.

There is a series of international harmonization treaties, known as the ICH treaties that enable drug development to be conducted on an international basis. These treaties specify the manner in which clinical trials are to be conducted, and if trials adhere to the specified requirements, then they are accepted by the regulatory bodies of in the signatory countries. In this way the Advaxis Phase I study conducted outside of the U.S. is accepted by the FDA.

#### Manufacturing

The FDA requires that any drug or formulation to be tested in humans be manufactured in accordance with its GMP regulations. This has been extended to include any drug which will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping, and the physical characteristics of the laboratories used in the production of these drugs.

We have entered into a Long Term Vaccine Supply Agreement with Cobra for the purpose of manufacturing our vaccines. Cobra has extensive experience in manufacturing gene therapy products for investigational studies. Cobra is a full service manufacturing organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotech industry. These services include the GMP manufacturing of DNA, recombinant protein, viruses, mammalian cells products and cell banking. Cobra's manufacturing plan for us calls for several manufacturing stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase I and Phase II trials.

We have entered into a GMP compliant filing of ADXS11-001 agreement with Vibalogics GmbH, Zeppelinstr. 2, 27472 Cuxhaven, Germany to fill up to 5,000 vials of our clinical supplies. This agreement was for €84,800 and is near completion in preparation for our Phase II CIN trial.

## Competition

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical and chemical companies, including Antigenics, Inc., Avi BioPharma, Inc., Biomira, Inc., Cellgenesis Inc., Biovest International, Biosante Pharmaceuticals, Inc., Dendreon Corporation, Pharmexa-Epimmune, Inc., Genzyme Corp., Progenics Pharmaceuticals, Inc., and Vical Incorporated each of which is pursuing cancer vaccines. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our products from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies, some of which have completed numerous clinical trials.

We expect that our products under development and in clinical trials will address major markets within the cancer sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the speed with which we can develop products, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Merck has developed the drug Gardasil and GSK has developed the drug Cervarix which can prevent cervical cancer by vaccinating women against the virus HPV, the cause of the disease. Gardasil is directed against four HPV species while Cervarix is directed against two. Neither of these agents have an approved indication for women who have a prior exposure to the HPV strains that they protect against, nor are women protected from other strains of HPV that the drugs do not treat. It has been written that these are cancer vaccines, which is not true. They are anti-virus vaccines intended to protect against strains of the HPV virus.

The presence of these agents in the market does not eliminate the market for a therapeutic vaccine directed against invasive cervical cancer and CIN for a number of reasons:

HPV is the most common sexually transmitted disease in the U.S., and since prior exposure to the virus renders these anti-viral agents ineffective they tend to be limited to younger women and do not offer protection for women who are already infected. This is estimated to be as much as (or more than) 25% of the female population of the U.S.

There are believed to be approximately 10 high risk species of HPV, but these agents only protect against the most common 2-4 strains. If a woman contracts a high risk HPV species that is not one of those the drugs will not work.

Women with HPV are typically infected for over twenty years or more before they manifest cervical cancer. Thus, the true prophylactic effect of these agents can only be inferred at this time. We believe that there currently exists a significant population of young woman who have not received these agents, or for whom they will not work, and who will manifest HPV related cervical disease for the next 40+ years. We believe this population will continue to grow until such time as a significant percentage of women who have not been exposed to HPV are vaccinated; which we believe is not likely to occur within the next decade or longer. We do not know at this time whether a significant number of women will be vaccinated to have an effect on the epidemiology of this disease. Currently, men are not vaccinated.

With the exception of the campaign to eradicate polio in which vaccination was mandatory for all school age children, vaccination is a difficult model to accomplish because it is virtually impossible to treat everyone in any given country, much less the entire world. This is especially true for cervical cancer as the incentive for men to be vaccinated is small, and infected men keep the pathogen circulating in the population.

Taken together, experts believe that there will be a cervical cancer and CIN market for the foreseeable future.

#### Scientific Advisory Board

We maintain a Scientific Advisory Board consisting of internationally recognized scientists who advise us on scientific and technical aspects of our business. The Scientific Advisory Board meets on an as needed basis to review specific projects and to assess the value of new technologies and developments to us. In addition, individual members of the scientific advisory board meet with us periodically to provide advice in particular areas of expertise. The scientific advisory board consists of the following members, information with respect to whom is set forth below: Yvonne Paterson, Ph.D.; Carl June, M.D.; Pramod Srivastava, Ph.D.; Bennett Lorber, M.D.; David Weiner, Ph.D.; and Mark Einstein, M.D.

Dr. Yvonne Paterson. For a description of our relationship with Dr. Paterson, please see “Partnerships and Agreements-Dr. Yvonne Paterson.”

Carl June, M.D. Dr. June is currently Facility Director, Human Immunology Center and Professor, Pathology and Laboratory Medicine Translational Research at the Abramson Cancer Center at Penn, and previously a Director of Translational Research at the Center and Investigator of the Abramson Family Cancer Research Institute. He is a graduate of the Naval Academy in Annapolis, and Baylor College of Medicine in Houston. He had graduate training in immunology and malaria with Dr. Paul-Henri Lambert at the World Health Organization, Geneva, Switzerland from 1978 to 1979, and post-doctoral training in transplantation biology with Dr. E. Donnell Thomas at the Fred Hutchinson Cancer Research Center in Seattle from 1983 to 1986. He is board certified in Internal Medicine and Medical Oncology. Dr. June founded the Immune Cell Biology Program and was head of the Department of Immunology at the Naval Medical Research Institute from 1990 to 1995. Dr. June rose to Professor in the Departments of Medicine and Cell and Molecular Biology at the Uniformed Services University for the Health Sciences in Bethesda, Maryland before assuming his current positions as of February 1, 1999. Dr. June maintains a research laboratory that studies various mechanisms of lymphocyte activation that relate to immune tolerance and adoptive immunotherapy.

Pramod Srivastava, Ph.D. Dr. Srivastava is Professor of Immunology at the University of Connecticut School of Medicine, where he is also Director of the Center for Immunotherapy of Cancer and Infectious Diseases. He holds the Physicians Health Services Chair in Cancer Immunology at the University of Connecticut School of Medicine. Professor Srivastava is the Scientific Founder of Antigenics, Inc. He serves on the Scientific Advisory Council of the Cancer Research Institute, New York, and was a member of the Experimental Immunology Study Section of the National Institutes of Health of the U.S. Government from 1994 to 1999. He serves presently on the board of directors of two privately held companies: Ikonisys, in New Haven, Connecticut and CambriaTech, Lugano, Switzerland. In 1997, he was inducted into the Roll of Honor of the International Union Against Cancer and was listed in Who's Who in Science and Engineering. He is among the twenty founding members of the Academy of Cancer Immunology, New York. Dr. Srivastava obtained his bachelor's degree in biology and chemistry and a master's degree in botany (paleontology) from the University of Allahabad, India. He then studied yeast genetics at Osaka University, Japan. He completed his Ph.D. in biochemistry at the Center for Cellular and Molecular Biology, Hyderabad, India, where he began his work on tumor immunity, including identification of the first proteins that can mediate tumor rejection. He trained at Yale University and Sloan-Kettering Institute for Cancer Research. Dr. Srivastava has held faculty positions at the Mount Sinai School of Medicine and Fordham University in New York City.

Bennett Lorber, M.D. Dr. Lorber attended Swarthmore College where he studied zoology and art history. He graduated from the University of Pennsylvania School of Medicine and did his residency in internal medicine and fellowship in infectious diseases at Temple University, following which he joined the Temple faculty. At Temple he rose through the ranks to become Professor of Medicine and, in 1988, was named the first recipient of the Thomas Durant Chair in Medicine. He is also a Professor of Microbiology and Immunology and served as the Chief of the Section of Infectious Diseases until 2006. He is a Fellow of the American College of Physicians, a Fellow of the Infectious Diseases Society of America, and a Fellow of the College of Physicians of Philadelphia where he serves as College Secretary and as a member of the Board of Trustees. Dr. Lorber's major interest in infectious diseases is in human listeriosis, an area in which he is regarded as an international authority. He has also been interested in the impact of societal changes on infectious disease patterns as well the relationship between infectious agents and chronic illness, and he has authored papers exploring these associations. He has been repeatedly honored for his teaching. Among his honors are 10 golden apples, the Temple University Great Teacher Award, the Clinical Practice Award from the Pennsylvania College of Internal Medicine, and the Bristol Award from the Infectious Diseases Society of America. In 1996 he was the recipient of an honorary Doctor of Science degree from Swarthmore College.

David B. Weiner, Ph.D. Dr. David Weiner received his B.S in Biology from the State University of New York and performed undergraduate research in the Department of Microbiology, Chaired by Dr. Arnie Levine, at Stony Brook University. He completed his MS and Ph.D. in Developmental Biology/Immunology from the Children's Hospital Research Foundation at the University of Cincinnati in 1986. He completed his Post Doctoral Fellowship in the



Department of Pathology at Penn in 1989, under the direction of Dr. Mark Greene. At that time he joined the Faculty at the Wistar Institute in Philadelphia. He was recruited back to Penn in 1994. He is currently an Associate Professor with Tenure in the Department of Pathology, and he is the Associate Chair of the Gene Therapy and Vaccines Graduate Program at Penn. Of relevance during his career he has worked extensively in the areas of molecular immunology, the development of vaccines and vaccine technology for infectious diseases and in the area of molecular oncology and immune therapy. His laboratory is considered one of the founders of the field of DNA vaccines as his group not only was the first to report on the use of this technology for vaccines against HIV, but was also the first group to advance DNA vaccine technology to clinical evaluation. In addition he has worked on the identification of novel approaches to inhibit HIV infection by targeting the accessory gene functions of the virus. Dr. Weiner has authored over 260 articles in peer reviewed journals and is the author of over 28 awarded U.S. patents as well as their international counterparts. He has served and still serves on many national and international review boards and panels including the NIH Study section, WHO advisory panels, the National Institute for Biological Standards and Control, Department of Veterans Affairs Scientific Review Panel, as well as the FDA Advisory panel - Center for Biologics Evaluation and Research, and Adult AIDS Clinical Trial Group, among others. He also serves or has served in an advisory capacity to several Biotechnology and Pharmaceutical Companies. Dr. Weiner has, through training of young people in his laboratory, advanced over 35 undergraduate scientists to Medical School or Doctoral Programs and has trained 28 Post Doctoral Fellows and 7 Doctoral Candidates as well as served on fourteen Doctoral Student Committees.

Mark Einstein, M.D. Dr. Einstein received his BS degree in Biology from the University of Miami, where he also received his MD with Research Distinction in Clinical Immunology. He also has an MS in Clinical Research Methods, which he received with Distinction. Dr. Einstein completed his residency in OB/GYN at Saint Barnabas Medical Center, and was a Galloway Fellow in Gynecologic Oncology at the Sloan-Kettering Cancer Center. Dr. Einstein has been at the Albert Einstein Cancer Center and Montefiore Medical Center since 1999, where he has been an attending physician, Assistant Professor of Gynecologic Oncology, and currently the Director of Clinical Research of the Division of Gynecologic Oncology at the Albert Einstein College of Medicine and Cancer Center, and at the Montefiore Medical Center. He is a Fellow of the American College of Obstetrics and Gynecology and the American College of Surgeons, as well as belonging to various research groups such as the American Association for Cancer Research and the American Society for Clinical Oncology. Dr. Einstein's honors and awards include; American Cancer Society Research Scholar, American Professors in Gynecology and Obstetrics McNeil Faculty Award, ACOG/3M Research Award, ACOG/Solvay Research Award, Berlex Oncology Foundation Scholar Award, and others. Dr. Einstein is a member of the GOG Vaccine subcommittee, chairs the Gynecologic Cancer Foundation National Cervical Cancer Education Campaign, sits on the Translational Research Working Group Roundtable at NIH/NCI, the NHI AIDS malignancy Consortium, the Gynecologic Cancer Foundation Task Force for Cervical Cancer Screening and Prevention, as well as three separate committees for the Society of Gynecologic Oncologists. Dr. Einstein is very active in the clinical assessment of new immunological technologies for the treatment of gynecologic cancers.

