

Advaxis, Inc.
Form 10KSB
January 16, 2008

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

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2007

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 Small Business Issuer in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

Technology Centre of New Jersey
675 US Highway One, Suite B113
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]

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 S No £

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements

Edgar Filing: Advaxis, Inc. - Form 10KSB

incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. £

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

State issuer's revenues for its most recent fiscal year. \$154,201

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of December 31, 2007 was approximately \$16,635,698 based upon the closing bid price of the registrant's Common Stock on the Over the Counter Bulletin Board, at December 31, 2007. (For purposes of determining this amount, only directors, executive officers, and 10% or greater stockholders and their respective affiliates have been deemed affiliates).

Registrant 107,957,977 shares of Common Stock, par value \$0.001 per share, issued and outstanding as of 12/31/07.

DOCUMENTS INCORPORATED BY REFERENCE

The Exhibits to this Annual Report have been incorporated by reference from other filings by the Company with the Securities and Exchange Commission.

Table of Contents
Form 10-KSB Index

PART I	1
Item 1: Description of Business	1
Item 2: Description of Property.	33
Item 3: Legal Proceedings.	33
Item 4: Submission of Matters to a Vote of Security Holders.	34
PART II	34
Item 5: Market For Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.	34
Item 6: Management’s Discussion and Analysis or Plan of Operation	34
Item 7: Financial Statements	47
Item 8: Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	69
Item 8A: Controls And Procedures	69
Item 8 B: Other Information.	70
PART III	70
Item 9: Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance With Section 16(a) of the Exchange Act.	70
Item 10: Executive Compensation	74
Item 11: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	82
Item 12: Certain Relationships and Related Transactions, and Director Independence.	84
Item 13: Exhibits	86
Item 14: Principal Accountant Fees and Services	91

PART 1

FORWARD LOOKING STATEMENTS

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

Item 1: Description of Business

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”). Until November 2004, we were a publicly-traded “shell” company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation (“Advaxis”), 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 20, 2006 reincorporation into Delaware. 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

On October 17, 2007, pursuant to a Securities Purchase Agreement, we completed a private placement resulting in \$7,384,235 in gross proceeds, pursuant to which we sold 49,228,334 shares of common stock at a purchase price of \$0.15 per share solely to institutional and accredited investors. Each investor received a five-year warrant to purchase an amount of shares of common stock that equals 75% of the number of shares of common stock purchased by such investor in the offering at a price of \$0.20 (the “\$0.20 Warrants”).

Concurrent with the closing of the private placement, the Company sold for \$1,996,666 to CAMOFI Master LDC and CAMHZN Master LDC, affiliates of its financial advisor, Centrecourt Asset Management (“Centrecourt”), an aggregate of (i) 10,000,000 shares of Common Stock, (ii) 10,000,000 \$0.20 Warrants, and (iii) 5-year warrants to purchase an additional 3,333,333 shares of Common Stock at a purchase price of \$0.001 per share (the “\$0.001 Warrants”). The

Company and the two purchasers agreed that the purchasers would be bound by and entitled to the benefits of the Securities Purchase Agreement as if they had been signatories thereto. The \$0.20 Warrants and \$0.001 Warrants contain the same terms, except for the exercise price. Both warrants provide that they may not be exercised if, following the exercise, the holder will be deemed to be the beneficial owner of more than 9.99% of the Company's outstanding shares of Common Stock. Pursuant to a consulting agreement dated August 1, 2007 with Centrecourt with respect to the anticipated financing, in which Centrecourt was engaged to act as Registrant's financial advisor, Registrant paid Centrecourt \$328,000 in cash and issued 2,483,333 \$0.20 Warrants to Centrecourt, which Centrecourt assigned to the two affiliates.

All of the \$0.20 Warrants and \$0.001 Warrants provide for adjustment of their exercise prices upon the occurrence of certain events, such as payment of a stock dividend, a stock split, a reverse split, a reclassification of shares, or any subsequent equity sale, rights offering, *pro rata* distribution, or any fundamental transaction such as a merger, sale of all of its assets, tender offer or exchange offer, or reclassification of its common stock. If at any time after October 17, 2008 there is no effective registration statement registering, or no current prospectus available for, the resale of the shares underlying the warrants by the holder of such warrants, then the warrants may also be exercised at such time by means of a "cashless exercise."

In connection with the private placement, we entered into a registration rights agreement with the purchasers of the securities pursuant to which we agreed to file a registration statement with the Securities and Exchange Commission with an effectiveness date within 90 days after the final closing of the offering. The resale of 49,228,334 shares of common stock and 36,921,250 shares underlying the warrants is being registered in the prospectus. The registration statement is anticipated to be declared effective on January 16, 2008. See “Private Placements.”

At the closing of this private placement, we exercised our right under an agreement dated August 23, 2007 with YA Global Investments, L.P. f/k/a Cornell Capital Partners, L.P. (“Yorkville”), to redeem the outstanding \$1,700,000 principal amount of our Secured Convertible Debentures due February 1, 2009 owned by Yorkville, and to acquire from Yorkville warrants expiring February 1, 2011 to purchase an aggregate of 4,500,000 shares of our common stock. We paid an aggregate of (i) \$2,289,999.01 to redeem the debentures at the principal amount plus a 20% premium and accrued and unpaid interest, and (ii) \$600,000 to repurchase the warrants.

Our Website

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

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 use the *Listeria* System licensed from the University of Pennsylvania (Penn) to secrete a protein sequence containing a tumor-specific antigen. Using the *Listeria* System, we believe we will force the body’s immune system to process and recognize the antigen as if it were foreign, creating the immune response needed to attack the cancer. We believe that the *Listeria* System is a broadly enabling platform technology that can be applied to many types of cancers. In addition, we believe there may be useful applications in infectious diseases and auto-immune disorders.

The therapeutic approach that comprises the *Listeria* System is based upon the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn, involving the creation of genetically engineered *Listeria* that stimulate the innate immune system and induce an antigen-specific immune response involving humoral and cellular components.

We have focused our initial development efforts upon cancer vaccines targeting cervical, breast, prostate, ovarian, lung and other cancers. Our lead products in development are as follows:

Product	Indication	Stage
Lovaxin C	Cervical intraepithelial neoplasia (CIN), cervical cancer, head and neck cancer.	Phase I/II completed in the fiscal fourth quarter 2007. Phase II study in CIN anticipated to commence in 3 rd quarter fiscal 2008. The Gynecologic Oncology Group (GOG) of the National Cancer Institute has agreed to conduct a cervical cancer study timing to be determined.
Lovaxin P	Prostate cancer	Preclinical; Phase I study anticipated to commence 2 nd quarter fiscal 2009
Lovaxin B	Breast cancer	Preclinical; Phase I study anticipated to commence in mid fiscal 2009

See “Item 1. Description of Business - Research and Development Programs”.

Since our formation, we have had a history of losses that as of October 31, 2007 have aggregated \$12,072,742, and because of the long development period for new drugs, we expect to continue to incur losses for an extended period of time. Our business plan to date has been realized by substantial outsourcing of virtually all major functions of drug development including scaling up for manufacturing, research and development, grant applications, clinical studies and others. The expenses of these outsourced services account for most of our accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or FDA-approved. Even if one or more of our products receives United States Food and Drug Administration, or FDA, approval or becomes commercially viable we are not certain that we will ever become a profitable business.

Strategy

During the next 12 to 24 months our strategic focus will be to achieve several objectives. The foremost of these objectives are as follows:

- Present our completed Phase I/II clinical study of Lovaxin C which document the practicability of using this agent safely in the therapeutic treatment of cervical cancer;
- Initiate our Investigational New Drug Application (IND) with the FDA for our Phase II clinical study of Lovaxin C in the therapeutic treatment of CIN;
- Initiate our Phase II clinical study of Lovaxin C in the therapeutic treatment of CIN;
- Continue the preclinical development work necessary to bring Lovaxin P into clinical trials, and initiate that trail;
- Continue the preclinical development work necessary to bring Lovaxin B into clinical trials, and initiate that trial;
- Continue the pre-clinical development of our product candidates, as well as continue research to expand and enhance our technology platform; and
- Initiate strategic and development collaborations with biotechnology and pharmaceutical companies.

