Advaxis, Inc.
Form 10-K
January 31, 2011

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

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

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2010

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-28489

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

Delaware	02-0563870
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
Technology Centre of New Jersey 675 US Highway One North Brunswick, New Jersey (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 x

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

Yes ¨ No x

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

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

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

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

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

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

As of April 30, 2010, the aggregate market value of the voting common equity held by non-affiliates was approximately $22,116,980 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 210,645,862 shares of Common Stock, par value $0.001 per share, issued and outstanding as of January 27, 2011.

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PART 1

FORWARD LOOKING STATEMENTS

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

Item 1: Business.

General

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

The discoveries that underlie this innovative technology are based upon the work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn. This technology involves the creation of genetically engineered Listeria that stimulate the immune system to induce antigen-specific anti-tumor immune response involving both innate and adaptive arms of the immune system. In addition, this technology facilitates the immune response by altering tumors to make them more susceptible to immune attack, and increasing the number and maturation of development of specific 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 (CIN)	Phase II Company sponsored study, commenced in March 2010 (with patient dosing commencing in June 2010).
	Cervical Cancer	Phase II Company sponsored study initiated in November 2010 in India. 110 Patients with advanced cervical cancer.
	Cervical Cancer	

		Phase II The Gynecologic Oncology Group of the National Cancer Institute has agreed to conduct a study which we expect will commence in early 2011.
	Head & Neck Cancer	Phase I The Cancer Research UK (CRUK) is funding a study of up to 45 patients at 3 UK facilities that we expect will commence in early 2011.
ADXS31-142	Prostate Cancer	Phase I Company sponsored (timing to be determined).
ADXS31-164	Breast Cancer	Phase I Company sponsored (timing to be determined).
ADXS31-164	Canine Osteosarcoma	Phase 1 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, 2010, we had an accumulated deficit of $27,416,000 and shareholders' deficiency of $14,802,631.

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

Series B Preferred Equity Financing

Pursuant to the terms of the preferred stock purchase agreement dated July 19, 2010, which we refer to as the Series B purchase agreement, with Optimus Life Sciences Capital Partners LLC, which we refer to as Optimus, as of January 27, 2011, we had issued and sold 422 shares of non-convertible, redeemable Series B preferred stock, which we refer to as our Series B preferred stock, to Optimus. The aggregate purchase price for the Series B preferred stock was $4.22 million. Under the terms of the Series B purchase agreement, Optimus remains obligated, from time to time until July 19, 2013, to purchase up to an additional 328 shares of Series B preferred stock at a purchase price of $10,000 per share upon notice from us to Optimus, and subject to the satisfaction of certain conditions, as set forth in the Series B purchase agreement. Among these conditions, we must have a sufficient number of registered shares underlying a warrant issued to an affiliate of Optimus. We currently have 4,010,038 registered shares available under our prospectus and will likely need to register additional warrant shares in order to require Optimus to purchase the remaining shares of Series B preferred stock.

In connection with the foregoing transaction, an affiliate of Optimus was granted warrants to purchase 40,500,000 shares of our common stock on July 19, 2010 at an exercise price of $0.25 to be adjusted in connection with the draw down of each tranche. As of January 27, 2011, Optimus has exercised warrants to purchase 36,489,962 shares of common stock at adjusted exercise prices ranging from $0.15 to $0.17 per share. As permitted by the terms of such warrants, the aggregate exercise price of $5,697,000 received by us is payable pursuant to four year full recourse promissory notes bearing interest at the rate of 2% per year.

On December 30, 2010, immediately following the issuance by us of 72 shares of Series B preferred stock pursuant to the Series B purchase agreement, we redeemed 226 shares of Series B preferred stock held by Optimus for an aggregate redemption price of $3,141,004 consisting of (i) cash in an amount of $76,622 and (ii) the cancellation of certain promissory notes issued by an affiliate of Optimus to us in the aggregate amount of $3,064,382.