#### Item 1A: Risk Factors.

You should carefully consider the risks described below as well as other information provided to you in this annual report, including information in the section of this document entitled "Forward-Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment.

#### Risks Related to our Business

We are a development stage company.

We are an early stage development stage company with a history of losses and can provide no assurance as to future operating results. As a result of losses which will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our production. Our deficit will continue to grow during our drug development period.

We have sustained losses from operations in each fiscal year since our inception, and we expect 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. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

As a result of our current lack of financial liquidity and negative stockholders equity, our auditors have expressed substantial concern about our ability to continue as a "going concern."

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL and Research tax credits and income earned on investments and grants. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated

expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2009 included a going concern explanatory paragraph.

There can be no assurance that we will receive additional funding from Optimus in connection with the preferred equity financing.

We have entered into the Optimus purchase agreement, pursuant to which Optimus has agreed to purchase up to 500 shares of our Series A preferred stock at a purchase price of \$10,000 per share from time to time (\$5.0 million in the aggregate), subject to our ability to effect and maintain an effective registration statement for the shares underlying the warrant initially issued in connection with the transaction to an affiliate of Optimus. During January 2010, Optimus purchased 145 shares and remains obligated, from time to time until September 24, 2012, to purchase up to an additional 355 shares upon notice from us to Optimus, if certain conditions set forth in the purchase agreement are satisfied, including among things that: (i) we must be in compliance with our SEC reporting obligations, (ii) our common stock must be quoted on the OTC Bulletin Board or another eligible trading market, (iii) a material adverse effect relating to, among other things, our results of operations, assets, business or financial condition must not have occurred since September 24, 2009, other than losses incurred in the ordinary course of business, (iv) we must not be in default under any material agreement, and (v) Optimus and its affiliates must not own more than 9.99% of our outstanding common stock, and (vi) we must comply with certain other requirements set forth in the Optimus purchase agreement. If we fail to comply with any of these requirements, including the ability to effect and maintain a registration statement underlying the warrant issued to an affiliate of Optimus, Optimus will not be obligated to purchase additional shares of our Series A preferred stock and we will not receive any additional funding from Optimus. Moreover, if we exercise our option to require Optimus to purchase additional shares of our Series A preferred stock, and our common stock has a closing price of less than \$0.20 per share on the trading day immediately preceding our delivery of the exercise notice, we will trigger certain anti-dilution protection provisions in certain outstanding warrants that would result in an adjustment to the number and price of a significant number of our outstanding warrants.

Our business will require substantial additional investment that we have not yet secured, and our failure to raise capital and/or pursue partnering opportunities will materially adversely affect our business, financial condition and results of operations.

We expect to continue to spend substantial amounts on research and development, including conducting clinical trials for our product candidates. However, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing on acceptable terms, secure funds from new partners or consummate a preferred equity financing under the Optimus purchase agreement. We cannot be assured that financing will be available at all. Our failure to raise a significant amount of capital in the near future, will materially adversely affect our business, financial condition and results of operations, and we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. Any additional investments or resources required would be approached, to the extent appropriate in the circumstances, in an incremental fashion to attempt to cause minimal disruption or dilution. Any additional capital raised through the sale of equity or convertible debt securities will result in dilution to our existing stockholders. No assurances can be given, however, that we will be able to achieve these goals or that we will be able to continue as a going concern.

We have significant indebtedness which may restrict our business and operations, adversely affect our cash flow and restrict our future access to sufficient funding to finance desired growth.

As of October 31, 2009, the face value of our outstanding indebtedness notes was approximately \$4.3 million, of which approximately \$1.0 million is outstanding to our chief executive officer. The total face value of the notes outstanding as of October 31, 2009, other than the Moore Notes, is due on or before July 30, 2010. We dedicate a substantial portion of our cash to pay interest and principal on our debt. If we are not able to service our debt, we would need to refinance all or part of that debt, sell assets, borrow more money or sell securities, which we may not be able to do on commercially reasonable terms, or at all.

As of October 31, 2009, \$3.3 million of this indebtedness is secured by substantially all of our assets. The terms of our notes include customary events of default and covenants that restrict our ability to incur additional indebtedness. These restrictions and covenants may prevent us from engaging in transactions that might otherwise be considered beneficial to us. A breach of the provisions of our indebtedness could result in an event of default under our outstanding notes. If an event of default occurs under our notes (after any applicable notice and cure periods), the holders would be entitled to accelerate the repayment of amounts outstanding, plus accrued and unpaid interest. In the event of a default under our senior indebtedness, the holders could also foreclose against the assets securing such obligations. In the event of a foreclosure on all or substantially all of our assets, we may not be able to continue to operate as a going concern.

Our limited operating history does not afford investors a sufficient history on which to base an investment decision.

We commenced our Listeria System vaccine development business in February 2002 and have existed as a development stage company since such time. Prior thereto we conducted no business. Accordingly, we have a limited operating history. Investors must consider the risks and difficulties we have encountered in the rapidly evolving vaccine and therapeutic biopharmaceutical industry. Such risks include the following:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of products;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
-

amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;

- need to rely on multiple levels of complex financing agreements with outside funding due to the length of the product development cycles and governmental approved protocols associated with the pharmaceutical industry; and

- dependence upon key personnel including key independent consultants and advisors.

We cannot be certain that our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

We can provide no assurance of the successful and timely development of new products.

Our products are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. Immunotherapy and vaccine products that we may develop are not likely to be commercially available until five to ten or more years. The proposed development schedules for our products may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in "Risk Factors," there can be no assurance that we will be able to successfully complete the development or marketing of any new products.

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of products;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of the product development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

We are subject to numerous risks inherent in conducting clinical trials.

We outsourced our clinical trials and entered into a contract with Numoda to manage the execution of two Phase II trials for the assessment of our agent ADXS11-001 in the treatment of advanced cervix cancer in women who have failed prior cytotoxic treatment, and in the treatment of CIN, the precursor condition to cervix cancer. We expect to conduct the CIN trial in the U.S. and we expect to conduct the cervix cancer trial in India in association with the clinical research organization Max Neeman International. These trials are scheduled to begin during the second fiscal quarter of 2010.

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 is 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.

Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties which, if unmet, could result in delays in, or termination of, our clinical trials. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our agent ADXS11-001. We are not certain that we will successfully recruit enough patients to complete our clinical trials. Delays in recruitment and such agreements would delay the initiation of the Phase II trials of ADXS11-001.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The successful development of biopharmaceuticals is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- Preclinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- Manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the product uneconomical; and
- The proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict.

We must comply with significant government regulations.

The research and development, manufacture and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recall or seizure of products, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the U.S. include: (1) the successful conclusion of



preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an Investigational New Drug Application, which we refer to as an IND, to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a Biologic License Application, which we refer to as a BLA, for a biological product, to allow commercial distribution of a biologic product. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our product candidates through clinical testing and to market.

We can provide no assurance that our products will obtain regulatory approval or that the results of clinical studies will be favorable.

In February 2006, we received permission from the appropriate governmental agencies in Israel, Mexico and Serbia to conduct Phase I clinical testing of ADXS11-001, our Listeria -based cancer vaccine that targets cervical cancer in women in those countries. The study was completed in the fiscal quarter ended January 31, 2008. The next step was to manufacture and test our product for future sale or distribution in the U.S. which required a filing of an IND with the FDA for our Phase II CIN trial. The filing was based on information from the Phase I trial and other pre-clinical information. On January 6, 2009 we received permission to conduct our clinical trial under this IND from the FDA. However, even though we are allowed to conduct this trial, as with any experimental agent, we are always at risk to be placed on clinical hold by the FDA at any time as our product may have effects on humans are not fully understood or documented. There can be delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from governmental authorities outside of the U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the Listeria System, and the proprietary technology of others with which we have entered into licensing agreements. As of October 31, 2009 we have licensed 24 patents that have been issued and licenses for 15 patents are pending from Penn filed in some of the largest markets in the world and we are negotiating to enter into a Second Amended and Restated Agreement with Penn for the rights to an additional 35 patents that Penn has applied for patents. Further, we rely on a combination of trade secrets and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking rights.

We are aware of a private company, Anza Therapeutics, Inc (formerly Cerus Corporation), which is no longer in existence, but had been developing Listeria vaccines. We believe that through our exclusive license with Penn we have earliest known and dominant patent position in the U.S. for the use of recombinant Listeria monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. We successfully defended our intellectual property by contesting a challenge made by Anza to our patent position in Europe on a claim not available in the U.S. The European Patent Office, which we refer to as the EPO, Board of Appeals in Munich, Germany has ruled in favor of The Trustees of Penn and its exclusive licensee Advaxis and reversed a patent ruling that revoked a technology patent that had resulted from an opposition filed by Anza. The ruling of the EPO Board of Appeals is final and can not be appealed. The granted claims, the subject matter of which was discovered by Dr. Yvonne Paterson, scientific founder of Advaxis, are directed to the method of preparation and composition of matter of recombinant bacteria expressing tumor antigens for treatment of patients with cancer. Based on searches of publicly available databases, we do not believe that Anza or any other third party owns any published Listeria patents or has any issued patent claims that might materially and adversely affect our ability to operate our business as currently contemplated in the field of recombinant Listeria monocytogenes. Additionally, our proprietary position that is the issued patents and licenses for pending applications restricts anyone from using plasmid based Listeria constructs, or those that are bioengineered to deliver antigens fused to LLO, ActA, or fragments of LLO or ActA.

We are dependent upon our license agreement with Penn; if we fail to make payments due and owing to Penn under our license agreement, our business will be materially and adversely affected.

Although we have obtained licenses with regard to the use of Penn's patents as described herein, we can provide no assurance that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights which may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms.

Pursuant to an option contained in our existing license agreement with Penn, as amended, we have been in negotiations with Penn since March 2007 to further amend and restate the terms of the license agreement to acquire the rights to use an additional 12 or more dockets (patentable research agents) under Penn's ownership which, as of October 31, 2009, have generated approximately 35 additional patent applications for Listeria and LLO-based vaccine dockets. As a condition to our exercising this option and entering into an amendment, we must, among other things, pay Penn a mutually agreeable option exercise fee and reimburse Penn for all of its historically accrued patent and

licensing expenses relating to these patents (dockets), including their legal and filing fees. As of October 31, 2009, such expenses totaled approximately \$548,105. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn over the form of payment and expect to reach a conclusion at the close of our next financial raise. If we fail to acquire a license to use the additional dockets and patent applications, our patent position may be materially and adversely affected. In addition, as of October 31, 2009, approximately \$328,820 in fees and expense are due and owing to Penn by us under our existing license agreement and other related agreements. While we consider our relationship with Penn to be good, we are in frequent communications over payment of past due invoices and other payables due to our lack of cash. If we fail to reach a mutual agreement, Penn may issue a default notice and we will have 60 days to cure the breach or be subject to the termination of the agreement.