Complete the Ongoing Phase I/II Clinical Study of Lovaxin C. This trial was conducted in Israel, Serbia and Mexico, and a total of 15 women with end-stage cervical cancer were treated. Three different dose levels were tested at 5 patients per dose, by administering the same dose twice to patients as an IV infusion at a 3 week interval. The study demonstrated Lovaxin C can be used safely in end-stage metastatic cervical cancer. In the two lower dose groups (a total of 10 patients) drug related side effects consisted of fever, chills, nausea and vomiting, comprising a flu like syndrome that is frequently associated with immunotherapies and is believed to result from the release of immune cytokines as part of an innate immune response. In the lower two dose levels symptoms were controlled with non-prescription analgesics and antihistamines. In the highest dose level (5 patients) tested symptoms were more severe and dose limiting. Thus, safe doses were established as well as a dosage ceiling, which is an objective of early stage human trials. In this trial of terminal cancer patients who had previously failed chemotherapy, radiotherapy, and surgery, 13 of 15 patients were evaluable for efficacy. Of these, 5 patients progressed, 7 patients were stable, and 1 patient had an objective Partial Response (PR) using commonly accepted RECIST criterion of response. 4 patients benefitted from Lovaxin C therapy. In the stable group, 3 patients experienced a reduction of their tumor burden by approximately 20%. The PR patient, who was diagnosed in 2004 and who had failed two courses of chemotherapy and a course of radiotherapy in 2004, upon demonstrating a response to Lovaxin C was given additional chemotherapy and surgery, and is currently tumor free, with an unimpaired performance status (ECOG=0, Karnofsky =100), and all laboratory values within normal limits.

Based upon the safety demonstrated in our phase I/II trial in advanced cervical cancer, we will be undertaking a phase II trial in stage 2/3 Cervical Intraepithelial Neoplasia (CIN). Stage 3 CIN is carcinoma *in situ*, and is a non-invasive form of cervical cancer. Stages 1 and 2 CIN are commonly called cervical dysplasia. Thus CIN is the name of the disease that can increase in severity to become invasive cervical cancer. While CIN frequently regresses spontaneously, over 250,000 surgical procedures are performed in the US annually to prevent progression from CIN to invasive cancer. This indication is characterized by young, otherwise healthy, women with strong immune systems and minimal disease. The company feels this will be a very responsive population to Lovaxin C and represent a significant market. While surgery is very effective, the removal of portions of the cervix can cause a condition termed

“incompetent cervix” which complicates full term pregnancy, and surgery does not confer any protection against recurrence of the disease. If Lovaxin C is a safe and effective treatment for CIN it will have the same therapeutic effect as surgery without the complications associated with removing tissue, and might provide a long lived immune response that confers protection against future recurrence.

Phase I/II studies will demonstrate therapeutic efficacy, as well as optimize the dosage and dosing regimen, the tests and assessments to be performed in phase III, to characterize the responding patient population, and to understand all factors possible for the purpose of defining and conducting a definitive test of the safety and efficacy of Lovaxin C for regulatory approval. Thereafter, and assuming that the results of this Phase II study are favorable, we intend to conduct Phase III clinical studies to demonstrate safety, efficacy and the potency of the investigational immunotherapy. Such studies are expected to occur in the next five to ten years. Throughout this process, we will be meeting with the FDA prior to and at the conclusion of each phase to reach a consensus before initiating any studies, to minimize regulatory risks during this clinical development process.

The Gynecologic Oncology Group (GOG), a collaborative treatment group associated with the National Cancer Institute, or NCI, has agreed to conduct the field work for an additional Phase II study in cervical cancer at its own expense (an estimated value of about \$1,500,000 to \$2,000,000). We estimate that we will conduct lab work valued at \$250,000 in support of this study. The timing for this trial is to be determined.

Finally, we are pursuing grant monies and an investigation team to research Lovaxin C effectiveness in treatment of head and neck cancer. The timing of this Phase II study is as yet unknown.

Following Phase III studies, we intend to prepare and file a Biologics License Application (BLA) with the FDA. Prior to submission of the BLA, depending upon the data, we intend to possibly seek a Special Protocol Assessment and/or a Fast Track designation from the FDA, which shortens the internal FDA review process. As we accrue clinical data demonstrating the safety, efficacy and potency of Lovaxin C in Phase I and II clinical studies, we will also explore other regulatory approval options with the FDA that could expedite the licensure of the final immunotherapy.

We intend to continue to devote a portion of our resources to the continued pre-clinical development and optimization of our product candidates as well as the continued research to expand our technology platform. Specifically, we intend to focus upon research relating to combining our *Listeria* System with new and additional tumor antigens which, if successful, may lead to additional cancer vaccines and other therapeutic products. 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 with universities, such as Penn and UCLA. See "Business - Partnerships and Agreements - University of Pennsylvania."

Background

Cancer

Despite tremendous advances in science, cancer remains a major health problem, and for many it continues to be the most feared of diseases. Although age-adjusted mortality rates for all cancer fell during the 1990's, particularly for the major cancer sites (lung, colorectal, breast, and prostate), mortality rates are still increasing in certain sites such as liver and non-Hodgkin's lymphoma. The American Cancer Society estimates that more than eight million Americans were treated for cancer in 1999. According to the HCUP, in 2000, treatment of the top five cancers resulted in \$10.8 billion in hospital costs.

Cancer is the second largest cause of death in the United States, exceeded only by heart disease. Approximately 1,399,790 new cases of cancer were expected to be diagnosed in 2006, and 564,830 Americans were expected to die from the disease. The NIH estimates the overall cost for cancer in the year 2005 at \$209.9 billion: \$74.06 billion for direct medical costs, \$17.5 billion for indirect morbidity costs (loss of productivity due to illness) and, \$118.4 billion for indirect mortality costs (cost of lost productivity due to premature death). (Source: cancer facts & figures 2006, American Cancer Society). The incidence rate of cervical cancer and CIN in the US is about 250,000 patients per year, with 800,000 cases in the top 7 pharmaceutical markets, worldwide (including the US).

Head and neck cancers is diagnosed in 49,000 Americans annually, 136,000 in the top 7 pharmaceutical markets, combined.

Prostate cancer is diagnosed in 253,000 Americans annually, 410,000 in the top 7 markets.

Breast cancer is diagnosed in 222,000 Americans, annually, 450,000 in the top 7 markets.

Immune System and Normal Antigen Processing

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

4

Innate Immunity:

Innate immunity is the first step in the recognition of a foreign antigen by lymphocytes is antigen processing by Antigen Processing Cells (APC). APCs are phagocytic cells that ingest particulate material, infectious agents and cellular debris. This non-specific ingestion Phagocytosis by these cells results in their activation and the release of soluble mediators called cytokines that assist the immune response.

Exogenous pathway of Adaptive Immunity (Class II pathway):

Proteins and foreign molecules ingested by APC are broken down inside digestive vacuoles into small pieces, called peptides, and the pieces are combined with proteins called Class 2 MHC (for Major Histocompatibility Complex) in a part of the cell called the endoplasmic reticulum. The MHC-peptide, termed and MHC-2 complex from the Class 2 (or exogenous) pathway, is then pushed out to the cell surface where it interacts with certain classes of lymphocytes (CD4+) such as helper T-cells that produce induce a proliferation of stimulate B-cells, which produce antibodies, or helper T cells that assist in the maturation of cytotoxic T-lymphocytes. This system is called the exogenous pathway, since it is the prototypical response to an exogenous antigen like bacteria.

Endogenous pathway of Adaptive Immunity (Class I pathway):

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

In clinical cancer, the body does not always recognize the cancer cells as foreign. *Listeria* based vaccines are unique for many reasons, one of which is that unlike viral vectors, DNA or peptide antigens or other vaccines, *Listeria* stimulates all of the above mechanisms of immune action. Our technology allows the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by utilizing a number of biologic characteristics of the *Listeria* bacteria and Advaxis proprietary antigen-fusion protein technology to stimulate multiple therapeutic immune mechanisms simultaneously in an integrated and coordinated manner.

Mechanism of Action

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

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

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

Figs 1-7. When *Listeria* enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called vacuoles or lysosomes, 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 are able to break out of the lysosomes and enter into the cytoplasm of the cell, where they are safe from lysosomal destruction. The bacteria multiply in the cell, and the *Listeria* is able to migrate into neighboring cells and spread without entering the extracellular space. Antigen produced by these bacteria enter the Class I pathway and directly stimulate a cytotoxic T cell response.

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

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

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

Thus, *Listeria* vaccines stimulate every immune pathway simultaneously. It has long been recognized that cytotoxic T lymphocytes (CTL) are the elements of the immune system that kill and clear cancer cells. The amplified CTL response to *Listeria* vaccines are arguably the strongest stimulator of CTL yet developed. The strength of this response is reflected in the data.

Also, many investigators have shown that LLO has adjuvant effects which result in the release of a variety of chemicals within the body, and within the tumor, termed cytokines, chemokines and co-stimulatory molecules. These agents facilitate the tumor killing effects of activated T cells by creating a local tumor environment that is most conducive for these actions to occur. Taken together, this is why it is believed that live *Listeria* which secrete LLO and escape from the phagocytotic vacuole exerts such profound immuno-stimulatory effects, while ingested *Listeria* that are digested within the vacuole and do not escape don't show these effects.