Recent Bridge Financings

From November 1, 2010 through November 10, 2010 we issued to certain accredited investors (i) junior unsecured convertible promissory notes in the aggregate principal face amount of $431,579, for an aggregate net purchase price of $410,000 and (ii) warrants to purchase 1,025,000 shares of our common stock at an exercise price of $0.17 per share, subject to adjustments upon the occurrence of certain events. The bridge notes were issued with an original issue discount of 5% (OID) and are convertible into shares of our common stock. These notes mature in 60 days from their origination. From November 1, 2010 through November 5, 2010 we also issued to certain accredited investors (i) junior unsecured convertible promissory notes in the aggregate principal face amount of $500,000, for an aggregate net purchase price of $425,000 and (ii) warrants to purchase 2,062,500 shares of our common stock at an exercise price of $0.17 per share, subject to adjustments upon the occurrence of certain events. The bridge notes were issued with an original issue discount of 15% (OID) and are convertible into shares of our common stock. These notes mature on or before August 31, 2011. 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 November 2010 the Company repaid four bridge notes issued during fiscal 2010 in the principal amounts of $187,582. With respect to all bridge notes issued from June, 2009 through January 27, 2011, an aggregate principal amount of $1,874,100 remain outstanding.

On January 3, 2011, we issued to a certain accredited investor, one junior unsecured convertible promissory note in the aggregate principal face amount of $352,941, for an aggregate net purchase price of $300,000 and (ii) warrants to purchase 1,500,000 shares of our common stock at an exercise price of $0.15 per share, subject to adjustments upon the occurrence of certain events. The bridge notes were issued with an original issue discount of 15% (OID) and are convertible into shares of our common stock. These notes mature in 9 months from their origination.

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

Strategy

During the next 24 months, we will focus on developing sufficient human clinical data on ADXS11-001, our first Listeria construct, to demonstrate clinical effectiveness in cervical cancer and it's medical predecessor condition, CIN. Beyond effectiveness specifically against HPV oncogenes, we also want to demonstrate more broadly that attenuated Listeria that secretes an antigen adjuvant fusion protein is an effective platform for multiple therapies against cancer and infectious disease. In the U.S., we have initiated a single blind, placebo controlled Phase II clinical trial of ADXS11-001 with three dosage arms in Cervical Intraepithelial Neoplasia (cervical dysplasia, CIN), a pre cancerous condition. In India, we have launched a 110 patient Phase II trial in advanced cervical cancer in women who have progressed after receiving cytotoxic therapy.

Within the next 3 months we will initiate in the U.S. another NCI-supported study in late stage cervical cancer , and a head and neck cancer study with CRUK in the UK. We have signed an agreement to collaborate in a clinical trial with the Gynecologic Oncology Group (GOG), one of NIH’s clinical research groups, which will underwrite the cost and whose members will execute the trial. It is expected that this US Phase II multi-center study will result in a cost avoidance benefit to Advaxis valued at between $7 million to $8 million in trial expenses. The CRUK initial study should be worth between $2.5 and 3.5 million.

The Company has entered into a clinical trials agreement with the School of Veterinary Medicine at Penn to investigate the use of its compound ADXS31-164 for the treatment of osteosarcoma in dogs. This disease is the leading cancer killer of large dogs and is a model for the treatment of human osteosarcoma, the leading fatal bone cancer in adolescents.

We have also initiated the production of human grade production of two new vaccines for which we expect to begin clinical development in 2011. Planning has begun for Phase I trials for ADXS31-142 for the treatment of prostate cancer, and ADXS 31-164 for the treatment of breast, brain and other cancers.