If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future. Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. Furthermore, in 2001, an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642. These patent rights are included in the patent rights licensed by us from Penn. GlaxoSmithKline plc, Penn and we expect that the issue will be resolved through a correction of inventorship to add certain GSK inventors, where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.

We do not intend to create facilities to manufacture our products and therefore are dependent upon third parties to do so. We currently have an agreement with Cobra Manufacturing for production of our immunotherapies and vaccines for research and development and testing purposes. Our reliance on third parties for the manufacture of our products creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to replace the development of our product candidates, our clinical testing program may not be able to go forward and our entire business plan could fail.

If we are unable to establish or manage strategic collaborations in the future, our revenue and product development may be limited.

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of ADXS11-001, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other product candidates. To date, we have not entered into any strategic collaborations with third parties capable of providing these services although we have been heavily reliant upon third party outsourcing for our clinical trials execution. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
-

coordination of our research and development programs with the research and development priorities of our collaborators; and

- effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of product development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our product candidates. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our product candidates. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if the product candidates are sold commercially. An individual may bring a liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;

- damage to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize product candidates; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We have insurance coverage on our Phase II CIN and cervical cancer trials for each clinical trial site. We do not have product liability insurance because we do not have products on the market. We currently are in the process of obtaining insurance coverage and to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

We may incur significant costs complying with environmental laws and regulations.

We and our contracted third parties will use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we will store these materials and wastes resulting from their use at our or our outsourced laboratory facility pending their ultimate use or disposal. We will contract with a third party to properly dispose of these materials and wastes. We will be subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may also incur significant costs complying with environmental laws and regulations adopted in the future.

If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.

Our research and development and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials will comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies which include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.

As of October 31, 2009, we had eight employees. We do not intend to significantly expand our operations and staff unless we get adequate financing. If funded then our new employees may include key managerial, technical, financial, research and development and operations personnel who will not have been fully integrated into our

operations. We will be required to expand our operational and financial systems significantly and to expand, train and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate any new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations.

As of January 1, 2009, we operate under an agreement with AlphaStaff, a professional employment organization that provides us with payroll and human resources services. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and other products, and unable to adequately address our management needs. As of the pay period ending January 4, 2009 we reduced the salary of the highly compensated employees to meet our economic challenges and our cash flow needs. As of October 31, 2009 substantially all of the back pay and reduced pay was restored.

We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.

We depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants, including Yvonne Paterson, Ph.D. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance.

#### Risks Related to the Biotechnology / Biopharmaceutical Industry

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the U.S., Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain products under development or manufactured by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for product development. Various companies are developing biopharmaceutical products that potentially directly compete with our product candidates even though their approach to such treatment is different. Several companies, such as Anza Therapeutics, Inc in particular, as well as Biosante Pharmaceuticals Inc., Antigenics, Inc., Avi BioPharma, Inc., Biomira, Inc., Biovest International, Dendreon Corporation, Pharmexa-Epimmune, Inc., Genzyme Corp., Progenics Pharmaceuticals, Inc., Vical Incorporated, and other firms with more resources than we have are currently developing or testing immune therapeutic agents in the same indications we are targeting.

We expect that our products under development and in clinical trials will address major markets within the cancer sector with a superior technology that is both safer and more effective than our competitors. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop products, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

#### Risks Related to the Securities Markets and Investments in our Common Stock

The price of our common stock may be volatile.



The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market after the sale of the shares of common stock by the selling stockholders may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock pursuant to the Optimus purchase agreement;
  - general economic conditions and trends;

- major catastrophic events;
- sales of large blocks of our stock;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- changes in the regulatory status of our product candidates, including results of our clinical trials;
- events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the U.S. and other countries;
- failure of our common stock to be listed or quoted on the Nasdaq Stock Market, NYSE Amex Equities or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.
- Inability of the accounting professional to keep up with the complex rules resulting from numerous financial instruments.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

You may have difficulty selling our shares because they are deemed "penny stocks."

Our common stock is deemed to be "penny stock" as that term is defined in Rule 3a51-1, promulgated under the Exchange Act. Penny stocks are, generally, stocks:

- with a price of less than \$5.00 per share;
- that are neither traded on a "recognized" national exchange nor listed on an automated quotation system sponsored by a registered national securities association meeting certain minimum initial listing standards; and
- of issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation for less than three years), or with average revenue of less than \$6.0 million for the last three years.

Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a "penny stock" for the investor's account. We urge potential investors to obtain and read this disclosure carefully before purchasing any shares that are

deemed to be “penny stock.”

Rule 15g-9 promulgated under the Exchange Act requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any “penny stock” to that investor. This procedure requires the broker-dealer to:

- obtain from the investor information about his or her financial situation, investment experience and investment objectives;
- reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has enough knowledge and experience to be able to evaluate the risks of “penny stock” transactions;
- provide the investor with a written statement setting forth the basis on which the broker-dealer made his or her determination; and
- receive a signed and dated copy of the statement from the investor, confirming that it accurately reflects the investor’s financial situation, investment experience and investment objectives.

Compliance with these requirements may make it harder for investors in our common stock to resell their shares to third parties. Accordingly, our common stock should only be purchased by investors, who understand that such investment is a long-term and illiquid investment, and are capable of and prepared to bear the risk of holding our common stock for an indefinite period of time.

A limited public trading market may cause volatility in the price of our common stock.

Our common stock began trading on the OTC Bulletin Board on July 28, 2005 and is quoted under the symbol ADXS.OB. The quotation of our common stock on the OTC Bulletin Board does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings. Also there are large blocks of restricted stock that have met the holding requirements under Rule 144 that can be unrestricted and sold. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price.

There is no assurance of an established public trading market.

A regular trading market for our common stock may not be sustained in the future. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time. The OTC Bulletin Board is an inter-dealer, over-the-counter market that provides significantly less liquidity than the Nasdaq Stock Market. Quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers. As such, investors and potential investors may find it difficult to obtain accurate stock price quotations, and holders of our common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock pursuant to the Optimus purchase agreement;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the technologies industries generally; and
- general economic and other national conditions.

We may not be able to achieve secondary trading of our stock in certain states because our common stock is not nationally traded.

Because our common stock is not listed for trading on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the U.S. in addition to federal securities law. This regulation covers any primary offering we might attempt and all secondary trading by our stockholders. If we fail to take appropriate steps to register our common stock or qualify for exemptions for our common stock in certain states or jurisdictions of the U.S., the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

If we fail to remain current on our reporting requirements, we could be removed from the OTC Bulletin Board, which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Companies trading on the OTC Bulletin Board, such as us, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTC Bulletin Board. For our third quarter 2009 we were unable to file our quarterly report on Form 10-Q in a timely manner, but we were able to make the filing and cure our compliance deficiency with the OTC Bulletin Board within the grace period allowed by the OTC Bulletin Board. If we fail to remain current on our reporting requirements, we could be removed from the OTC Bulletin Board. As a result, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective, and failure to improve them could lead to errors in our financial statements that could require a restatement or untimely filings, which could cause investors to lose confidence in our reported financial information, and a decline in our stock price.

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our “disclosure controls and procedures”, as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e), as of the end of the twelve month period ended October 31, 2009, concluded that as of October 31, 2009, our internal controls over financial reporting were not effective to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified by the SEC, and that material information relating to our company is made known to management, including chief executive officer and chief financial officer, particularly during the period when our periodic reports are being prepared, to allow timely decisions regarding required disclosure.

In addition, our management assessed the effectiveness of our internal control over financial reporting as of October 31, 2009 on criteria for effective internal control over financial reporting described in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management has determined that as of October 31, 2009, there were material weaknesses in our internal control over financial reporting. For example, during the review of the financial statements for the three month period ended July 31, 2009, it was determined that our initial presentation and accounting of certain of our convertible debt and warrants in our financial statements was not correct. In light of this material weakness, we concluded that we did not maintain effective internal control over financial reporting as of July 31, 2009. Our management is responsible for establishing and maintaining adequate internal control over financial reporting for us. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. We revised our financial statements for the three month period ended July 31, 2009, prior to filing our quarterly report on Form 10-Q for the period ended July 31, 2009, but cannot offer assurances that we will not have additional material weaknesses. While we have taken steps to improve our internal controls and procedures, there may continue to be material weaknesses or deficiencies in our internal controls or ineffectiveness of our disclosure controls and procedures. As a result of the material weakness in our internal controls and the ineffectiveness of our disclosure controls and procedures as of October 31, 2009, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

We may be exposed to potential risks resulting from new requirements under Section 404 of the Sarbanes-Oxley Act of 2002.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, beginning with our fiscal year ended October 31, 2008, we were required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. Furthermore, beginning with our fiscal year ending October 31, 2010, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we have maintained, in all material respects, effective internal control over financial reporting for our fiscal year then ending and for each fiscal year thereafter. Although we have completed our assessment of the effectiveness of our internal control over financial reporting, we expect to incur additional expenses and diversion of management’s time as a result of performing the system and process evaluation, testing and remediation required in order for us and our auditors to comply with the auditor attestation requirements.

Our executive officers and directors can exert significant influence over us and may make decisions that do not always coincide with the interests of other stockholders.

Our officers and directors, and their affiliates, in the aggregate, beneficially own, as of January 27, 2010, 17.2% of the outstanding shares of our common stock. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights in us may be reduced.

We expect to continue to incur product development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

Additional authorized shares of common stock available for issuance may adversely affect the market.

We are authorized to issue 500,000,000 shares of our common stock. As of January 27, 2010, we had 127,201,243 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants and options. As of October 31, 2009, we had outstanding options to purchase 18,331,591 shares of our common stock at a weighted average exercise price of \$0.16 per share and outstanding warrants to purchase 127,456,301 shares of our common stock, with exercise prices ranging from \$0.17 to \$0.29 per share. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Moreover, warrants to purchase up to approximately 73.0 million shares of our common stock are subject to “full ratchet” anti-dilution protection upon certain equity issuances below \$0.17 per share (as may be further adjusted).

We are able to issue shares of preferred stock with rights superior to those of holders of our common stock. Such issuances can dilute the tangible net book value of shares of our common stock.

Our Certification of Incorporation provides for the authorization of 5,000,000 shares of “blank check” preferred stock. Pursuant to our Certificate of Incorporation, our board of directors is authorized to issue such “blank check” preferred stock with rights that are superior to the rights of stockholders of our common stock, at a purchase price then approved by our board of directors, which purchase price may be substantially lower than the market price of shares of our common stock, without stockholder approval. Such issuances can dilute the tangible net book value of shares of our common stock. Pursuant to the Optimus purchase agreement, Optimus has agreed to purchase up to 500 shares of our Series A preferred stock at a purchase price of \$10,000 per share from time to time until September 24, 2012 (\$5.0 million in the aggregate), subject to certain conditions. As of January 20, 2010, Optimus has purchased 145 shares.

We do not intend to pay dividends other than to holders of our Series A preferred stock.

We do not intend to pay dividends other than to holders of our Series A preferred stock. Holders of Series A preferred stock will be entitled to receive dividends, which will accrue in shares of Series A preferred stock on an annual basis at a rate equal to 10% per annum from the issuance date. Accrued dividends will be payable upon redemption of the Series A preferred stock.