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

1. Very strong innate immune response
2. Stimulates inordinately strong killer T cell response
3. Stimulates helper T cells
4. Stimulates release of and/or up-regulates immuno-stimulatory cytokines, chemokines, co-stimulatory molecules
5. Adjuvant activity creates a local tumor environment that supports anti-tumor efficacy
6. Minimizes inhibitory T cells (T regs) and inhibitory cytokines and shifts to Th-17 pathway
7. Stimulates the development and maturation of all Antigen Presenting Cells and effector T cells & reduces immature myeloid cells

Research and Development Program

Overview

We use genetically engineered *Listeria* monocytogenes as a therapeutic agent. We start with an attenuated strain of *Listeria*, and then add to this bacterium a plasmid that encodes a protein sequence that includes a portion of the LLO molecule (including the PEST sequence) and the tumor antigen of interest. This protein is secreted by the *Listeria* inside the antigen processing cells, which then results in the immune response as discussed above.

We can use different tumor antigens (or other antigens: e.g. allergy or infectious disease) in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, Lovaxin C, uses a Human Papillomavirus derived antigen that is present in cervical cancers. Lovaxin B 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. The table below shows a list of potential products and their current status:

Product	Indication	Stage
Lovaxin C		

Edgar Filing: Advaxis, Inc. - Form 10KSB

	Cervical intraepithelial neoplasia (CIN), cervical cancer, head and neck cancer	Phase I/II completed in the fiscal fourth quarter 2007. Phase II study in CIN anticipated to commence in the 3 rd quarter fiscal 2008. The Gynecologic Oncology Group (GOG) of the National Cancer Institute has agreed to conduct a cervical cancer study timing to be determined.
Lovaxin P	Prostate cancer	Preclinical; Phase I study anticipated to commence in the 2 nd quarter fiscal 2009
Lovaxin B	Breast cancer	Preclinical; Phase I study anticipated to commence in mid fiscal 2009.

Partnerships and Agreements

University of Pennsylvania

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

This license, unless sooner terminated in accordance with its terms, terminates upon the later (a) expiration of the last to expire Penn patent rights; or (b) twenty years after the effective date. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date, in connection with Dr. Paterson and requires us to raise capital, 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 5.9% 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, as follows: 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 payments we are not expecting to begin paying within the next five years). In addition, under the license, executed on February 13, 2007 we are obligated to pay an annual maintenance fee on December 31, in 2008, 2009, 2010, 2011 and 2012 and each December 31st thereafter for the remainder of the term of the agreement of \$50,000, \$70,000, \$100,000, \$100,000 and \$100,000, respectively until the first commercial sale of a Penn licensed product. Under the amended and restated agreement during fiscal 2007 we paid a total of \$157,134 in license payments in addition to the \$215,700 previously paid or a total of \$372,834 in Penn license payments. Under the agreement prior to the amendment and restatement we were required to pay \$660,000 to Penn upon receiving financing or on certain dates on or before December 15, 2007, whichever is earlier. Overall the amended and restated agreement payment terms reflect lower near term requirements but were more than offset by higher longer 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 shall be entitled to certain milestone payments, as follows: \$2,500,000 shall be due for first commercial sale of the first product in the cancer field. In addition, \$1,000,000 will be due upon the date of first commercial sale of a product in each of the secondary strategic fields sold. Therefore, the total potential amount of milestone payments is \$3,500,000 in the cancer field.

As a result of our payment obligations under the license assuming we have net sales in the aggregate amount of \$100 million from our cancer products, our total payments to Penn over the next ten years could reach an aggregate of \$5,420,000. If over the next 10 years our net sales total an aggregate amount of only \$10 million from our cancer products, total payments to Penn could reach be \$4,445,000.

This license also grants us exclusive negotiation and exclusive options until June 17, 2009 to obtain exclusive licenses to new inventions on therapeutic vaccines developed by Drs' Paterson and Fred Frankel and their lab. Each option is granted to us at no cost and provides a six month exercise period from the date of disclosure. Once exercised we have a 90 day period to negotiate in good faith a comprehensive license agreement at licensing fees up to \$10,000. We exercised the option under this agreement resulting in approximately 28 patent applications. The license fees, legal expense, and other filing expenses for such applications are expected to cost approximately \$400,000.

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

Penn is not involved in management of our company or in our decisions with respect to exploitation of the patent portfolio.

9

Dr. Yvonne Paterson

Dr. Paterson is a Professor in the Department of Microbiology at Penn and the inventor of our licensed technology. She has been an invited speaker at national and international health field conferences and leading academic institutions. She has served on many federal advisory boards, such as the NIH expert panel to review primate centers, the Office of AIDS Research Planning Fiscal Workshop, and the Allergy and Immunology NIH Study Section. She has written over 140 publications in immunology (including a recently published book) with emphasis during the last several years on the areas of HIV, AIDS and cancer research. Her instruction and mentorship has trained over 30 post-doctoral and doctoral students in the fields of Biochemistry and Immunology, many of whom are research leaders in academia and industry.

Dr. Paterson is currently the principal investigator on grants from the federal government and charitable trusts totaling approximately \$560,000 dollars per year and the program director of training grants totaling approximately \$1.6 million per year. Her research interests are broad, but her laboratory has been focused for the past ten years on developing novel approaches for prophylactic vaccines against infectious disease and immunotherapeutic approaches to cancer. The approach of the laboratory is based on a long-standing interest in the properties of proteins that render them immunogenic and how such immunogenicity may be modulated within the body.

Consulting Agreement. We entered into a renewed consulting agreement with Dr. Paterson on January 28, 2005 with an initial term expiring on January 31, 2006 with automatic renewals for up to six additional periods of six months each pursuant to which we have had access to Dr. Paterson's consulting services for one full day per week. We are currently in our fourth renewal period. 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 agreement, as of October 17, 2007, Dr. Paterson receives \$7,000 per month. Upon the closing of an additional \$9 million in equity capital, Dr. Paterson's rates shall increase to \$9,000 per month. In addition, on February 1, 2005, Dr. Paterson received options to purchase 400,000 shares of our common stock at an exercise price of \$0.287 per share with 40,000 fully vested when granted and the remaining 360,000 options vesting equally over 48 months; provided that Dr. Paterson remains a consultant over the four year period. Since February 1, 2006 through October, 2007 she earned and accrued \$40,000 in fees and on October 24, 2007 she was paid \$40,000 for these fees, she holds options to purchase a total of 569,048 shares of Common Stock of which 456,548 are options exercisable within 60 days of October 31, 2007.

Sponsored Research Agreement.

We entered into a sponsored research agreement on December 6, 2006 with Penn and Dr. Paterson under which we are obligated to pay \$159,598 per year for a total period of 2 years covering the development of potential vaccine candidate based on our Listeria technology as well as other basic research projects.

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

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

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

Dr. David Filer

We have entered a consulting agreement with Dr. David Filer, a biotech consultant. The Agreement commenced on January 7, 2005 and has a six month term, which was extended upon the agreement of both parties. It provides that he will provide to us for three days per month during the term of the agreement assistance on our development efforts, reviewing our scientific technical and business data and materials and introducing us to industry analysts, institutional investors collaborators and strategic partners. In consideration for the consulting services we pay Dr. Filer \$2,000 per month. In addition, Dr. Filer received options to purchase 40,000 shares of common stock which are currently vested. As of October 1, 2007 we entered into a new two year agreement at a monthly fee of \$5,000 including 1,500,000 \$0.20 Warrants as consideration for his assistance in the raise on October 17, 2007 as well as his advisory services and assistance. This agreement is cancelable within 90 days notice.

Freemind Group LLC (“Freemind”)

We have entered into an agreement with Freemind to develop and manage our grant writing strategy and application program. With Advaxis to pay Freemind according to a fee structure based on achievement of grants awarded to us at the rate of 6-7% of the grant amount. Advaxis will also pay Freemind fixed consulting fees based on the type of grants submitted, ranging from \$5,000-7,000 depending on the type of application submitted. Freemind has extensive experience in accessing public financing opportunities, the national SBIR and related NIH/NCI programs. Freemind has assisted us in the past to file grant applications with NIH covering the use of Lovaxin C for cervical dysplasia. We have paid Freemind as of October 31, 2007, fees aggregating \$23,500.

University of California

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

Cobra Biomanufacturing PLC

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

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

In May 2007 we entered into a research and development consulting service agreement for manufacturing work in the amount of \$94,500 plus consumables. As of October 31, 2007 we’ve paid \$85,657 excluding consumables.

In October, 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. The contract is for \$576,450 plus consumables and as of October 31, 2007 we have paid \$194,408 excluding consumables.