Although the company has been successful in obtaining clinical funding from the U.S. and UK, 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 Listeria to create vaccines for many different diseases, our longer term strategy will be to license the commercial development of ADXS11-001 for the indications of CIN, cervical and head and neck cancers, and other HPV related diseases. 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 basic science and the continued pre-clinical development and optimization of our technology so as to develop it to its full potential and to find additional 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

Cancer is the second largest cause of death in the U.S., exceeded only by heart disease. The cost of treating cancer patients in 2008 was estimated to be $228.1 billion in healthcare costs and another $188 billion in indirect costs resulting from morbidity and lost productivity (source: Facts & Figures 2009, American Cancer Society). The American Cancer Society’s most recent estimates for newly diagnosed cervical cancer in the U.S. in 2010 was 12,200 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). Overall predicted incidence and mortality rates for 2009 are set forth below

Percent of U.S. deaths due to cancer in 2006

Immune System and Normal Antigen Processing

People, are continually confronted with potentially infectious agents. The immune system has evolved multiple mechanisms to fight disease, including including innate immunity, two forms of adaptive immunity humoral (antibody), and cellular immunity that mobilize the body's natural defenses against these foreign agents to eliminate them.

Innate Immunity:

Innate immunity is the first step in the recognition of a foreign antigen. It is a non-specific protective response that also underlies the generation of an adaptive (antigen- specific) immune responses. It is characterized by the release of various soluble mediators of immune response such as cytokines, chemokines and other molecules.

Exogenous pathway of Adaptive Immunity (Class II pathway):

Proteins and foreign molecules ingested by Antigen Presenting Cells, or APCs, are broken down inside digestive vacuoles into small pieces, 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, migrates to the cell surface where it interacts with certain classes of lymphocytes (CD4+) called helper T-cells that support the function of cytotoxic T-lymphocytes (killer T cells). This interaction renders CD4+ cells antigen specific, and they express their function whenever they encounter the antigen to which they've been activated. This system is called the exogenous pathway, since it is the prototypical response to an antigen from outside of the cell, like bacteria.

Endogenous pathway of Adaptive Immunity (Class I pathway):

The endogenous pathway provides immune protection against antigens created within the cytoplasm of the APC (as opposed exogenous molecules contained within he digestive phagosome). These intracellular antigens are typically broken down by within the cell and directed to the endoplasmic reticulum, where they are incorporated into an MHC-1 protein and trafficked to the cell surface. MHC-1 complexes activate CD8+ cytotoxic T-lymphocytes, which then kill cells that express the specific antigen to which these cells are now activated. The endogenous pathway is needed for elimination of virus-infected or cancerous cells.

Listeria generated adaptive immune responses are directed at the activation of T cells. Listeria tends not to stimulate antibody formation.

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. We use a bioengineered form of Listeria to activate the immune system to treat cancer, infectious diseases, or allergic syndromes. 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 biological 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 monocytogenes (Lm) is a bacterium well known to medical science because it can cause an infection in humans. Listeria is a rare, but serious, cause 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 food. It is not laterally transmitted from person to person. As Lm is in the soil and thus found on leafy vegetables, in meat and dairy products, and is a common microbe in our environment , we are exposed to it constantly. 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. This is rare, and fortunately, many common antibiotics can kill and sterilize Listeria. Advaxis has a number of strains of Listeira that are bioengineered for use as a human vaccine vector. These vaccines are highly attenuated, which means they are much less pathogenic. Advaxis vaccines are between 10,000 and 100,000 times weaker (and less able to cause disease) than wild type Listeria.

Live Listeria is one of the strongest known stimulators of 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 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.
APCs are scavenging cells 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. Because Listeria infects APC, and our vaccines secrete biologically active molecules from within APC, our live attenuated Lm vaccines have the ability to direct an immune attack in a way no other therapy can.

When Listeria enters the body, it is seen as foreign by the antigen presenting 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 presenting 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. Antigens 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 creates 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 creating a hole in the outer cell membrane. This would destroy the host cell. 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). When a PEST sequence is detected 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 to the proteosome 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. Moreover, LLO is a very strong adjuvant, which means it is a strong stimulator of innate immunity.

Other mechanisms that Advaxis vaccines employ include Listeria's ability to increase the synthesis of myeloid cells such as Antigen Presenting Cells ("APC") and macrophages, 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 are created that support and facilitate a therapeutic response.