## Item 2. Properties.

Our corporate offices are currently located at a biotech industrial park located at 675 U.S. Highway 1, North Brunswick, NJ 08902. Our current Lease Amendment Agreement dated as of March 1, 2008 with the NJEDA has expired, but they have agreed to extend our lease on a monthly basis until December 31, 2010, for two research and development laboratory units (total of 1,600 s.f.) and one office (total of 655 s.f.). We believe our facility will be sufficient for our near term purposes and the facility offers additional space for the foreseeable future. Our monthly payment on this facility is approximately \$6,286 per month. In the event that our facility should, for any reason, become unavailable, we believe that alternative facilities are available at competitive rates.

## Item 3. Legal Proceedings.

As of the date hereof, there are no material pending legal proceedings to which we are a party or of which any of our property is the subject. In the ordinary course of our business we may become subject to litigation regarding our products or our compliance with applicable laws, rules, and regulations.

## Item 4. Submission of Matters to a Vote of Security Holders.



None.

PART II

Item 5. Market For Our Common Stock and Related Stockholder Matters.

Since July 28, 2005, our common stock has been quoted on the OTC Bulletin Board under the symbol ADXS.OB. The following table shows, for the periods indicated, the high and low bid prices per share of our common stock as reported by the OTC Bulletin Board. These bid prices represent prices quoted by broker-dealers on the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

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	Fiscal 2009		Fiscal 2008	
	High	Low	High	Low
First Quarter (November 1-January 31)	\$ 0.06	\$ 0.01	\$ 0.20	\$ 0.13
Second Quarter (February 1-April 30)	\$ 0.05	\$ 0.02	\$ 0.15	\$ 0.09
Third Quarter (May 1 - July 31)	\$ 0.21	\$ 0.04	\$ 0.135	\$ 0.058
Fourth Quarter (August 1 - October 31)	\$ 0.19	\$ 0.06	\$ 0.07	\$ 0.03

As of January 27, 2010, there were approximately 100 stockholders of record. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of stockholders of record. Based on information available to us, we believe there are approximately 1,700 non-objecting beneficial owners of our shares of our common stock in addition to the stockholders of record.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

Holders of Series A preferred stock will be entitled to receive dividends, which will accrue in shares of Series A preferred stock on an annual basis at a rate equal to 10% per annum from the issuance date. Accrued dividends will be payable upon redemption of the Series A preferred stock. The Series A preferred stock ranks, with respect to dividend rights and rights upon liquidation:

- senior to our common stock; and
- junior to all of our existing and future indebtedness

Equity Compensation Plan Information

The following table provides information regarding the status of our existing equity compensation plans at October 31, 2009:

Plan category	Number of shares of common stock to be issued on exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the previous columns)
Equity compensation plans approved by security holders	7,680,192	\$ 0.22	301,333

Equity compensation plans not approved by security holders	10,651,399	\$	0.10	3,350,000
Total	18,331,591	\$	0.16	3,651,333

## ITEM 6. Selected Financial Data.

Not required.

## ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, product demand, market acceptance and other factors discussed in this report under the heading "Risk Factors". This Management's Discussion and Analysis of Financial Conditions and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this report.

## Overview

Advaxis is 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 Penn which can be engineered to secrete a variety of different protein sequences containing tumor-specific antigens leading to the development of a variety of different products. We believe this vaccine technology is capable of stimulating the body's immune system to process and recognize the antigen that has a therapeutic effect upon cancer. We believe that 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 no customers. Since our inception in 2002, we have focused our development efforts upon understanding our technology and establishing a product development pipeline that incorporates this technology in the therapeutic cancer vaccines area targeting cervical, head and neck, prostate, breast, and a pre cancerous indication of CIN. Although no products have been commercialized to date, research and development and investment continues to be placed behind the pipeline and the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entail risk and expense. We anticipate that our ongoing operational costs will increase significantly when we begin several of our clinical trials.

The following factors, among others, could cause actual results to differ from those indicated in the above forward-looking statements: increased length and scope of our clinical trials, failure to recruit patients, increased costs related to intellectual property related expenses, increased cost of manufacturing and higher consulting costs. These factors or additional risks and uncertainties not known to us or that we currently deem immaterial may impair business operations and may cause our actual results to differ materially from any forward-looking statement.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

We expect our future sources of liquidity to be primarily debt and equity capital raised from investors, as well as licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties. Of the \$5,809,571 worth of grants applied for, we were awarded one grant from the NIH in August 2009 for \$210,739.

On January 15, 2010 we 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 from the sale of our State Net Operating Losses through December 31, 2008 and our research tax credit for fiscal years 2007 and 2008.

If additional capital were raised through the sale of equity or convertible debt securities, the issuance of such securities would result in additional dilution to our existing stockholders. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. Any sale of our common stock below \$0.17 per share (as may be further adjusted) will trigger a significant dilution due to the anti-dilution protection provisions in certain of our outstanding warrants and debt instruments.

## Plan of Operations

If we are successful in our financing plans we intend to use a significant portion of the proceeds currently under way to conduct our two Phase II trials using ADXS11-001, our lead product candidate in development using our Listeria System. One will be a U.S. study in CIN, the other, the other, an Indian study in cervical cancer. We also anticipate using the funds to further our pre-clinical and clinical, research and development efforts in developing product candidates and to maintain our preclinical capabilities and strategic activities. Our corporate staff will be responsible for the general and administrative activities.

During the next 24 months, our strategic focus will be to achieve the following goals and objectives:

- Continue to raise funding to recruit patients in our U.S. based Phase II clinical study of ADXS11-001 in the therapeutic treatment of CIN and our Indian based Phase II study in late stage cervical cancer;
- Continue to execute our two Phase II clinical studies of ADXS11-001 in the therapeutic treatment of CIN and late-stage cervical cancer managed by our clinical partner Numoda;

- Continue to work on our grant from the NIH awarded in August 2009 for \$210,000 to develop a single bioengineered *Listeria monocytogenes* (Lm) vaccine to deliver two different antigen-adjuvant proteins.
- Continue to focus on our collaboration with the GOG to carry out our Phase II clinical trial of our ADXS11-001 candidate in the treatment of cervical cancer largely underwritten by the NCI;
- Continue to focus on our collaboration with the CRUK to carry out our Phase II clinical trial of our ADXS11-001 candidate in the treatment of head and neck cancer largely underwritten by the CRUK;
  - Continue to work with our strategic and development collaborations with academic laboratories;
- Continue the development work necessary to bring ADXS31-142 in the therapeutic treatment of prostate cancer into clinical trials, and initiate that trial provided that funding is available;
- Continue the development work necessary to bring ADXS31-164 in the therapeutic treatment of breast cancer into clinical trials, and initiate that trial when and if funding is available; and
- Continue the pre-clinical development of other product candidates, as well as continue research to expand our technology platform.

Our projected annual staff, overhead and preclinical expenses are estimated to be approximately \$4.1 million starting in fiscal year beginning November 1, 2009. The cost of our Phase II clinical studies in therapeutic treatment of CIN and late stage cancer of the cervix is estimated to be approximately \$8.0 million over the estimated 30 month period of the trial. Therefore we must raise additional funds in order to fund the entire Phase II trials. Our Phase II ADXS11-001 clinical studies are anticipated to commence in February 2010. If we can raise additional funds we intend to commence the clinical work in prostate cancer by late 2010 or beyond and breast cancer by 2011 or beyond. The timing and estimated costs of these projects are difficult to predict and depends on factors such as our ability to raise funds and enter into a corporate partnership.

Overall, given the development stage of our business, our financial needs are driven, in large part, by the progress of our clinical trials and those of the GOG and CRUK as well as preclinical programs. The cost of these clinical trial projects is significant. As a result, we will be currently attempting to raise additional debt or equity now and in the future. If the clinical progress continues to be successful and the value of our company increases, we may attempt to accelerate the timing of the required financing and, conversely if the trial or trials are not successful we may slow our spending and the timing of additional financing will be deferred. While we will attempt to attract a corporate partnership and grants, we have not assumed the receipt of any additional financial resources in our cash planning.

We anticipate that our research and development expenses will increase significantly as a result of our expanded development and commercialization efforts related to clinical trials, product development, and development of strategic and other relationships required ultimately for the licensing, manufacture and distribution of our product candidates. We regard three of our product candidates as major research and development projects. The timing, costs and uncertainties of those projects are as follows:

ADXS11-001 - Phase II CIN Trial Summary Information (U.S. 80 Patients)

- Cost incurred to date: approximately \$1.1 million
- Estimated future clinical costs: \$5.7 million to \$6.0 million

- Anticipated Timing: start February 2010; completion August 2012 or beyond

Uncertainties:

- The FDA (or relevant foreign regulatory authority) may place the project on clinical hold or stop the project;
  - One or more serious adverse events in otherwise healthy patients enrolled in the trial;
    - Difficulty in recruiting patients;
    - Delays in the program;
    - Material cash flows; and

- Anticipated Timing: Unknown at this stage and dependent upon successful trials, adequate fund raising, entering a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

ADX11-001 - Phase II Cancer of the Cervix Trial Summary Information (India: 110 Patients)

- Cost incurred to date: approximately \$101,650
- Estimated future clinical costs: \$2.1 million to \$2.3 million
- Anticipated Timing: start February 2010; completion August 2012 or beyond

Additional Uncertainties:

- One or more serious adverse events in these late stage cancer patients enrolled in the trial; and
- Difficulty in recruiting patients especially in a new country.

ADX11-001 - Phase II Cancer of the Cervix Trial Summary Information (U.S. GOG/NCI: 63 Patients)

- Cost incurred to date: less than \$10,000
- Estimated future clinical costs: \$500,000 (Government absorbed cost \$2.5 million to \$3.0 million)
- Anticipated Timing: to be determined

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on GOG/NCI controlled study;
- Delays in the program; and
- Given the economic environment the trial may not get funded.

ADX11-001 - Phase II Cancer of the Head and Neck Trial Summary Information (U.K. CRUK: approximately 45 Patients)

- Cost incurred to date: less than \$25,000
- Estimated future clinical costs: \$500,000 (CRUK to absorb cost \$2.5 million to \$3.0 million)
- Anticipated Timing: to be determined

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on CRUK controlled study;
- Delays in the program; and
- Given the economic environment the trial may not get funded.



ADXS31-142 - Pre Clinical and Phase I Trial Summary Information (TBD Prostate Cancer 30 Patients)

- Cost incurred to date: approximately \$200,000
- Estimated future costs: \$3.0 million to \$3.5 million
- Anticipated Timing: to be determined

Additional Uncertainties:

- New agent; and

- FDA (or foreign regulatory authority) may not approve the study.

ADXS31-164 - Phase I trial Summary Information (TBD Breast Cancer 24 Patients)

- Cost incurred to date: \$450,000
- Estimated future costs: \$3.0 million to \$3.5 million
- Anticipated Timing: to be determined

Results of Operations

Fiscal Year 2009 Compared to Fiscal Year 2008

Revenue. Our revenue decreased by \$36,046, or 55%, to \$29,690 for the year ended October 31, 2009 (“Fiscal 2009 Period”) as compared with \$65,736 for the year ended October 31, 2008 (“Fiscal 2008 Period”) due to a grant from the State of New Jersey received in the Fiscal 2008 Period not being repeated in Fiscal 2009 Period in addition to the State’s request to refund \$5,769 in Fiscal 2009 Period in residual grant money received in the prior fiscal year. These decreases were partially offset in the Fiscal 2009 Period by \$35,059 revenue received for a NIH grant.