LVEP Management, LLC

The Company entered into a consulting agreement with LVEP Management LLC (LVEP) dated as of January 19, 2005, and amended on April 15, 2005, and October 31, 2005, pursuant to which Mr. Roni Appel served as Chief Executive Officer, Chief Financial Officer and Secretary of the Company and was compensated by consulting fees paid to LVEP. LVEP is owned by the estate of Scott Flamm (deceased January 2006) previously, one of our directors and a principal shareholder. Pursuant to an amendment dated December 15, 2006 (“effective date”) Mr. Appel resigned as President and Chief Executive Officer and Secretary of the Company on the effective date, but remains as a board member and was a consultant to the company until December 15, 2007. The term of the agreement as amended is 24 months from effective date. Mr. Appel will devote 50% of his time over the first 12 months of the consulting period. Also as a consultant, he will be paid at a rate of \$22,500 per month in addition to benefits as provided to other

company officers. He will receive severance payments over an additional 12 months at a rate of \$10,416.67 per month and shall be reimbursed for family health care. All his stock options became fully vested on the effective date and are exercisable over the term. Also, Mr. Appel was issued 1,000,000 shares of our common stock on January 2, 2007. He received a \$250,000 bonus with \$100,000 paid on January 3, 2007 and the remainder was paid in October, 2007.

Pharm-Olam International Ltd. (“POI”)

In April 2005, we entered into a consulting agreement with Pharm-Olam International Ltd. (POI), based on which POI is to execute and manage our Phase I/II clinical trial in Lovaxin C with POI to contractually receive in consideration \$430,000 plus reimbursement of certain expenses of \$181,060. On December 13, 2006 we approved a change order reflecting the changes to the protocol the cost of which is estimated at \$92,000 for a total contractual obligation of \$522,000 excluding certain pass through expenses. As of October 31, 2007 we’ve paid \$294,800 toward the \$522,000 portion of the agreement and this agreement is still ongoing. In February 2007 we entered into a change order agreement for a pre-clinical toxicology study for \$79,920 and as of October 31, 2007 we’ve paid \$64,280.

The Investor Relations Group, Inc (“IRG”)

We entered into an agreement with IRG whereby IRG is to serve as an investor relations and public relations consultant. The term of this agreement is on a month to month basis. In consideration for performing its services, IRG is to be paid \$10,000 per month plus out of pocket expenses, and 200,000 common shares over a period of 18 months commencing October 1, 2005, provided the agreement has not terminated. Through October 31, 2007 we issued 200,000 shares per the agreement.

Biologics Consulting Group, Inc. (“BCG”)

On June 1, 2006 we entered into an agreement with BCG and on June 11, 2007 we entered into an amendment No. 1 to provide biologics regulatory consulting services to the Company in support of the IND submission to the FDA. The tasks to be performed under this Agreement will be agreed to in advance by the Company and BCG. The term of the amendment No. 1 is from June 1, 2007 to June 1, 2008. This is a time and material agreement.

MediVector, Inc. (“MI”)

In May 2007 we entered into a Master Service Agreement covering three projects to serve in clinical study planning, management and execution for our upcoming Phase II clinical study. The cost of the three projects are estimated to be approximately \$350,000 over the term. As of October 31, 2007 we’ve paid them \$47,000. The term of the projects is defined as the completion of the final study reports of the clinical trial.

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 (effective date) we entered into a 20-year exclusive worldwide license and a right to grant sublicenses pursuant to our license agreement with Penn. Penn currently has 12 issued and 46 pending patents in the United States and other countries including Japan, Canada, Israel, Australia, and the European Union, through the Patent Cooperation Treaty (PCT) system pursuant to which we have an exclusive license to exploit the patents. We believe that these patents will allow us to take a strong lead in the United States e field of *Listeria*-based therapy.

Patents

U.S. Patent No. 6,051,237, issued April 18, 2000. Patent Application No. 08/336,372, filed November 8, 1994 for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector.” Expires April 18, 2017.

U.S. Patent No. 6,565,852, issued May 20, 2003, Paterson, et al., CIP Patent Application No. 09/535,212, filed March 27, 2000 for “Specific Immunotherapy of Cancer Using a Live

Recombinant Bacterial Vaccine Vector.” Expires November 8, 2014.

U.S. Patent No. 6,099,848, issued August 8, 2000, Frankel et al., Patent Application No. 08/972,902 “Immunogenic Compositions Comprising DAL/DAT Double-Mutant, Auxotrophic, Attenuated Strains of Listeria and Their Methods of Use.” Filed November 18, 1997. Expires November 18, 2017.

U.S. Patent No. 6,504,020, issued January 7, 2003, Frankel et al. Divisional Application No. 09/520,207 “Isolated Nucleic Acids Comprising Listeria DAL And DAT Genes”. Filed March 7, 2000, Expires November 18, 2017.

U.S. Patent No. 6,635,749, issued October 21, 2003, Frankel, et al. Divisional U.S. Patent Application No. 10/136,253 for “Isolated Nucleic Acids Comprising Listeria DAL and DAT Genes.” Filed May 1, 2002, Expires November 18, 2017.

U.S. Patent No. 5,830,702, issued November 3, 1998, Portnoy, et al. Patent Application No. 08/366,477, filed December 30, 1994 for “Live, Recombinant Listeria SSP Vaccines and Productions of Cytotoxic T Cell Response” Expires November 3, 2015.

US Patent No. 6,767,542 issued July 27, 2004, Paterson, et al. Patent Application No. 09/735,450 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed December 13, 2000. Expires March 29, 2020.

US Patent No. 6,855,320 issued February 15, 2005, Paterson. Patent Application No. 09/537,642 for “Fusion of Non-Hemolytic, Truncated Form of Listeriolysin o to Antigens to Enhance Immunogenicity.” Filed March 29, 2000. Expires March 29, 2020.

US Patent No. 7,135,188 issued November 14, 2006, Paterson, Patent Application No. 10/441,851 for “Methods and compositions for immunotherapy of cancer.” Filed May 20, 2003. Expires November 8, 2014.

Patent Applications

U.S. Patent Application No. 10/239,703 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed September 24, 2002, Paterson, et al.

U.S. Patent Application No. 20050048081, “Immunogenic Compositions Comprising DAL/DAT Double Mutant, Auxotrophic Attenuated Strains Of Listeria And Their Methods Of Use,” Filed September 11, 2003, Frankel et al.

U.S. Patent Application No. 10/835,662, “Compositions and methods for enhancing the immunogenicity of antigens,” Filed April 30, 2004, Paterson et al.. U.S. Patent Application No. 20060135457 Methods for constructing antibiotic resistance free bacterial vaccines. Filed **June 22**, 2006.

U.S. Patent Application No. 20060104991 Methods for constructing antibiotic resistance free bacterial vaccines Filed May 18, 2006.

U.S. Patent Application No. 10/949,667, “Methods and compositions for immunotherapy of cancer,” Filed September 24, 2004, Paterson et al.

U.S. Patent Application No. 11/223,945, “Listeria-based and LLO-based vaccines,” Filed September 13, 2005, Paterson et al.

U.S. Patent Application No. 11/727,889, “Compositions and Methods Comprising a MAGE-B Antigen” Gravekamp, Paterson, Maciag. Filed March 28, 2007.

U.S. Patent Application No. 11/798,177 “Compositions and Methods Comprising KLK3 or SOLH1 Antigens” Filed May, 10, 2007.

U.S. Patent Application No. 11/376,564, “Compositions and methods for enhancing the immunogenicity of antigens,” Filed March 16, 2006, Paterson et al.

U.S. Patent Application No. 11/376,572, “Compositions and methods for enhancing the immunogenicity of antigens,” Filed March 16, 2006, Paterson et al.

Edgar Filing: Advaxis, Inc. - Form 10KSB

U.S. Patent Application No. 11/373,528, “Compositions and methods for Enhancing Immunogenicity of Antigens,” Filed March 13, 2006,

U.S. Patent Application No. 11/415,271, Methods and Compositions for Treatment of Non-Hodgkin’s Lymphoma, “Filed May 2, 2006, Protein Vaccine of.

U.S. Patent Application No. 10/541,614 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004.

U.S. Patent Application No. 11/203,408 for “Methods for Constructing Anitbiotic Resistance Free Vaccines.” Filed August 15, 2005.

U.S. Patent Application No. 11/203,415 for “Methods for Constructing Anitbiotic Resistance Free Vaccines.” Filed August 15, 2005.

U.S. Patent Application No. 20070003567 for “Compositions and methods for Enhancing Immunogenicity of Antigens”. Filed January 4, 2007.

U.S. Patent Application No. 20060269561 for “Compositions and Methods For Treatment of Non-Hodgkins Lymphoma”. Filed November 30, 2006.