Finally, in a manner that appears to be unique to Advaxis live attenuated Listeria vaccines: they can reduce the number and function of immunosuppressive cells that tumors recruit to protect them from therapeutic immune attack. 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. Advaxis has either published scientific papers or presented data at scientific meetings about the ability of our vaccines to reduce the number of regulatory T cells (Tregs) and Myeloid Derived Suppressor Cells (MDSC); and that MDSC which remain are less immunosuppressive. This renders tumors susceptible to immune attack. The ability to reduce the effect of immunosuppressive cells within tumors is currently under clinical investigation by other companies and is believed to be a significant mechanism of achieving a therapeutic response.

Advaxis live attenuated 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. The strains of Listeria that we use are cleared by animals such as SCID mice or IFN-gamma knockout mice that lack adaptive immune responses and are thus profoundly immuno-compromised.

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 one of the strongest stimulators 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 we have 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. One of the strongest known stimulators of innate immunity
   a. Lm-LLO vaccines are cleared in SCID mice by innate immunity alone
2. Stimulate a very strong adaptive immune response
   a. High titers of activated CD4+, CD8+, APC, and TIL
3. Alters Tumor Microenvironment
   a. Reduces both Tregs, MDSC & TAM in tumors but not in surrounding tissue
4. Stimulate synthesis of new immune cells and maturation of existing cells
   a. Marrow, tissue and blood born effects
5. Stimulates chemotaxis and extravasation of activated immune cells
   a. Chemokine mediated effects and effects directly on vascular endothelium increase TIL
6. Lm infects tumors with Intra-tumoral effects
   a. Tumor killing, chemotaxic focus, & local innate immune effects
7. Initiates epitope spreading
   a. Vaccines directed against one antigen result in immune activation against other antigens

Importantly, Advaxis live attenuated Listeria vaccines do not stimulate antibody formation, which is important because other types of cancer vaccines such as those that use viruses develop antibody responses which inactivate them and prevent them being used repetitively in a vaccine regimen. These types of vaccines are inactivated by antibody responses before they can effectively deliver their immune payload which revents them from stimulating a therapeutic response. Advaxis vaccines can be used effectively in a multidose vaccine regimen as they are not inactivated by antibody responses.

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 presenting 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, ADX11-001uses 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. ADXS31-142 is directed against PSA, and antigen of importance in prostate cancer.

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 attributed 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 0.2% 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 of $100,000 on December 31, 2010, 2011 and 2012 and each December 31st thereafter for the remainder of the term of the agreement 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.

On May 10, 2010, we entered into a second amendment to the Penn license agreement pursuant to which we acquired exclusive licenses for an additional 27 patent applications related to our proprietary Listeria vaccine technology. As per the terms of the second amendment, we acknowledged that we owed Penn approximately $249,000 in patent expenses and $130,000 in sponsored research agreement fees; such fees being paid prior to October 31, 2010. As part of this amendment we exercised our option for the rights to seven additional patent dockets, including 23 additional patent applications, at an option exercise fee payable in the form of $35,000 in cash and $70,000 in our common stock (approximately 388,889 shares of our common stock based on a price of $0.18 per share) and at a cost of approximately $462,000. As of January 27, 2011, the Company had paid $250,000 and $212,000 remained outstanding.

Strategically we intend to maintain our relationship 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 is a fellow of the American Academy for the Advancement of Science, and 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 with emphasis during the last several years on the areas of HIV, AIDS and cancer research. She has trained over forty post-doctoral and doctoral students in the fields of Biochemistry and Immunology. Dr. Paterson is also the Chairman of our Scientific Advisory Board.

Consulting Agreement. On January 28, 2005 we entered into a consulting agreement with Dr. Paterson, which expired on January 31, 2009. 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 believe that Dr. Paterson's continuing research will serve as a source of ongoing findings and data that both supports and strengthens 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.

Cancer Research UK

On February 9, 2010, we announced that Cancer Research UK (CRUK), the UK organization dedicated to cancer research, has agreed to fund the cost of a clinical trial to investigate the use of ADXS11-001, our lead 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. We 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, The Royal Marsden Hospital in London, and Cardiff Hospital at the University of Wales. At such time, enrollment officials anticipate recruiting a maximum of 45 patients.