Research and Development Expenses. Research and development expenses decreased by \$166,283 or 7%, to \$2,315,557 for the Fiscal 2009 Period as compared with \$2,481,840 for the Fiscal 2008 Period, principally attributable to the following:

- Clinical trial expenses increased by \$866,111, or 304%, to \$1,150,880 from \$284,769 primarily due to the close out of our Phase I trial in the Fiscal 2008 Period which was offset by the start-up costs of our phase II cervical cancer study in India and CIN study in the US both in the Fiscal 2009 Period.
- Wages, options and lab costs decreased by \$215,180 or 18% to \$969,639 from \$1,184,819 principally due to the recording of the full year’s bonus accrual in Fiscal 2008 Period that was reversed in Fiscal 2009 Period or \$279,558. No bonus accrual was recorded nor paid in Fiscal 2009 Period. Overall the lab costs were lower by \$80,387 due to the priority given to the lower cost of grant and publication writing. These lower costs were partially offset by \$120,182 in higher option expense relating to new grants in Fiscal 2009 Period and \$24,583 in wages primarily due to the new hire of the Executive Director, Product Development in March 2008.
- Consulting expenses decreased by \$25,195, or 18%, to \$114,970 from \$140,165, principally due to higher option expense of \$54,903 recorded in Fiscal 2009 Period relating to the true-up of unvested options at higher stock prices compared to a credit to option expense of \$42,307 due to the true up of unvested option expense recorded in prior fiscal periods at lower stock prices. This increase of option expense which was offset in part by the lower effort required to prepare the Investigational New Drug filing for the FDA or \$80,098 in the Fiscal 2009 Period compared to the same period last year.
- Subcontracted research expenses decreased by \$172,473, or 100%, to \$0 from \$172,473 reflecting the completion of the project prior to Fiscal 2009 Period performed by Dr. Paterson at Penn, pursuant to a sponsored research agreement ongoing in the Fiscal 2008 Period.
- Manufacturing expenses decreased by \$592,907, to \$80,067 from \$672,974, or 88% resulting from the completion of our clinical supply program for the upcoming phase II trials prior to Fiscal 2009 Period compared to the manufacturing program in the Fiscal 2008 Period.

- Toxicology study expenses decreased by \$26,640, to \$0 or 100% due the completion in Fiscal 2008 Period of our toxicology study by Pharm Olam in connection with our ADXS111-001 product candidates in anticipation of clinical studies in 2008.

General and Administrative Expenses. General and administrative expenses decreased by \$334,547, or 11%, to \$2,701,133 for the Fiscal 2009 Period as compared with \$3,035,680 for the Fiscal 2008 Period primarily attributable to the following:

- Wages, Options and benefit expenses decreased by \$40,953, or 3% to \$1,169,227 from \$1,210,180 principally due to the reversal of a twelve month bonus accrual in Fiscal 2009 Period or \$89,877 that was recorded as expense in Fiscal 2008 Period (no bonus accrual was recorded nor paid in Fiscal 2009 Period) and less stock was issued in Fiscal 2009 Period compared to \$43,030 worth of stock was issued primarily to the CEO per his employment agreement in Fiscal 2008 Period. These lower expenses were partially offset by higher option expense of \$77,949 primarily due to new stock options granted in Fiscal 2009 Period and \$14,005 in overall higher wages and related fees in the Fiscal 2009 Period than Fiscal 2008 Period.

- Consulting fees decreased by \$350,136, or 82%, to \$77,783 from \$427,919. This decrease was primarily attributed to a one-time payment in settlement of Mr. Appel's (our previous President & CEO) employment agreement of \$144,615 recorded in the Fiscal 2008 Period. In addition, consulting expenses were sharply down by \$255,521 due to no financial advisor fees in Fiscal 2009 Period compared to \$256,571 recorded in the Fiscal 2008 Period attributed to the close of the October 17, 2007 offering. These lower fees were partially offset by \$50,000 fees recorded for the Sage Group (Business Development Consultants) in Fiscal 2009 Period for seeking corporate partnerships that didn't occur in Fiscal 2008 Period.
- Offering expenses increased by \$396,128 to \$449,646 from \$53,518. The \$396,128 increase in offering expenses recorded in Fiscal 2009 Period consists of legal costs in preparation for financial raises and SEC filings that didn't occur in Fiscal 2008 Period, partially offset by non-cash warrants expense.
- Increases in legal, accounting, professional and public relations expenses of \$77,389, or 14%, to \$643,032 from \$565,643, primarily as a result of a higher overall legal, patent expenses and filing fees of \$107,870 partially offset by lower public relations and tax preparation fees in Fiscal 2009 Period than in the Fiscal 2008 Period.
- Amortization of intangibles and depreciation of fixed assets decreased by \$86,189, or 44%, to \$111,156 from \$197,345 primarily due to a \$91,453 write-off of our trademarks in the Fiscal 2008 Period partially offset by an increase in fixed assets and intangibles in the Fiscal 2009 Period compared to the Fiscal 2008 Period.
- Analysis Research cost decreased by \$101,949 or 100%, to \$0 from \$101,949 due to a one time report and business analysis report in the Fiscal 2008 Period not repeated in Fiscal 2009 Period.
- Recruiting fees for the Executive Director of Product Development in Fiscal 2008 Period was \$63,395 and there was no such expense in Fiscal 2009 Period.
- Overall occupancy and conference related expenses decreased by \$165,442 or 40% to \$250,290 from \$415,732. Conference and dues and subscription expenses have decreased by \$145,396 in the Fiscal 2009 Period due to lower participation in cancer conferences. In addition lower travel related to the reduced conferences attendance, taxes and other miscellaneous expenses amounted to a decrease of \$20,046 in the Fiscal 2009 Period than incurred in Fiscal 2008 Period.

Other Income (expense). The change in the fair value of common stock warrant liability and embedded derivative liability was \$5,845,229 compared to zero in the prior year resulting from improvements in the share price, the anticipated pay down of our June 2009 bridge notes, and the sale of preferred stock authorized during September 2009 would lead to a qualified equity financing thereby reducing risk associated with the establishment of these liability accounts during June 2009. Interest expense increased to \$851,008 compared to \$11,263 in the prior year resulting from interest accrued on our outstanding notes including accreted interest on the value of the warrant and embedded derivative liabilities. Interest earned on investments for the Fiscal 2009 and Fiscal 2008 Periods amounted to \$0 and \$46,629, respectively. See also Fair Value of Warrants , Warrant Liability and Embedded Conversion Feature below.

Income Tax. In the Fiscal 2009 Period there was a net change of \$922,020 recorded due to a gain recorded from the receipt of a NOL tax sale received from the State of New Jersey tax program. There was no comparable gain in Fiscal 2008 Period as this was the first year we were awarded this NOL credit.

We anticipate an increase in Research and Development expenses as a result of expanded development and commercialization efforts related to clinical trials, and product development, and expenses to be incurred in the development of strategic and other relationships required ultimately if the licensing, manufacture and distribution of

our product candidates are undertaken.

#### Liquidity and Capital Resources

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL tax sale and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2009 and 2008, we had an accumulated deficit of \$16,603,800 and \$17,533,044, respectively, and shareholders' deficiency of \$15,733,328 and \$839,311, respectively. Based on our available cash of approximately \$660,000 on October 31, 2009, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail or cease operations in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2009 included a going concern explanatory paragraph.

Our business will require substantial additional investment that we have not yet secured, and our failure to raise capital and/or pursue partnering opportunities will materially adversely affect our business, financial condition and results of operations. 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. Further, we will not have sufficient resources to develop fully any new products or technologies unless we are able to raise substantial additional financing on acceptable terms or secure funds from new partners. We cannot be assured that financing will be available at all. Any additional investments or resources required would be approached, to the extent appropriate in the circumstances, in an incremental fashion to attempt to cause minimal disruption or dilution. Any additional capital raised through the sale of equity or convertible debt securities will result in dilution to our existing stockholders. No assurances can be given, however, that we will be able to achieve these goals or that we will be able to continue as a going concern.

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 purchase 1,431,250 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 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 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.

Pursuant to the Optimus purchase agreement, Optimus has agreed to purchase, upon the terms and subject to the conditions set forth therein and described below, up to \$5.0 million of non-convertible, redeemable Series A preferred stock at a price of \$10,000 per share. Under the terms of the purchase agreement, from time to time until September 24, 2012, in our sole discretion, we may present Optimus with a notice to purchase a specified amount of Series A preferred stock, which Optimus is obligated to purchase on the 10th trading day after the date of the notice, subject to satisfaction of certain closing conditions (including our ability to effect and maintain an effective registration statement for the shares underlying the warrant, issued to an affiliate of Optimus in connection with the transaction). We will determine, in our sole discretion, the timing and amount of Series A preferred stock to be purchased by Optimus, and may sell such shares in multiple tranches. Optimus will not be obligated to purchase the Series A preferred stock upon our notice (i) in the event the closing price of our common stock during the nine trading days following delivery of our notice falls below 75% of the closing price on the trading day prior to the date such notice is delivered to Optimus or (ii) to the extent such purchase would result in Optimus and its affiliates beneficially owning more than 9.99% of our outstanding common stock. During January 2010, (i) Optimus purchased 145 shares and remains obligated to purchase up to an additional 355 shares (subject to the foregoing conditions) and (ii) the affiliate of Optimus has exercised warrants to purchase 11,563,000 shares of common stock at an adjusted exercise price of \$0.17 per share.

On June 18, 2009, we completed the June 2009 bridge financing. The June 2009 bridge financing was a private placement with certain accredited investors pursuant to which we issued (i) senior convertible promissory notes in the aggregate principal face amount of \$1,131,353, for an aggregate net purchase price of \$961,650 and (ii) warrants to

purchase 2,404,125 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.

During October, 2009, we completed the sale of additional bridge notes. This bridge financing was a private placement with certain accredited investors pursuant to which we issued (i) junior convertible promissory notes in the aggregate principal face amount of \$2,147,059 for an aggregate net purchase price of \$1,825,000 and (ii) warrants to purchase 4,562,500 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 the bridge notes were issued with an original issue discount of 15% and are convertible into shares of our common stock as described below.

In the event we consummate an equity financing with aggregate gross proceeds of not less than \$2.0 million, which we refer to as a qualified equity financing, prior to the second business day immediately preceding the maturity date of our bridge notes, as the case may be, then prior to the respective maturity date, the holders will have the option to convert all or a portion of the respective notes into the same securities sold in such qualified equity financing at an effective per share conversion price equal to 90% of the per share purchase price of the securities issued in the qualified equity financing. In the event we do not consummate a qualified equity financing prior to the second business day immediately preceding the respective maturity date, then the holders shall have the option to convert all or a portion of the June 2009 bridge notes or October 2009 bridge notes, as the case may be, into shares of common stock, at an effective per share conversion price equal to 50% of the volume-weighted average price per share of our common stock over the five consecutive trading days immediately preceding the third business day prior to the maturity date. To the extent a holder does not elect to convert its bridge notes as described above, the principal amount of the bridge notes not so converted shall be payable in cash on the respective maturity date.

In connection with the June 2009 bridge financing, we entered into a Security Agreement, dated as of June 18, 2009 with the investors in the June 2009 bridge financing. The Security Agreement grants the investors a security interest in all of our tangible and intangible assets, as further described on Exhibit A to the Security Agreement. We also entered into a Subordination Agreement, dated as of June 18, 2009 with the investors in the June 2009 bridge financing and Mr. Moore. Pursuant to the Subordination Agreement, Mr. Moore subordinated certain rights to payments under the Moore Note to the right of payment in full in and in cash of all amounts owed to the investors pursuant to the June 2009 bridge notes; provided, however, that principal and interest of the Moore Note may be repaid prior to the full payment of the investors in certain circumstances.