U.S. Patent Application No. 20060210540 for “Compositions and Methods for enhancing the immunogenicity of Antigens” Filed September 21, 2006. Use of Protein Vaccine using Act A or LLO terminal fragments.

U.S. Patent Application No. 20050118184 for, “Compositions and methods for Enhancing Immunogenicity of Antigens” Filed June 2, 2005.

International

Patents

Australian Patent No. 730296, Patent Application No. 14108/99 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Issued November 13, 1998. Frankel, et al. Expires November 13, 2018.

Canadian Patent Application No. 2,309,790 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Filed May 18, 2000, Frankel, et al. Issued January 9, 2007.

Japanese Patent Application No. 515534/96, filed November 3, 1995 for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector”, Paterson, et al. Issued August 10, 2007

Patent Applications

Canadian Patent Application No. 2,204,666, for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector”. Filed November 3, 1995, Paterson et al.

Canadian Patent Application No. 2,404,164 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001. Paterson, et al.

European Patent Application No. 01928324.1 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001. Paterson, et al.

European Patent Application No. 98957980.0 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Filed May 18, 2000, Frankel, et al.

Israel Patent Application No. 151942 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001, Paterson, et al.

Japanese Patent Application No. 2001-570290 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001, Paterson, et al.

PCT International Patent Application No. PCT/US06/44681 for “Methods For Producing, Growing, And Preserving *Listeria* Vaccine Vectors.” Filed November 16, 2006, Rothman, et al.

Canadian Patent Application No. 2,581,331 for “*Listeria*-Based and LLO-Based Vaccines.” Filed September 14, 2005.

European Patent Application No. 5811815.9 for “Listeria-Based and LLO-Based Vaccines.” Filed September 14, 2005.

Japanese Patent Application No. 2007-533537 for “Listeria-Based and LLO-Based Vaccines.” Filed September 14, 2005.

PCT International Patent Application No. PCT/US07/06292 “Compositions and Methods for Enhancing the Immunogenicity of Antigens.” Filed March 13, 2007

Australian Patent Application No. 20044204751 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004.

Canadian Patent Application No. 2512812 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004

European Patent Application No. 1594560 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004

Hong Kong Patent Application No. 6104227.1 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004

Israeli Patent Application No. 169553 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004

Japanese Patent Application No. 2006-500840 for “Enhancing the Immunogenicity of Bioengineered Listeria Monocytogenes by Passing through Live Animal Hosts.” Filed January 8, 2004

Australian Patent No. 2005271247 for “Antibiotic Resistance Free DNA Vaccines.” Filed August 15, 2005

Canadian Patent Application No. 2577270 for “Antibiotic Resistance Free DNA Vaccines.” Filed August 15, 2005

European Patent Application No. 5810446.4 for “Antibiotic Resistance Free DNA Vaccines.” Filed August 15, 2005

Japanese Patent Application No. 2007-525862 for “Antibiotic Resistance Free DNA Vaccines.” Filed August 15, 2005

Australian Patent Application No. 2005271246 for “Methods for Constructing Antibiotic Resistance Free Vaccines.” Filed August 15, 2005

Canadian Patent Application No. 2,577,306 for “Methods for Constructing Antibiotic Resistance Free Vaccines.” Filed August 15, 2005

European Patent Application No. EP05808671.1 for “Methods for Constructing Antibiotic Resistance Free Vaccines.” Filed August 15, 2005

Japanese Patent Application No. 2007-525867 for “Methods for Constructing Antibiotic Resistance Free Vaccines.” Filed August 15, 2005

PCT International Patent Application.No. PCT/US06/43987 “LLO-Encoding DNA/Nucleic Acid Vaccines and Methods Comprising Same.” Filed November 13, 2006

United States

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

Pursuant to our license with Penn, we have an option to license from Penn any new future invention conceived by either Dr. Yvonne Paterson or by Dr. Fred Frankel in the vaccine area until June 17, 2009. We intend to expand our intellectual property base by exercising this option and gaining access to future inventions. Further, our consulting agreement with Dr. Paterson provides, among other things, that, to the extent that Dr. Paterson's consulting work results in new inventions, such inventions will be assigned to Penn, and we will have access to those inventions under license agreements to be negotiated. See "Item 1. Description of Business -Partnerships and agreements -Penn."

Our approach to the intellectual property portfolio is to aggressively 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 have become aware of a public company, Cerus Corporation, which has issued a press release claiming to have a proprietary *Listeria* -based approach to a cancer vaccine. We believe that through our exclusive license with Penn of U.S. Patent Nos. 5,830,702, 6,051,237 and 6,565,852, we have earliest known and dominant patent position in the United States for the use of recombinant *Listeria monocytogenes* expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. Based on searches of publicly available databases, we do not believe that Cerus or The University of California Berkeley (which is where Cerus' consulting scientist works) or any other third party owns any published *Listeria* patents or has any issued patent claims that might materially negatively affect our freedom to operate our business as currently contemplated in the field of recombinant *Listeria monocytogenes*.

Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent) which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. Cerus' allegations in the Opposition are that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live *Listeria*, is deficient because of (i) insufficient disclosure in the specifications of the granted claims, (ii) the inclusion of additional subject matter in the granted claims, and (iii) a lack of inventive steps of the granted claims of the EP 835 Patent. This patent does not affect the manner in which Advaxis makes or uses its vaccine products but would preclude Cerus from using certain methodologies they require.

On November 29, 2006, following oral proceedings, the Opposition Division of the European Patent Office determined that the claims of the patent as granted should be revoked due to lack of inventive step under European Patent Office rules based on certain prior art publications. This decision has no material effect upon our ability to conduct business as currently contemplated.

As of November 20, 2007, Cerus spun its immunotherapy/listeria development effort off into a separate, privately financed company.

We have reviewed the formal written decision and filed an appeal on May 29, 2007. As of December 31, 2007 no ruling has been made. There is no assurance that we will be successful. If such ruling is upheld on appeal, our patent position in Europe may be eroded. The likely result of this decision will be increased competition for us in the European market for recombinant live *Listeria* based vaccines for tumor specific antigens. Regardless of the outcome, we believe that our freedom to operate in Europe, or any other territory, for recombinant live *Listeria* based vaccine for tumor specific antigen products will not be diminished.

Lovaxin has been registered as a trademark in Israel, Australia, South Korea, Hong Kong and Taiwan.

The U.S. trademark application for Lovaxin has been allowed by the United States Patent and Trademark Office. Trademark applications in China and in the European Union for Lovaxin are also pending. The Chinese application was recently published for opposition, and the European Union application has passed through the opposition stage.

The Canadian trademark application for Lovaxin has been opposed by Aventis Pharma S.A. That opposition proceeding is pending.

In 2006, Nycomed Pharma, of Sweden, claimed owner of the mark Levaxin, filed an opposition to our CTM (European Union) application to register Lovaxin. The opposition was refused solely on procedural grounds. If our CTM application is ultimately granted, Nycomed Pharma may file to cancel such registration of Lovaxin. Nycomed Pharma has also demanded that we cease to use Lovaxin in Sweden.

The U.S. trademark applications for Advaxis and for Advaxis and design, Serial Nos. 78/252527 and 78/252586, have been withdrawn. Oppositions to those applications have been terminated in favor of Aventis, Inc.

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 contract research organizations.

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

Protocols. Before commencing human clinical studies, the sponsor of a new drug must typically receive governmental and institutional approval. In the US Federal approval is obtained by submitting an investigational new drug application, or IND, to the FDA. The application contains what is known in the industry as a *protocol*. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

- who must be recruited as qualified participants;
- how often, and how to administer the drug;
- what tests to perform on the participants; and
- what dosage of the drug to give to the participants.

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, but its records are audited by the FDA. Its members are not appointed by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board is convened by the institution where the protocol will be conducted and its role is to protect the rights of the participants in the clinical studies. It must approve the protocols to be used, and then oversees the conduct of the study, including: the communications which the company or contract research organization conducting the study at that specific site proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

Clinical Trials. Human clinical studies or testing of a potential product prior to Federal approval are generally done in three stages known as Phase I through 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 healthy participants, typically 24 to 100 people at a time. 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. Cancer drugs, however, are a special case, as they are not given to normal healthy people. Typically, cancer therapeutics are initially tested on very late stage cancer patients.

Phase II. Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to three years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks

and probable effectiveness, a company will continue to review the substance in Phase III studies. It is during phase II that everything that goes into a phase III test is determined.

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

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

Phase IV. The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

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 Food and Drug Administration 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 FDA and the sponsor to improve the efficiency of preclinical and clinical development, and to reach agreement on the design of the major clinical efficacy studies that will be needed to support approval. Under the Fast Track program, a sponsor also has the option to submit and receive review of parts of the NDA or BLA on a rolling schedule approved by FDA, which expedites the review process.