National Cancer Institute Gynecologic Oncology Group

On December 15, 2009, we announced our Phase II Trial Collaboration with the National Cancer Institute Gynecologic Oncology Group to study ADXS11-001 in a study of up to 63 patients. We will collaborate in a multicenter, Phase II clinical trial of our lead drug candidate, ADXS11-001, in the treatment of advanced cervix cancer in women who have failed prior cytotoxic therapy. This Phase II trial is underwritten by GOG and will be conducted by GOG investigators. The study's patients are very sick and rapidly progressing similar to the population that was treated in our Phase I trial of ADXS11-001. Under this agreement we are responsible for covering the costs of translational research and have agreed to pay a total of $8,003 per patient, with the bulk of the costs of this study underwritten by NCI.

On November 1, 2010 the Vaccine Section of National Cancer Institute and Advaxis have entered into a Collaborative Research and Development Agreement (CRADA) for the development of live attenuated Listeria vaccines for the treatment of cancer. Advaxis will provide all live Listeria vaccines. NCI will use different in vitro and in vivo models to elucidate the effect of Advaxis live attenuated Listeria vaccines on many different types of immune cells, and will investigate the mechanisms by which live Listeria vaccines reduce cancer induced immune inhibition that protects tumors from immune attack. Advaxis and NCI will use the results of this work to enhance the anti-tumor effects of live Listeria vaccines as therapeutic agents for the treatment of cancer and as therapeutic immune adjuvants that alter the tumor milieu which will enable them to be used with other modalities of cancer treatment. The cost of the CRADA is $150,000 annually and the length of the agreement is three years.

University of British Columbia (UBC)

Advaxis entered into a structured collaboration with the laboratory of Dr. Tobias Kollmann at the University of British Columbia (UBC) to develop live attenuated Listeria vaccines for the treatment of infectious disease and to develop new dosage forms of Listeria vaccines. The same immune-stimulating properties that are under development at Advaxis to develop live Listeria vaccines as safe and effective therapies for the treatment of cancer, also may have application for the treatment of infectious disease. Dr. Kollmann is an immunologist and neonatal vaccinologist who has published extensively on the use of Listeria vaccines as potential therapeutic agents for the treatment of childhood diseases. Under the terms of this collaboration, Dr. Kollmann will use Advaxis' proprietary Listeria vaccine vectors for the development of novel infectious disease applications.

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 $35,000 through October 31, 2010.

Recipharm AB (formerly Cobra Biomanufacturing PLC)

In July 2003, we entered into an agreement with Cobra Biomanufacturing PLC, which has recently been purchased by Recipharm AB, for the purpose of manufacturing our cervical cancer vaccine ADXS11-001. Recipharm has extensive experience in manufacturing gene therapy products for investigational studies. Recipharm is a manufacturing organization that manufactures and supplies biologic therapeutics for the pharmaceutical and biotech industry. These services include the Good Manufacturing Practices, or GMP, manufacturing of DNA, recombinant protein, viruses, mammalian cell products and cell banking. Recipharm'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. Recipharm has agreed to surrender the right to $300,000 of its outstanding fees for manufacturing in exchange for future royalties from the sales of ADXS11-001 at the rate of 1.5% of net sales, with royalty payments not to exceed $2.0 million.

On 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 UK, and likely to be required by other regulatory bodies in the future. Currently the company has two agreements with Recipharm-Cobra; one to conduct ongoing stability testing of the ADXS11-001 vaccine which they have manufactured, and another to provide analytic services and certification necessary to import ADXS11-001 for use in the UK head and neck study mentioned above. For the year ending October 31, 2010, the company paid Cobra approximately $33k under the agreement.

Vibalogics GmbH

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 cover the fill and finish operations as well as specific tests that have to be performed in order to release the clinical materials for human use. Advaxis has recently entered into agreements with Vibalogics to produce two new vaccines, ADXS31-142 and ADXS31-164 for human use and clinical development.