On September 22, 2008, we entered into a note purchase agreement with our Chief Executive Officer, Thomas A. Moore, pursuant to which we agreed to sell to Mr. Moore, from time to time, Moore Notes. On June 15, 2009, we amended the terms of the Moore Notes to increase the amounts available from \$800,000 to \$950,000 and to change the maturity date of the Moore Notes from June 15, 2009 to the earlier of January 1, 2010 or our next equity financing resulting in gross proceeds to us of at least \$6.0 million. 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 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.

The Moore Notes bear interest at a rate of 12% per annum, compounded quarterly, and may be prepaid in whole or in part at our option without penalty at any time prior to maturity. In consideration of Mr. Moore's agreement to purchase the Moore Notes, we agreed that concurrently with an equity financing resulting in gross proceeds to us of at least \$6.0 million, we will issue to Mr. Moore a warrant to purchase our common stock, which will entitle Mr. Moore to purchase a number of shares of our common stock equal to one share per \$1.00 invested by Mr. Moore in the purchase of the Moore Notes. The terms of these warrants were subsequently modified by our board of directors based on the terms of the June 2009 bridge financing increasing the number of shares underlying the warrant from one share per \$1.00 invested to two and one-half shares. The terms of these warrants were further modified by our board of directors in connection with the February 2010 amendment based on the terms of certain amendments to the June 2009 bridge notes increasing the number of warrants from two and one-half warrants per \$1.00 invested to three warrants. The final terms are anticipated to contain the same terms and conditions as warrants issued to investors in the subsequent financing (which are currently exercisable at \$0.17 per share). As of October 31, 2009, \$947,985 in notes were outstanding and payable to Mr. Moore.

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.

#### Off-Balance Sheet Arrangements

As of October 31, 2009, we had no off-balance sheet arrangements, other than our lease for space. There were no changes in significant contractual obligations during the year ended October 31, 2009.

#### Critical Accounting Estimates

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:



- It requires assumption to be made that were uncertain at the time the estimate was made, and
- Changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

Actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, warrant valuation, impairment of intangibles, dilution caused by ratchets in the warrants and other agreements.

**Share-Based Payment.** We record compensation expense associated with stock options in accordance with SFAS No. 123R, "Share Based Payment," which is a revision of SFAS No. 123. We adopted the modified prospective transition method provided under SFAS No. 123R. Under this transition method, compensation expense associated with stock options recognized in the first quarter of fiscal year 2007, and in subsequent quarters, includes expense related to the remaining unvested portion of all stock option awards granted prior to April 1, 2006, the estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123.

We estimate the value of stock options awards on the date of grant using the Black-Scholes-Merton option-pricing model. The determination of the fair value of the share-based payment awards on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, expected term, risk-free interest rate, expected dividends and expected forfeiture rates. The forfeiture rate is estimated using historical option cancellation information, adjusted for anticipated changes in expected exercise and employment termination behavior. Our outstanding awards do not contain market or performance conditions; therefore we have elected to recognize share based employee compensation expense on a straight-line basis over the requisite service period.

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) relative to new grants may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option-pricing models to estimate share-based compensation under SFAS 123(R). Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Employee stock options may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements.

#### Fair Value of Warrants , Warrant Liability and Embedded Conversion Feature

Warrants were issued in connection with various financings throughout our history. We estimate the fair value of these instruments using the Black-Scholes model, which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term and the closing price of our common stock. Changes in assumptions used to estimate the fair value of these derivative instruments could result in a material change in the fair value of the instruments. We believe the assumptions outlined below used to estimate the fair values of the warrants are reasonable. Accounting for all outstanding warrants related to our determination that all of the outstanding warrants were reclassified as liabilities due to the fact that the conversion feature on the June 2009 bridge notes could require us to issue shares in excess of its authorized amount. All outstanding warrants have been recorded as a liability effective June 18, 2009, based on their fair value calculated using the Black-Scholes valuation model and the following assumptions: First we estimated the probability of three different outcomes (i) that we would be able to meet the QEF at the current warrant price of \$0.20 (prior to anti-dilution adjustments) per share, (ii) the QEF price would be \$0.15 per share and trigger a 10% discount and (iii) not meet the QEF (“Non-QEF Pricing”) and trigger an effective per share conversion price equal to 50% of the VWAP per share of the Common Stock over the five (5) consecutive trading days immediately preceding the third business day prior to the Maturity Date. We estimated that there was an equal probability for each scenario. The fair value of the warrant liability under each outcome was determined and then averaged the outcomes to estimate the warrant value of \$12,785,695 at June 18, 2009.

In accounting for the 2009 bridge notes’ embedded conversion feature and warrants described above, we considered the guidance contained in EITF 00-19, “ Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In, a Company’s Own Common Stock ,” and SFAS 133 “ Accounting for Derivative Instruments and Hedging Activities .” We determined that the conversion feature in the June 2009 bridge notes represented an embedded derivative since the debenture is convertible into a variable number of shares based upon a conversion formula which could require us to issue shares in excess of its authorized amount. The convertible debentures are not considered “conventional” convertible debt under EITF 00-19 and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability.

As of October 31, 2009, we had outstanding warrants to purchase 127,456,301 shares of our common stock (adjusted for anti-dilution provision to-date) with exercise prices ranges from \$0.187 to \$0.287 per share. These warrants include 2,404,125 warrants issued to holders of 2009 bridge notes at an exercise price of \$0.20 per warrant (prior to anti-dilution adjustments).

#### New Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board, or FASB, ratified Emerging Issues Task Force (EITF) Issue No 07-5, “ Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock ” (EITF 07-5). EITF 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature indexed to the entities own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which is our first quarter of fiscal 2010. Many of the warrants issued by us contain a strike price adjustment feature, which upon adoption of EITF 07-5, may result in the instruments no longer being considered indexed to our own stock. Accordingly, adoption of EITF 07-5 may change the current classification (from equity to liability) and the related accounting for many warrants outstanding at that date, even though we now record warrants and the embedded derivative as a liability under the guidance contained in EITF 00-19, “Accounting for Derivative Financial Instrument Indexed to and Potentially Settled In a Company’s Own Common Stock,” and SFAS 133 “Accounting for Derivative Instruments and Hedging Activities.” We determined that the conversion feature in the June 2009 bridge notes represented an embedded derivative since the debenture is convertible into a variable number of shares based upon a conversion formula. The convertible debentures are not considered “conventional” convertible debt under EITF 00-19 and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability. We are currently evaluating the impact the adoption of EITF 07-5 may have on our financial position, results of operation, or cash flows.

In May 2009, FASB issued Statement of Financial Accounting Standards No. 165, Subsequent Events (“SFAS 165”), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale as to why the date was selected. SFAS 165 is effective for interim and annual periods ended after June 15, 2009. We have adopted the provisions of SFAS 165.

Management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the accompanying financial statements.

Item 7A. Quantitative Qualitative Disclosures About Market Risk.

Not Required

Item 8: Financial Statements and Supplementary Data.

The index to Financial Statements appears on page F-1, the Report of the Independent Registered Public Accounting Firm appears on page F-2, and the Financial Statements and Notes to Financial Statements appear on pages F-3 to F-22.

Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

None

Item 9A(T): Controls and Procedures.

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is: (1) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure; and (2) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

Changes in Internal Control Over Financial Reporting

During the year ended October 31, 2009, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Assessment of the Effectiveness of Internal Controls over Financial Reporting

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our “disclosure controls and procedures”, as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e), as of the end of the twelve month period ended October 31, 2009, concluded that as of October 31, 2009, our internal controls over financial reporting were not effective to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified by the SEC, and that material information relating to our company is made known to management, including chief executive officer and chief financial officer, particularly during the period when our

periodic reports are being prepared, to allow timely decisions regarding required disclosure.

In addition, our management assessed the effectiveness of our internal control over financial reporting as of October 31, 2009 on criteria for effective internal control over financial reporting described in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management has determined that as of October 31, 2009, there were material weaknesses in our internal control over financial reporting. For example, during the review of the financial statements for the three month period ended July 31, 2009, it was determined that our initial presentation and accounting of certain of our convertible debt and warrants in our financial statements was not correct. In light of this material weakness, we concluded that we did not maintain effective internal control over financial reporting as of July 31, 2009. Our management is responsible for establishing and maintaining adequate internal control over financial reporting for us. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. We revised our financial statements for the three month period ended July 31, 2009, prior to filing our quarterly report on Form 10-Q for the period ended July 31, 2009, but cannot offer assurances that we will not have additional material weaknesses. While we have taken steps to improve our internal controls and procedures, there may continue to be material weaknesses or deficiencies in our internal controls or ineffectiveness of our disclosure controls and procedures.

We are a non-accelerated filer and are required to comply with the internal control reporting and disclosure requirements of Section 404 of the Sarbanes-Oxley Act for fiscal years ending October 31, 2010. Although we are working to comply with these requirements, we have limited financial personnel, making compliance with Section 404 very difficult and cost ineffective, if not impossible.

Attestation Report of our Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this annual report.

Item 9B: Other Information.

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 installments 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.

In consideration of Mr. Moore's initial agreement to purchase the Moore Notes, we agreed that concurrently with an equity financing resulting in gross proceeds to us of at least \$6.0 million, we will issue to Mr. Moore a warrant to purchase our common stock, which will entitle Mr. Moore to purchase a number of shares of our common stock equal to one share per \$1.00 invested by Mr. Moore in the purchase of the Moore Notes. The terms of these warrants were subsequently modified by our board of directors based on the terms of the June 2009 bridge financing increasing the number of shares underlying the warrant from one share per \$1.00 invested to two and one-half shares. The terms of these warrants were further modified by our board of directors to increase the number of warrants from two and one-half warrants per \$1.00 invested to three warrants. The final terms are anticipated to contain the same terms and conditions as warrants issued to investors in the subsequent financing (which are currently exercisable at \$0.17 per share).

PART III

Item 10: Directors, Executive Officers, Corporate Governance.

Executive Officers, Directors and Key Employees

The following are our executive officers and directors and their respective ages and positions as of January 20, 2010:

Name	Age	Position
Thomas A. Moore	59	Chief Executive Officer and Chairman of our Board of Directors
James Patton, MD	51	Director
Roni A. Appel	42	Director
Thomas McKearn, MD, Ph.D.	60	Director
Richard Berman	67	Director
John Rothman, Ph.D.	61	Executive Vice President of Clinical and Scientific Operations
Mark J. Rosenblum	56	Chief Financial Officer, Senior Vice President and Secretary

Thomas A. Moore. Effective December 15, 2006, Mr. Moore was appointed our Chairman and Chief Executive Officer. He is currently also a director of MD Offices, an electronic medical records provider, and Opt-e-scrip, Inc., which markets a clinical system to compare multiple drugs in the same patient. He also serves as Chairman of the board of directors of Mayan Pigments, Inc., which has developed and patented Mayan pigment technology. Previously, from June 2002 to June 2004 Mr. Moore was President and Chief Executive Officer of Biopure Corporation, a developer of oxygen therapeutics that are intravenously administered to deliver oxygen to the body's tissues. From 1996 to November 2000 he was President and Chief Executive Officer of Nelson Communications. Prior to 1996, Mr. Moore had a 23-year career with the Procter & Gamble Company in multiple managerial positions, including President of Health Care Products where he was responsible for prescription and over-the-counter medications worldwide, and Group Vice President of the Procter & Gamble Company.