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

The Orphan Drug Act provides incentives to develop and market drugs ("Orphan Drugs") for rare disease conditions in the United States. A drug that receives Orphan Drug designation and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. A drug which is considered by the FDA to be different than such FDA-approved Orphan Drug is not barred from sale in the United States during such exclusive marketing period even if it receives approval for the same claim. We can provide no assurance that the Orphan Drug Act's provisions will be the same at the time of the approval, if any, of our products.

Other Regulations

Various Federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movements, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, are

used in connection with our research or applicable to our activities. They include, among others, the United States 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.

Manufacturing

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

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

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both from biotechnology firms and from major pharmaceutical and chemical companies, including Antigenics, Inc., Avi BioPharma, Inc., Biomira, Inc., Cellgenesis Inc., Biovest International, Cell Genesys, Inc., Cerus Corporation, Dendreon Corporation, 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 relative 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. See "Item 1. Description of Business - Research and Development Programs" and "Item 1. Description of Business - Competition".

We have become aware of a public company, Cerus Corporation, which has issued a press release claiming to have a proprietary *Listeria* -based approach to a cancer vaccine. We believe that through our exclusive license with Penn, we have earlier priority filing dates of certain applications and a dominant patent position for the use of recombinant *Listeria* monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. Based on searches of publicly available databases, we do not believe that Cerus or The University of California Berkeley (which is where Cerus' consulting scientist works) or any other third party owns any published *Listeria* patents or has any issued patent claims that might materially negatively affect our freedom to operate our business as currently contemplated in the field of recombinant *Listeria* monocytogenes.

Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent) which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. Cerus' allegations in the Opposition are that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live *Listeria*, is deficient because of (i) insufficient disclosure in the specifications of the granted claims, (ii) the inclusion of additional subject matter in the granted claims, and (iii) a lack of inventive steps of the granted claims of the EP 835 Patent.

On November 29, 2006, following oral proceedings, the Opposition Division of the European Patent Office determined that the claims of the patent as granted should be revoked due to lack of inventive step under European Patent Office rules based on certain prior art publications. This decision has no material effect upon our ability to conduct business as currently contemplated, as this patent does not affect the manner in which Advaxis makes or uses its vaccine products but would preclude Cerus from using certain methodologies they require.

We have reviewed the formal written decision and filed an appeal on May 29, 2007. As of December 31, 2007 no ruling has been made. There is no assurance that we will be successful. If such ruling is upheld on appeal, our patent position in Europe may be eroded. The likely result of this decision will be increased competition for us in the European market for recombinant live *Listeria* based vaccines for tumor specific antigens. Regardless of the outcome, we believe that our freedom to operate in Europe, or any other territory, for recombinant live *Listeria* based vaccine for tumor specific antigen products will not be diminished.

For more information about Cerus Corporation and its claims with respect to *Listeria* -based technology, you should visit their web site at www.cerus.com or to view it's publicly filed documents.

Scientific Advisory Board

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

Dr. Yvonne Paterson. For a description of our relationship with Dr. Paterson, please see above.

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

Pramod Srivastava, Ph.D. Dr. Srivastava is Professor of Immunology at the University of Connecticut School of Medicine, where he is also Director of the Center for Immunotherapy of Cancer and Infectious Diseases. He holds the Physicians Health Services Chair in Cancer Immunology at the University. 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 (1994 to 1999). He serves presently on the Board of Directors of two privately held companies: Ikonisys (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 20 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 serves as the Chief of the Section of Infectious Diseases. 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. On two occasions the graduating medical school class dedicated their yearbook to Dr. Lorber. 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 the University of Pennsylvania 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 the University of Pennsylvania 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 the University of Pennsylvania. 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 28+ awarded US patents as well as their international counterparts. He has served and still serves on many national and international review boards and panels including NIH Study section, WHO advisory panels, the NIBSC, Department of Veterans Affairs Scientific Review Panel, as well as the FDA Advisory panel - CEBR, and AACTG 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 14 Doctoral Student Committees.

Employees

As of October 31, 2007, we employ nine employees, all of whom are on a full-time basis. Of these nine employees eight employees hold the following degrees: 1 MD/PhD, 4 PhD's 1 MS & 2 BS and five serve in the research and one serves in the clinical development area and three serve in the general and administration area.

Our Chairman and Chief Executive Officer, Mr. Tom Moore joined our company on December 15, 2006. Mr. Roni Appel previously served as our President and Chief Executive Officer during the fiscal year 2006 resigned from this position on December 15, 2006. Mr. Appel still serves as a board of director member and remains as consultant to the company until December 15, 2007.

Dr. John Rothman our Vice President of Clinical and Officer joined the company on March 7, 2005. Fred Cobb our Vice President, Finance and Principal Financial Officer joined the company on February 20, 2006. Doctor Vafa Shahabi our Director of Research and Development joined the company on March 1, 2005. Two of our Senior Scientists joined the company from Doctor Paterson's lab at Penn.

We anticipate increasing the number of employees in the clinical area and the research and development area to support clinical requirements, and in the general and administrative and business development areas over the next two years.

Compensation of Officers and Directors

The aggregate compensation paid to our directors and executive officers, including stock based compensation option value and other compensation for the twelve months ended October 31, 2005, 2006 and 2007 was approximately \$715,583, \$970,669 and \$2,071,941, respectively. This amount has no amounts set aside or accrued to provide pension, severance, retirement, or similar benefits or expenses, and does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders and other benefits commonly reimbursed or paid by similarly situated companies. With the exception of Mr. Berman who receives \$2,000 a month

in company stock at a set price of \$0.50 per share, none of our directors so far has received any compensation for his services as a director other than stock options and reimbursement of expenses.

Compensation Committee Interlocks And Insider Participation

There were no interlocking relationships between us and other entities that might affect the determination of the compensation of its directors and executive officers.

RISK FACTORS

Risks Specific to Us

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 losses are expected to continue, due to the substantial investment in research and development, for the next five to ten or more years. At October 31, 2007, we had an accumulated deficit of \$12,072,742 and stockholders' equity of \$4,267,979. We expect to spend substantial additional sums on the continued 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.

We will require substantial additional financing in order to meet our business objectives.

Although we believe that the net proceeds received from private placements including our October 2007 offering of shares of our common stock and warrants, will be sufficient to finance our currently-planned operations through the third fiscal Quarter 2008, they will not be sufficient to meet the full fiscal year 2008 nor, our longer-term cash requirements or cash requirements for the commercialization of certain products currently in development. We will be required to sell additional equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, to raise substantial additional capital during the five-to ten-year period of product development and the FDA testing through Phase III testing. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. If we fail to raise sufficient additional financing, we will not be able to develop our product candidates, we will be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates and outsource or eliminate several business functions. Even if we are successful in raising such additional financing, we may not be able to successfully complete planned clinical trials, development, and marketing of all, or of any, of our product candidates. In such event, our business, prospects, financial condition and results of operations could be materially 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 may not be able to conduct our clinical trial for Lovaxin C. See "Management's Discussion and Analysis and Results of Operations."

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 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 may not be able to conduct our next Lovaxin C clinical trial.

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 complete successfully the development or marketing of any new products. See “Item 1. Description of Business - Research and Development Program.”

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development (R&D) 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 must outsource our clinical trials and are in the process of negotiating with third parties to manage and execute our next trial. We are not certain that we will successfully conclude our recruitment for the completion of our next clinical trials. Delay in concluding recruitment and such agreements would delay the initiation of the Phase II Trial of Lovaxin C.

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 could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. 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 Lovaxin C.

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

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

The successful development of biopharmaceuticals is highly uncertain.

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

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

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

We must comply with significant government regulations.

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

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an Investigational New Drug Application, or IND, to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a Company and acceptance and approval by the FDA of a New Drug Application, or NDA, for a drug product or a "BLA" for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our product candidates through clinical testing and to market.

In 2007, we completed a phase I/II trial of Lovaxin C that demonstrated both safe doses and a dosage ceiling in end-state cervical cancer patients. Based in part upon this work, we intend to open a U.S. IND in early 2008; however no assurances can be provided that such an IND will be granted by the FDA.

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

We received in February 2006 permission from the appropriate governmental agencies in Israel, Mexico and Serbia to conduct in those countries Phase I clinical testing of *Lovaxin C*, our Listeria-based cancer vaccine that targets cervical cancer in women. The study was completed in the fourth fiscal quarter of 2007. However, the testing, marketing and manufacturing of any product for sale or distribution in the United States will require filing of an IND with and the approval of the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval or further approval, if any, from Israel, Mexico or Serbia and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products is ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from governmental authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist. See "Item 1. Description of Business - Governmental Regulation."