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 multicenter Phase II U.S. trial of ADXS11-001 in CIN and to act as our U.S. CRO for the multicenter phase 2 study of ADXS11-001 in progressive cervix cancer being co inducted in India. The scope of this agreement covers over three years and is estimated to cost $11.2 million for both trials. In May 2010, we issued 3,500,000 shares of common stock to Numoda Capital at a price per share of $0.17 in satisfaction of $595,000 of services rendered to us by the Numoda Corporation. During the year ending October 31, 2010, the company paid Numoda approximately $3.2 million for clinical trial activities.

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, 2010 the Company has an outstanding balance due to POI of $223,619.

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, 2010 Penn has 32 issued and 33 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. This follows and agreement dated May 10, 2010, in which we entered into a second amendment to the 20-year exclusive worldwide license agreement with Penn, which we refer to as the Second Amendment Agreement. Pursuant to the Second Amendment Agreement, we acquired exclusive licenses for additional patent applications related to our proprietary Listeria vaccine technology that were not included in the initial agreement. As of January 27, 2011, we acknowledged that we owe Penn approximately $212,000 in patent expenses pursuant to the Second Amendment Agreement.

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 are also aware of Aduro Biotech, a company comprised in part of former Cerus and Anza employees that has recently formed to investigate Listeria vaccines based upon Anza’s technology. We believe that through our exclusive license with Penn, we have the 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 (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 cannot 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, Aduro 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 we refer to as the CFR, 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 of the Lovaxin name.

On May 26, 2009, the United States Patent and Trademark Office, which we refer to as the PTO, approved our patent application “ Compositions and Methods for Enhancing the Immunogenicity of Antigencs ”. This patent application covers the use of Listeria monocytogenes 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 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.

Between February and December of 2009 the U.S., 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 Listeria monocytogenes, which we refer to as Lm , appears to be more immunogenic and less virulent that prior vaccine strains.

Between January and March of 2010, the USPTO issued two patents to Penn (each of which are covered by the Penn license agreement) that cover the composition of matter, uses and methods using the Lm protein Act A in antigen fusion proteins. We are currently holding patents relating to two families of antigen-adjuvant fusion proteins; one based on LLO and one based on ActA.

Governmental Regulation

The Drug Development Process

The 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 Clinical Research Organizations (CRO).

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:

- Criteria for participant inclusion/ exclusion;
- Dosing requirements and timing;
- Tests to be performed; and
- Evaluations and data assessment.

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 oversight of the communications which we or the CRO

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 therapies are initially tested on late stage cancer patients.

Phase II. Phase II trials involve larger numbers of participants at a time who 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 drug in Phase III studies.

Phase III. Phase III studies involve testing even larger 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.

Biologic License Application (BLA). The results of the clinical trials using biologics are submitted to the FDA as part of BLA. Following the completion of Phase III studies, if the sponsor of a potential product in the U.S. believes it has sufficient information to support the safety and effectiveness of their product, the sponsor submits a BLA to the FDA requesting that the product be approved for sale. 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 Program 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, movement, 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 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 an agreement with Cobra Biomanufacturing (now Recipharm) for the purpose of manufacturing our vaccines. Recipharm has extensive experience in manufacturing gene therapy products for investigational studies. Recipharm is a full service manufacturing organization that manufactures and supplies biologic based therapeutics for the pharmaceutical and biotech industry. These services include the GMP manufacturing of stability testing, and cell banking. Recipharm'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.

Beginning in April 2008, we entered into a number of Agreements with Vibalogics to manufacture clinical grade material for two new vaccines to develop in the clinic as new drugs; ADXS31-142, a vaccine for the treatment of prostate cancer, and ADXS31-164, a vaccine for the treatment of breast, brain and other cancers. Cobra's manufacturing plan for us calls for GMP manufacturing in several 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, filling, finishing, and the development of a storage stable, room temperature, dried form of our vaccines.