Mr. Moore is subject to a five year injunction, which came about because of a civil action captioned Securities & Exchange Commission v. Biopure Corp. et al., No. 05-11853-PBS (D. Mass.), filed on September 14, 2005, which alleged that Mr. Moore made and approved misleading public statements about the status of FDA regulatory proceedings concerning a product manufactured by his former employer, Biopure Corp. Mr. Moore vigorously defended the action. On December 11, 2006, the SEC and Mr. Moore jointly sought a continuance of all proceedings based upon a tentative agreement in principle to settle the SEC action. The SEC's Commissioners approved the terms of the settlement, and the court formally adopted the settlement.

Dr. James Patton. Dr. Patton has served as a member of our board of directors since February 2002, as Chairman of our board of directors from November 2004 until December 31, 2005 and as Advaxis' Chief Executive Officer from February 2002 to November 2002. Since February 1999, Dr. Patton has been the Vice President of Millennium Oncology Management, Inc., which provides management services for radiation oncology care to four sites. Dr. Patton has been a trustee of Dundee Wealth US, a mutual fund family since October 2006. In addition, was the President of Comprehensive Oncology Care, LLC since 1999, a company which owned and operated a cancer treatment facility in Exton, Pennsylvania until its sale in 2008. From February 1999 to September 2003, Dr. Patton also served as a consultant to LibertyView Equity Partners SBIC, LP, a venture capital fund based in Jersey City, New Jersey. Dr. Patton served as a director of Pinpoint Data Corp. From February 2000 to November 2000, Dr. Patton served as a director of Healthware Solutions. From June 2000 to June 2003, Dr. Patton served as a director of LifeStar Response. He earned his B.S. from the University of Michigan, his Medical Doctorate from Medical College of Pennsylvania, and his M.B.A. from Penn's Wharton School. Dr. Patton was also a Robert Wood Johnson Foundation Clinical Scholar. He has published papers regarding scientific research in human genetics, diagnostic test performance and medical economic analysis.

Roni A. Appel. Mr. Appel has served as a member of our board of directors since November 2004. He was President and Chief Executive Officer from January 1, 2006 and Secretary and Chief Financial Officer from November 2004, until he resigned as our Chief Financial Officer on September 7, 2006 and as our President, Chief Executive Officer and Secretary on December 15, 2006. From 1999 to 2004, he has been a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1998 he was an attorney and completed his MBA at Columbia University.

Dr. Thomas McKearn. Dr. McKearn has served as a member of our board of directors since July 2002. He brings to us a 25 plus year experience in the translation of biotechnology science into oncology products. First as one of the founders of Cytogen Corporation, then as an Executive Director of Strategic Science and Medicine at Bristol-Myers Squibb and now as the VP of Strategic Medical Affairs at Agennix, Inc. (formerly GPC-Biotech), he has worked at bringing the most innovative laboratory findings into the clinic and through the FDA regulatory process for the benefit of cancer patients who need better ways to cope with their afflictions. Prior to entering the biotechnology industry in 1981, Dr. McKearn did his medical, graduate and post-graduate training at the University of Chicago and served on the faculty of the Medical School at the University of Pennsylvania.

Richard Berman. Mr. Berman has served as a member of our board of directors since September 1, 2005. In the last five years, he served as a professional director and/or officer of about a dozen public and private companies. He is currently Chairman of NexMed, Inc., a public biotech company, and National Investment Managers. Mr. Berman is a director of six public companies: Broadcaster, Inc., Easy Link Services International, Inc., NexMed, Inc., National Investment Managers, Advaxis, Inc., and NeoStem, Inc. Previously, Mr. Berman worked at Goldman Sachs and was Senior Vice President of Bankers Trust Company, where he started the M&A and Leverage Buyout Departments. He is a past Director of the Stern School of Business of New York University, where he earned a B.S. and an M.B.A. He also has law degrees from Boston College and The Hague Academy of International Law.



John Rothman, Ph.D. Dr. Rothman joined our company in March 2005 as Vice President of Clinical Development and as of December 12, 2008 he was appointed to Executive Vice President of Clinical and Scientific Operations. From 2002 to 2005, Dr. Rothman was Vice President and Chief Technology Officer of Princeton Technology Partners. Prior to that he was involved in the development of the first interferon at Schering Inc., was director of a variety of clinical development sections at Hoffman LaRoche, and the Senior Director of Clinical Data Management at Roche. While at Roche his work in Kaposi's Sarcoma became the clinical basis for the first filed BLA which involved the treatment of AIDS patients with interferon. Dr. Rothman completed his doctorate at California University Los Angeles.

Mark J. Rosenblum. Effective as of January 5, 2010, Mr. Rosenblum joined our company as our Chief Financial Officer, Senior Vice President and Secretary. Mr. Rosenblum was the Chief Financial Officer of HemobioTech, Inc., a public company primarily engaged in the commercialization of human blood substitute technology licensed from Texas Tech University, from April 1, 2005 until December 31, 2009. From August 1985 through June 2003, Mr. Rosenblum was employed by Wellman, Inc., a public chemical manufacturing company. Between 1996 and 2003, Mr. Rosenblum was the Chief Accounting Officer, Vice President and Controller at Wellman, Inc. Mr. Rosenblum holds both Masters in Accountancy and a B.S. degree from the University of South Carolina. Mr. Rosenblum is a certified public accountant.

## Board of Directors

### Board of Directors

Each director is elected for a period of one year and serves until the next annual meeting of stockholders, or until his or her successor is duly elected and qualified. Officers are elected by, and serve at the discretion of, our board of directors. The board of directors may also appoint additional directors up to the maximum number permitted under our by-laws, which is currently nine.

### Committees of the Board of Directors

Our board of directors has three standing committees: the audit committee, the compensation committee, and the nominating and corporate governance committee.

#### Audit Committee

The audit committee of our board of directors consists of Mr. Berman and Dr. Patton with Mr. Berman serving as the audit committee's financial expert as defined under Item 407 of Regulation S-K of the Securities Act of 1933, as amended, which we refer to as the Securities Act. Our board of directors has determined that the audit committee financial expert is independent as defined in (i) Rule 10A-3(b)(i)(ii) under the Exchange Act and (ii) under Section 121 B(2)(a) of the NYSE Amex Equities Company Guide (although our securities are not listed on the NYSE Amex Equities but are quoted on the OTC Bulletin Board).

The audit committee is responsible for the following:

- reviewing the results of the audit engagement with the independent registered public accounting firm;
- identifying irregularities in the management of our business in consultation with our independent accountants, and suggesting an appropriate course of action;
  - reviewing the adequacy, scope, and results of the internal accounting controls and procedures;
- reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm;
  - reviewing the auditors' fees; and
- recommending the engagement of auditors to the full board of directors.

#### Compensation Committee

The compensation committee of our board of directors consists of Mr. Berman and Dr. McKearn. The compensation committee determines the salaries and incentive compensation of our officers subject to applicable employment agreements, and provides recommendations for the salaries and incentive compensation of our other employees and consultants.

#### Nominating and Corporate Governance Committee

The nominating and corporate governance committee of our board of directors consists of Mr. Berman and Mr. Moore. The functions of the nominating and corporate governance committee include the following:

- identifying and recommending to the board of directors individuals qualified to serve as members of our board of directors and on the committees of the board;
- advising the board with respect to matters of board composition, procedures and committees;

- developing and recommending to the board a set of corporate governance principles applicable to us and overseeing corporate governance matters generally including review of possible conflicts and transactions with persons affiliated with directors or members of management; and
  - overseeing the annual evaluation of the board and our management.

The nominating and corporate governance committee will be governed by a charter, which we intend to adopt.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and each person who owns more than ten percent of a registered class of our equity securities (collectively, “Reporting Persons”) to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and our other equity securities. Reporting Persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file. Based solely on the Company’s review of the copies of the forms received by it during the fiscal year ended October 31, 2009 and written representations that no other reports were required, the Company believes that each person who, at any time during such fiscal year, was a director, officer or beneficial owner of more than ten percent of the Company’s common stock complied with all Section 16(a) filing requirements during such fiscal year.

Code of Ethics

We have adopted a code of ethics that applies to our officers, employees and directors, including our principal executive officers, principal financial officer and principal accounting officer. The code of ethics sets forth written standards that are designated to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in reports and documents that a we file with, or submit to, the SEC and in other public communications made by us;
  - compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting of violations of the code to an appropriate person or persons identified in our code of ethics; and
  - accountability for adherence to our code of ethics.

A copy of our code of ethics has been filed with the SEC as an exhibit to our Form 8K dated November 12, 2004 and a copy of our code is posted on our website at [www.advaxis.com](http://www.advaxis.com).

Item 11: Executive Compensation

Summary Compensation Table

The following table sets forth the information as to compensation paid to or earned by our Chief Executive Officer and our two other most highly compensated executive officers during the fiscal years ended October 31, 2009 and 2008. These individuals are referred to in this report as our named executive officers. As none of our named executive officers received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal years ended October 31, 2009 and 2008, we have omitted those columns from the table.

Name and	Fiscal Year	Salary (\$)	Bonus (\$)	Stock	Option	All Other	Total (\$)
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Principal Position				Award(s) (1) (\$)	Award(s) (1)	Compensation(\$)			
Thomas A. Moore, CEO and Chairman	2009	350,000	—	71,250	(2)	115,089	17,582	(3)	553,919
	2008	352,692	—	—		156,364	27,626	(4)	536,682
Dr. John Rothman, Executive VP of Science & Operations	2009	250,000	-	11,550	(5)	82,911	23,797	(6)	368,258
	2008	255,000	55,000	23,378	(5)	25,092	27,862	(6)	386,332
Fredrick D. Cobb, VP Finance	2009	180,000	-	29,167	(7)	55,117	7,685	(6)	271,968
	2008	182,923	40,000	15,585	(8)	19,977	7,136	(6)	265,621

- (1) The amounts shown in this column represent the compensation expense incurred by us for the fiscal year in accordance with FAS 123(R) using the assumptions described under “ Share-Based Compensation Expense ” in Note 2 to our financial statements included elsewhere in this report.
- (2) Represents 750,000 shares of the Company’s common stock granted to him based on the financial raise milestone in his employment agreement valued at the market close price on April 4, 2008.
- (3) Based on our cost of Mr. Moore’s coverage for health care.
- (4) Based on our cost of Mr. Moore’s coverage for health care and interest received for the Moore Notes.
- (5) Represents: (i) \$30,000 of base salary paid in shares of our common stock in lieu of cash, based on the average monthly stock price, with the minimum set at \$0.20 per share, and (ii) the compensation expense incurred in connection with 150,000 shares earned but not issued in 2009 and 196,339 shares earned, but not issued in 2008.
- (6) Based on our cost of his coverage for health care and the 401K company match he received.
- (7) Represents: (i) \$20,000 of base salary paid in shares of our common stock in lieu of cash, based on the daily average closing stock price per month retrospectively to January 1, 2008, and (ii) the compensation expense incurred in connection with 704,342 shares earned, but not issued.
- (8) Represents: (i) \$20,000 of base salary paid in shares of our common stock in lieu of cash, based on the average monthly stock price, with the minimum set at \$0.20 per share, and (ii) the compensation expense incurred in connection with 130,893 shares earned, but not issued.

#### Discussion of Summary Compensation Table

We are party to an employment agreement with each of our named executive officers who is presently employed by us. Each employment agreement sets forth the terms of that officer’s employment, including among other things, salary, bonus, non-equity incentive plan and other compensation, and its material terms are described below. In fiscal 2008 and fiscal 2009, we granted stock options to our named executive officers to purchase shares of our common stock and issued stock to our Chief Executive Officer. The material terms of these grants are also described below.