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

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the *Listeria* System, and the proprietary technology of others with which we have entered into licensing agreements. We have licensed twelve patents that have been issued and thirty-nine patents are pending from Penn. Further, we rely on a combination of trade secrets and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking rights.

We believe that our technology and the technology licensed from Penn do not infringe the rights of others; however, we cannot assure you that the technology licensed from Penn will not, in the future be found to infringe upon the rights of others. We have become aware of a public company, Cerus Corporation, which has issued a press release claiming to have a proprietary *Listeria* -based approach to a cancer vaccine. We believe that through our exclusive license with Penn, we have earlier priority filing dates of certain applications and a dominant patent position for the use of recombinant *Listeria* monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. Based on searches of publicly available databases, we do not believe that Cerus or The University of California Berkeley (with whom Cerus' consulting scientist is affiliated) or any other third party owns any published *Listeria* patents or has any issued patent claims that might, if we fail our Cerus appeal, materially negatively affect our freedom to operate our business as currently contemplated in the field of recombinant *Listeria* monocytogenes.

Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent), which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. Cerus' allegations in the Opposition are that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live *Listeria*, is deficient because of insufficient disclosure in the specifications of the granted claims, the inclusion of additional subject matter in the granted claims, and a lack of inventive steps of the granted claims of the EP 835 Patent. We appealed this decision.

On November 29, 2006, following oral proceedings, the Opposition Division of the European Patent Office determined that the claims of the patent as granted should be revoked due to lack of inventive step under European Patent Office rules based on certain prior art publications. This decision has no material effect upon our ability to conduct business as currently contemplated.

We have reviewed the formal written decision and filed an appeal on May 29, 2007. As of December 31, 2007 no ruling has been made. There is no assurance that we will be successful. If such ruling is upheld on appeal, our patent position in Europe may be eroded. The likely result of this decision will be increased competition for us in the European market for recombinant live *Listeria* based vaccines for tumor specific antigens. Regardless of the outcome, we believe that our freedom to operate in Europe, or any other territory, for recombinant live *Listeria* based vaccine for tumor specific antigen products will not be diminished.

As of November 20, 2007, Cerus spun its immunotherapy development efforts off into a privately financed company.

Others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology or the licensed technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of our intellectual property, enter into royalty agreements or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on acceptable terms, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking right. See “Item 1. Description of Business—Patents and Licenses.”

We are dependent upon our license agreement with Penn, as well as proprietary technology of others.

The manufacture and sale of any products developed by us will involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained licenses with regard to the use of Penn’s patents as described herein and certain of such processes, products and information of others, we can provide no assurance that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights which may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms.

If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing or the patents of others, potentially causing increased costs and delays in product development and introduction or preclude the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future. Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. Furthermore, in 2001, an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642. These patent rights are included in the patent rights licensed by us from Penn. GSK, Penn and we expect that the issue will be resolved through a correction of inventorship to add certain GSK inventors, where necessary and appropriate, an assignment of GSK’s possible rights under these patent rights to Penn, and a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above. See “Item 1. Description of Business - Patents and Licenses.” To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. See “Item 1. Description of Business -Partnerships and Agreements - Penn.”

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

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

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

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

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

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

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

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

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

We currently have insurance covering our clinical trial sites. We do not have product liability insurance because we do not have products on the market. We intend to obtain insurance coverage and to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

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

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

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

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

At the date of this report, we have nine employees. We intend to expand our operations and staff as needed. Our new employees may include key managerial, technical, financial, research and development and operations personnel who will not have been fully integrated into our operations. We expect the expansion of our business to place a significant strain on our limited managerial, operational and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials of Lovaxin C and other products, and unable to adequately address our management needs. See “Item 6. Management’s Discussion and Analysis or Plan of Operations,” “Item 1. Description of Business - Strategy,” and “Item 1. Description of Business—Employees.”

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

We depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants, including Yvonne Paterson, Ph.D. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. See “Item 10. Executive Compensation—Employment Agreements.”

Risks Related to the Biotechnology / Biopharmaceutical Industry

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

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and

elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

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

We expect that our products under development and in clinical trials will address major markets within the cancer sector with a superior technology that is both safer and more effective than our competitors. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop products, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position. See "Item 1. Description of Business - Research and Development Programs" and "Item 1. Description of Business - Competition."

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

The price of our common stock may be volatile.

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

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- major catastrophic events;
- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our product candidates, including results of our clinical trials;
- events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to be listed or quoted on the Nasdaq Stock Market, American Stock Exchange or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

Our common stock is considered to be “penny stock.”

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

- with a price of less than \$5.00 per share;
- that are not traded on a “recognized” national exchange;
- whose prices are not quoted on the NASDAQ automated quotation system; or
- of issuers with net tangible assets less than \$2,000,000 (if the issuer has been in continuous operation for at least three years) or \$5,000,000 (if in continuous operation for less than three years), or with average revenue of less than \$6,000,000 for the last three years.

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

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

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

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

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

Our common stock began trading on the OTC:BB on July 28, 2005 and is quoted under the symbol ADXS.OB. The quotation of our common stock on the OTC: BB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short

time and our shareholders could suffer losses or be unable to liquidate their holdings. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price.

There is no assurance of an established public trading market.

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

- The issuance of new equity securities pursuant to a future offering;

Changes in interest rates;

Competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;

Variations in quarterly operating results;

Change in financial estimates by securities analysts;

The depth and liquidity of the market for our common stock;

Investor perceptions of our company and the technologies industries generally; and

General economic and other national conditions.

Our common stock is quoted on the OTC:BB. In addition we are subject to a covenant to use our best efforts to apply to be listed on the American Stock Exchange or quoted on the Nasdaq National Stock Market.

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

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

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

Companies trading on the OTC:BB, such as us, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTC:BB. If we fail to remain current on our reporting requirements, we could be removed from the OTC:BB. As a result, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning with our year ending October 31, 2008, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting for fiscal years ending on or after December 15, 2007. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we have maintained, in all material respects, effective internal control over financial reporting for fiscal years ending on or after December 15, 2008. We have not yet completed our assessment of the effectiveness of our internal control over

financial reporting. We expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

Our executive officers, directors and principal stockholders control our business and may make decisions that are not in our best interests.

Our officers, directors and principal stockholders, and their affiliates, in the aggregate, beneficially own, as of October 31, 2007, 14.7% of the outstanding shares of our common stock on a fully diluted basis. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders.

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

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

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

We are authorized to issue 500,000,000 shares of our common stock. As of October 31, 2007, we had 107,957,977 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants and options. As of October 31, 2007, we had outstanding 8,512,841 options to purchase shares of our common stock at a weighted exercise price of \$0.22 per share and outstanding warrants to purchase 84,380,437 shares of our common stock, with exercise prices ranging from \$0.195 to \$0.274 per share along with 3,333,333 warrants purchased for \$0.149 with an exercise price of \$0.001 per share. Pursuant to our 2004 Stock Option Plan, 2,381,525 shares of common stock are reserved for issuance under the plan. Pursuant to our 2005 Stock Option Plan, 5,600,000 shares of common stock are reserved for issuance under the plan. In addition, we have granted 1,001,399 options as non-plan options. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution.

Shares eligible for future sale may adversely affect the market.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. The Company's most recent prospectus covered 109,482,917 issued and outstanding shares of our common stock, which represents approximately 101.4% of our outstanding shares of our common stock as of October 17, 2007. As additional shares of our common stock become available for resale in the public market pursuant to this offering, and otherwise, the supply of our common stock will increase, which could decrease its price. Some or all of the shares of common stock may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares of common stock. In general, a person who has held restricted shares for a period of one year may, upon filing with the SEC a notification on Form 144, sell into the market common stock in an amount equal to the greater of 1% of the outstanding shares or the average weekly number of shares sold in the last four weeks prior to such sale. Such sales may be repeated once each three months, and any of the restricted shares may be sold by a non-affiliate after they have been held two years.

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

Our Certification of Incorporation provide for the authorization of 5,000,000 shares of “blank check” preferred stock. Pursuant to our Certificate of Incorporation, our Board of Directors is authorized to issue such “blank check” preferred stock with rights that are superior to the rights of stockholders of our common stock, at a purchase price then approved by our Board of Directors, which purchase price may be substantially lower than the market price of shares of our common stock, without stockholder approval. Such issuances can dilute the tangible net book value of shares of our common stock.

32

We do not intend to pay dividends.

We have never declared or paid any dividends on our securities. We currently intend to retain our earnings for funding growth and, therefore, do not expect to pay any dividends in the foreseeable future.

Item 2: Description of Property.