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 Aduro Biotech, Antigenics Inc., Avi BioPharma, Inc., Biomura 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 GlaxoSmithKline, which we refer to as 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 strains while Cervarix is directed against two. Neither of these agents has 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 treated 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. The number of women who are already infected with HPV is estimated to be as much as (or more

than) 25% of the female population of the U.S.

There are approximately 10 high risk strains 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 drugs 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.

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 (SAB) 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 SAB 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.; 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."

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 NIH 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, 2010, we had an accumulated deficit $27,416,000 and shareholders' deficiency of $14,802,631. 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, 2010 included a going concern explanatory paragraph.

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

We have entered into the Series B purchase agreement, pursuant to which Optimus has agreed to purchase up to $7.5 million of our Series B preferred stock from time to time, subject to our ability to effect and maintain an effective registration statement for the shares underlying the warrant issued to an affiliate of Optimus to purchase up to 40,500,000 shares of common stock, issued in connection with the transaction. As of January 27, 2011, Optimus had purchased an aggregate of 422 shares of Series B preferred stock and remains obligated, from time to time until July 19, 2013, to purchase up to an additional 328 shares of Series B preferred stock upon notice from us to Optimus, if certain conditions set forth in the Series B 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 July 19, 2010, other than losses incurred in the ordinary course of business, (iv) we must not be in default under any material agreement, (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 Series B purchase agreement. If we fail to comply with any of these requirements, Optimus will not be obligated to purchase our Series B preferred stock and we will not receive any funding from Optimus. Moreover, if we exercise our option to require Optimus to purchase our Series B preferred stock, and our common stock has a closing price of less than $0.15 per share on the trading day immediately preceding our delivery of the exercise notice, we may trigger at closing certain anti-dilution protection provisions in certain outstanding warrants that would result in an adjustment to the number and price of certain outstanding warrants.

We may not be able to require Optimus to purchase the entire $7.5 million of Series B preferred stock issuable under the Series B purchase agreement.

In connection with our Series B preferred equity financing, we issued to an affiliate of Optimus a three-year warrant to purchase up to 40,500,000 shares of our common stock, at an initial exercise price of $0.25 per share. As of January 27, 2011, 4,010,038 warrants remain outstanding. The warrant provides that on each tranche notice date under the Series B purchase agreement, (i) that portion of the warrant equal to 135% of the tranche amount will vest and become exercisable (and such vested portion may be exercised at any time during the exercise period on or after such tranche notice date) and (ii) the exercise price will be adjusted to the closing sale price of a share of our common stock on such tranche notice date. We are not permitted to deliver a tranche notice under the Series B purchase agreement if the number of registered shares underlying the warrant is insufficient to cover the portion of the warrant that will vest and become exercisable in connection with such tranche notice. We currently have 4,010,038 registered shares underlying the warrant available under our prospectus and will likely need to register additional warrants shares in order to require Optimus to purchase the remaining shares of Series B preferred stock. We cannot assure you that we will be able to timely effect and maintain a registration statement for any such additional warrant shares so as to permit us to require Optimus to purchase the entire $7.5 million of Series B preferred stock under the Series B purchase agreement.

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 Series B 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 December 31, 2010, our total outstanding indebtedness was approximately $2.14 million, which included the face value of our outstanding bridge notes in the amount of approximately $1.5 million, a note outstanding to BioAdvance in the amount of $40,000 and the note outstanding to our chief executive officer in the amount of approximately $0.6 million. The total face value of the notes outstanding as of November 30, 2010 is due on or before August 31, 2011. 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. In addition, our failure to timely repay (or extend) amounts due and owing under our outstanding senior and junior bridge notes, may trigger the anti-dilution protection provisions in substantially all of our warrants (other than the warrants issued to the affiliate of Optimus), in which case holders of our common stock will experience significant additional dilution. As of December 31, 2010, approximately 73 million warrants would be subject to these anti-dilution protection provisions.

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 outsource the management of our clinical trials to third parties. 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;