**Moore Employment Agreement and Option Agreements.** We are party to an employment agreement with Mr. Moore, dated as of August 21, 2007 (memorializing an oral agreement dated December 15, 2006), that provides that he will serve as our Chairman of the Board and Chief Executive Officer for an initial term of two years. For so long as Mr. Moore is employed by us, Mr. Moore is also entitled to nominate one additional person to serve on our board of directors. Following the initial term of employment, the agreement was renewed for a one year term, and is automatically renewable for additional successive one year terms, subject to our right and Mr. Moore’s right not to renew the agreement upon at least 90 days’ written notice prior to the expiration of any one year term.

Under the terms of the agreement, Mr. Moore was entitled to receive a base salary of \$250,000 per year, subject to increase to \$350,000 per year upon our successful raise of at least \$4.0 million (which condition was satisfied on November 1, 2007) and subject to annual review for increases by our board of directors in its sole discretion. The agreement also provides that Mr. Moore is entitled to receive family health insurance at no cost to him. Mr. Moore’s employment agreement does not provide for the payment of a bonus.

In connection with our hiring of Mr. Moore, we agreed to grant Mr. Moore up to 1,500,000 shares of our common stock, of which 750,000 shares were issuable on November 1, 2007 upon our successful raise of \$4.0 million and

750,000 shares are issuable upon our successful raise of an additional \$6.0 million (which condition was satisfied in January 2010). In addition, on December 15, 2006, we granted Mr. Moore options to purchase 2,400,000 shares of our common stock. Each option is exercisable at \$0.143 per share (which was equal to the closing sale price of our common stock on December 15, 2006) and expires on December 15, 2016. The options vest in 24 equal monthly installments. On July 21, 2009, we granted Mr. Moore options to purchase 2,500,000 shares of our common stock. Each option is exercisable at \$0.10 per share (which was equal to the closing sale price of our common stock on July 21, 2009) and expires on July 21, 2019. One-third of these options vested on the grant date, and the remaining vest in one-third installments on the first and second anniversary of the grant.

We have also agreed to grant Mr. Moore options to purchase an additional 1,500,000 shares of our common stock if the price of common stock (adjusted for any splits) is equal to or greater than \$0.40 for 40 consecutive business days. Pursuant to the terms of his employment agreement, all options will be awarded and vested upon a merger of the company which is a change of control or a sale of the company while Mr. Moore is employed. In addition, if Mr. Moore's employment is terminated by us, Mr. Moore is entitled to receive severance payments equal to one year's salary at the then current compensation level.

Mr. Moore has agreed to refrain from engaging in certain activities that are competitive with us and our business during his employment and for a period of 12 months thereafter under certain circumstances. In addition, Mr. Moore is subject to a non-solicitation provision for 12 months after termination of his employment.

**Rothman Employment Agreement and Option Agreements.** We previously entered into an employment agreement with Dr. Rothman, Ph.D., dated as of March 7, 2005, that provided that he would serve as our Vice President of Clinical Development for an initial term of one year. Dr. Rothman's current salary is \$280,000, consisting of \$250,000 in cash and \$30,000 in stock, payable in our common stock, issued on a semi-annual basis, based on the average closing stock price for such six month period, with a minimum price of \$0.20. While the employment agreement has expired and has not been formally renewed in accordance with the agreement, Dr. Rothman remains employed by us and is currently our Executive V.P. of Clinical and Scientific Operations.

In addition, on March 1, 2005, we granted Dr. Rothman options to purchase 360,000 shares of our common stock. Each option is exercisable at \$0.287 per share (which was equal to the closing sale price of our common stock on March 1, 2005) and expires on March 1, 2015. All of these options have vested. On March 29, 2006, we granted Dr. Rothman options to purchase 150,000 shares of our common stock. Each option is exercisable at \$0.26 per share (which was equal to the closing sale price of our common stock on March 29, 2006) and expires on March 29, 2016. One-fourth of these options vested on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. On February 15, 2007, we granted Dr. Rothman options to purchase 300,000 shares of our common stock. Each option is exercisable at \$0.165 per share (which was equal to the closing sale price of our common stock on February 15, 2007) and expires on February 15, 2017. One-fourth of these options vested on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. Pursuant to the terms of the 2005 plan, at least 75% of Dr. Rothman's options will be vested upon a merger of the company which is a change of control or a sale of the company while Dr. Rothman is employed, unless the administrator of the plan otherwise allows for all options to become vested. On July 21, 2009, we granted Mr. Rothman options to purchase 1,750,000 shares of our common stock. Each option is exercisable at \$0.10 per share (which was equal to the closing sale price of our common stock on July 21, 2009) and expires on July 21, 2019. One-third of these options vested on the grant date, and the remaining vest in one-third installments on the first and second anniversary of the grant.

Dr. Rothman has agreed to refrain from engaging in certain activities that are competitive with us and our business during his employment and for a period of 18 months thereafter under certain circumstances. In addition, Dr. Rothman is subject to a non-solicitation provision for 18 months after termination of his employment.

**Cobb Employment Agreement and Option Agreements.** We entered into an employment agreement with Mr. Cobb, dated as of February 20, 2006, that provided that he would serve as our Vice President of Finance. Mr. Cobb's current salary is \$200,000, consisting of \$180,000 in cash and \$20,000 in stock, payable in our common stock, issued on a semi-annual basis, based on the average closing stock price for such six month period, with a minimum price of \$0.20. Mr. Cobb has resigned as an officer of the Company, but has agreed to continue as an employee of ours on a part-time basis for a three month period in order to assist with the transition of our newly hired Chief Financial Officer. During the transition period, Mr. Cobb will continue to receive the base salary and health care benefits that he was receiving prior to his resignation. Mr. Cobb also received eight weeks of accrued vacation pay and 752,142 shares of common stock that were previously earned but not yet issued. In addition, we agreed to extend the



expiration date of all his options that will be vested on his last day as an employee of ours to the date that is five years from his last day of employment (provided that such date is not more than 10 years after the date of grant).

In addition, on February 20, 2006, we granted Mr. Cobb options to purchase 150,000 shares of our common stock. Each option is exercisable at \$0.26 per share (which was equal to the closing sale price of our common stock on February 20, 2006) and expires on February 20, 2016. One-fourth of these options vest on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. On September 21, 2006, we granted Mr. Cobb options to purchase 150,000 shares of our common stock. Each option is exercisable at \$0.16 per share (which was equal to the closing sale price of our common stock on September 21, 2006) and expires on September 21, 2016. One-fourth of these options vest on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. On February 15, 2007, we granted Mr. Cobb options to purchase 150,000 shares of our common stock. Each option is exercisable at \$0.165 per share (which was equal to the closing sale price of our common stock on February 15, 2007) and expires on February 15, 2017. One-fourth of these options vest on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. Pursuant to the terms of the 2005 plan, at least 75% of Mr. Cobb's options will be vested upon a merger of the company which is a change of control or a sale of the company while Mr. Cobb is employed, unless the administrator of the plan otherwise allows for all options to become vested. On July 21, 2009, we granted Mr. Cobb options to purchase 1,000,000 shares of our common stock. Each option is exercisable at \$0.10 per share (which was equal to the closing sale price of our common stock on July 21, 2009) and expires on July 21, 2019. One-third of these options vested on the grant date, and the remaining vest in one-third installments on the first and second anniversary of the grant.

Mr. Cobb has agreed to refrain from engaging in certain activities that are competitive with us and our business during his employment and for a period of 18 months thereafter under certain circumstances. In addition, Mr. Cobb is subject to a non-solicitation provision for 18 months after termination of his employment.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information about the number of outstanding equity awards held by our named executive officers at October 31, 2009.

Name	Option Awards		Equity Incentive Plan Awards:		Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Options (#) Price (\$)	Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Number of Awards	Equity Incentive Plan Awards: Market or Limited Shares, Other Rights That Have Not Vested (\$)
Thomas A. Moore	833,333	1,666,667 (1)	-	0.100	-	-	-	-
				7/21/19				
	2,400,000	-	-	0.143	12/15/16	750,000 (2)	97,500 (3)	-
Dr. John Rothman	583,333	1,166,667 (4)	-	0.100	-	-	-	-
				7/21/19				
	360,000	-	—	0.287	3/1/15	—	—	—
	131,250	18,750 (5)	—	0.260	3/29/16	—	—	—
	187,500	131,250 (6)	—	0.165	2/15/17	—	—	—
Fredrick D. Cobb	333,333	666,667 (7)	-	0.100	-	-	-	-
				7/21/19				
	131,250	18,750 (8)	—	0.260	2/20/16	—	—	—
	112,500	37,500 (9)	—	0.160	9/21/16	—	—	—
	93,750	56,250 (10)	—	0.165	2/15/17	—	—	—

- (1) Of these options, approximately 833,333 will become exercisable on each anniversary date of July 21, 2010 and 2011.
- (2) In connection with our hiring of Mr. Moore, we agreed to grant Mr. Moore up to 1,500,000 shares of our common stock, of which 750,000 shares were issued on April 4, 2008 upon our successful raise of \$4.0 million and 750,000 shares are issuable upon our successful raise of an additional \$6.0 million.
- (3) Based on the closing sale price of \$0.13 per share of common stock on October 31, 2009 (the last day of our fiscal year).
- (4) Of these options, approximately 583,333 will become exercisable on each anniversary date of July 21, 2010 and 2011.
- (5) Of these options, 9,375 became exercisable on December 29, 2009 and will become exercisable on March 29, 2010.

- (6) Of these options, 18,750 became exercisable on November 15, 2009 and will become exercisable February 15, May 15, August 15 and November 15 of each year until February 15, 2011.
- (7) Of these options, approximately 333,333 will become exercisable on each anniversary date of July 21, 2010 and 2011.
- (8) Of these options, 9,375 became exercisable on November 20, 2009 and will become exercisable on February 20, 2010.
- (9) Of these options, 9,375 became exercisable on December 21, 2009 and will become exercisable on March 21, 2010, June 21, 2010 and September 21, 2010.
- (10) Of these options, 9,375 became exercisable on November 15, 2009 and will become exercisable on February 15, May 15 and August 15 and November 15, of each year until February 15, 2011.

#### Director Compensation

With the exception of Mr. Berman, who receives \$2,000 a month in shares of our common stock based on the average closing price of our common stock for the preceding month, none of our directors received any compensation for his services as a director other than options to purchase shares of our common stock and reimbursement of expenses. Each director is granted options to purchase shares of our common stock upon joining our board of directors and as the compensation committee so directs. In addition, each non-employee director earned compensation in shares of the company's common stock and cash for the twelve months ended October 31, 2009 but none were paid or issued.

All of our other non-employee directors receive a combination of cash compensation and awards of share of our common stock. Each non-employee directors receives \$2,000 for each board meeting attended in person and \$750 for each telephonic board meeting. In addition, each member of a committee of our board of directors receives \$2,000 per meeting attended in person held on days other than board meeting days and \$750 for each telephonic committee meeting. This plan is contingent upon stockholder approval at our next annual meeting.

The table below summarizes the compensation that was earned by our non-employee directors for the fiscal year ended October 31, 2009. As none of our non-employee directors received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal year ended October 31, 2009, we have omitted those columns from the table.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All other Compensation (\$)	Total (\$)
Roni A. Appel	\$ 7,500	\$ 1,848(2)	\$ 12,464(3)	—	\$ 21,812
Dr. James Patton	11,250	1,848(2)	12,464(3)	—	25,562
Dr. Thomas McKearn	10,500	1,848(2)	23,518(4)	—	35,866
Richard Berman	3,750	31,840(5)	21,972(6)		