Our corporate offices are currently located at a biotech industrial park located at 675 Rt. 1, Suite B113, North Brunswick, NJ 08902. We have entered into a lease effective June 1, 2005; and certain lease amendments as of November 15, 2005 and a second Lease Amendment as of March 15, 2006 and a third lease amendment as of October 1, 2006 with the New Jersey Economic Development Authority (NJEDA) which will continue on a monthly basis for two research and development Laboratory units (total of 1,600 s.f.) and two offices (total of 250 s.f.). Our facility will be sufficient for our near term purposes and the facility offers additional space for our foreseeable future. Our monthly payment on this facility is approximately \$6,000 per month. The term of the lease expires on May 31, 2008 and upon mutual consent, this lease may be renewed for one year. NJEDA billed the company for a one time Milestone Rent based on raising greater than \$1MM but less than \$5MM equity raise. The company paid \$2,500 for this milestone for the conversion of the debenture into the equity. In the event that our facility should, for any reason, become unavailable, we believe that alternative facilities are available at competitive rates.

Item 3: Legal Proceedings.

We have become aware of a public company, Cerus Corporation, which has issued a press release claiming to have a proprietary *Listeria* -based approach to a cancer vaccine. We believe that through our exclusive license with Penn of U.S. Patent Nos. 5,830,702, 6,051,237 and 6,565,852, we have earliest known and dominant patent position in the United States for the use of recombinant *Listeria* monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. Based on searches of publicly available databases, we do not believe that Cerus or The University of California Berkeley (which is where Cerus' consulting scientist works) or any other third party owns any published *Listeria* patents or has any issued patent claims that might materially negatively affect our freedom to operate our business as currently contemplated in the field of recombinant *Listeria* monocytogenes.

Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent) which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. Cerus' allegations in the Opposition are that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live *Listeria*, is deficient because of (i) insufficient disclosure in the specifications of the granted claims, (ii) the inclusion of additional subject matter in the granted claims, and (iii) a lack of inventive steps of the granted claims of the EP 835 Patent. This patent does not affect the manner in which Advaxis makes or uses its vaccine products but would preclude Cerus from using certain methodologies they require.

On November 29, 2006, following oral proceedings, the Opposition Division of the European Patent Office determined that the claims of the patent as granted should be revoked due to lack of inventive step under European Patent Office rules based on certain prior art publications. This decision has no material effect upon our ability to conduct business as currently contemplated.

As of November 20, 2007, Cerus spun its immunotherapy/*Listeria* development effort off into a separate, privately financed company.

We have reviewed the formal written decision and filed an appeal on May 29, 2007. As of December 31, 2007 no ruling has been made. There is no assurance that we will be successful. If such ruling is upheld on appeal, our patent position in Europe may be eroded. The likely result of this decision will be increased competition for us in the

European market for recombinant live *Listeria* based vaccines for tumor specific antigens. Regardless of the outcome, we believe that our freedom to operate in Europe, or any other territory, for recombinant live *Listeria* based vaccine for tumor specific antigen products will not be diminished.

As of the date hereof, there are no material legal proceedings threatened against us. In the ordinary course of our business we may become subject to litigation regarding our products or our compliance with applicable laws, rules, and regulations.

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

NONE

PART II**Item 5: Market For Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.**

Since July 28, 2005, our Common Stock has quoted on the OTC:BB symbol ADXS. The following table shows, for the periods indicated, the high and low sales prices per share of our Common Stock as reported by the OTC:BB. As of December 31, 2007 there were approximately 132 stockholders of record and the closing sale price of Advaxis common stock \$0.17 per share as reported by the OTC:BB.

	Common Stock			
	Fiscal 2007		Fiscal 2006	
	High	Low	High	Low
First Quarter November 1-January 31	\$ 0.21	\$ 0.14	\$ 0.27	\$ 0.16
Second Quarter February 1- April 30	\$ 0.54	\$ 0.15	\$ 0.37	\$ 0.21
Third Quarter May 1 -July 31	\$ 0.36	\$ 0.24	\$ 0.30	\$ 0.17
Fourth Quarter August 1, - October 31	\$ 0.27	\$ 0.10	\$ 0.25	\$ 0.13

Item 5(a)

Equity Compensation Plan (1)

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	7,511,442(2)	\$ 0.22	470,083
Equity compensation plans not approved by security holders	1,001,399(3)	\$ 0.143	-
Total	8,512,841		470,083

(1) As of October 31, 2007

(2) The Company's 2004 and 2005 Stock Option Plan

(3) Options granted outside of plans

Item 6: Management’s Discussion and Analysis or Plan of Operation

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

Overview

We are a biotechnology company utilizing multiple mechanisms of immunity with the intent to develop cancer vaccines that are more effective and safer than existing vaccines. We believe that by using our licensed *Listeria* System to engineer a live attenuated *Listeria monocytogenes* bacteria to secrete a protein sequence containing a tumor-specific antigen, we will enable the body's immune system to process and recognize the antigen as if it were foreign, creating the immune response needed to attack the cancer. The licensed *Listeria* System, developed at Penn over the past 10 years, provides a scientific basis for believing that this therapeutic approach induces a significant immune response to the tumor. Accordingly, we believe that the *Listeria* System is a broadly enabling platform technology that can be applied in many cancers, infectious diseases and auto-immune disorders.

Our therapeutic approach is based upon, and we have obtained an exclusive license with respect to, the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn involving the creation of genetically engineered *Listeria* that stimulate the innate immune system and induce an antigen-specific immune response involving humoral and cellular components.

We have focused our initial development efforts on four lead compounds and completed a Phase I/II clinical study of Lovaxin C, a potential cervical cancer vaccine, in the fourth fiscal quarter 2007. See "Item 1. Description of Business - Research and Development Program".

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 on June 18, 1998 under the name Great Expectations and Associates, Inc. In 1999, we became a reporting company under the Exchange Act, as amended. We were a publicly-traded "shell" company without any business until November 12, 2004, when we acquired Advaxis through the Share Exchange, as a result of which Advaxis became our wholly-owned subsidiary and our sole operating company. We then changed our name to Advaxis. On March 29, 2006, we merged into Advaxis (the subsidiary) and thereby changed our state of incorporation from the state of Colorado to the state of Delaware. For financial reporting purposes, we have treated the Share Exchange as a recapitalization. As a result of the foregoing as well as the fact that the Share Exchange is treated as a recapitalization of Advaxis rather than as a business combination, the historical financial statements of Advaxis became our historical financial statements after the Share Exchange.

On November 12, 2004, December 8, 2004 and January 4, 2005 (the "Three Tranche Private Placement") we effected a private placement to "accredited investors", as defined in Rule 501(a) of Regulation D under the Securities Act of an aggregate of 11,334,495 shares of our common stock and warrants to purchase an aggregate of 11,334,495 additional shares for net proceeds of approximately \$3,253,000.

On November 12, 2004, \$595,000 of our promissory notes plus accrued interest was converted into an aggregate of 2,136,441 shares of our common stock and warrants to purchase 2,223,549 shares of our common stock.

On January 12, 2005, we effected a private placement to an accredited investor for approximately \$1,100,000 of 3,832,753 shares of our common stock and warrants to purchase 3,832,753 additional shares.

On February 2, 2006 we sold to Cornell Capital Partners ("Cornell"), \$3,000,000 principal amount of our Secured Convertible Debentures due February 1, 2009 (\$1,500,000 on February 2, 2006 and \$1,500,000 on March 8, 2006) bearing interest at 6% per annum payable at maturity and issued it warrants to purchase 4,500,000 shares of our common stock. The net proceeds were approximately \$2,740,000.

A substantial part of our efforts in 2007 consisted of obtaining additional financing in order to continue our research and development efforts. This included taking the following actions:

On August 24, 2007, we issued and sold an aggregate of \$600,000 principal amount promissory notes bearing interest at a rate of 12% per annum and warrants to purchase an aggregate of 150,000 shares of our common stock to three investors including Thomas Moore, our Chief Executive Officer. Mr. Moore invested \$400,000 and received warrants for the purchase of 100,000 shares of Common Stock. The promissory note and accrued but unpaid interest thereon are convertible at the option of the holder into shares of our common stock upon the closing by the Company of a sale of its equity securities aggregating \$3,000,000 or more in gross proceeds to the Company at a conversion rate which shall be the greater of a price at which such equity securities were sold or the price per share of the last reported trade of our common stock on the market on which the common stock is then listed, as quoted by Bloomberg LP. At any time prior to conversion, we have the right to prepay the promissory notes and accrued but unpaid interest thereon.

On October 17, 2007, we effected a private placement to accredited investors for approximately 49,228,334 shares of common stock and warrants to purchase 36,921,250 additional shares. Concurrent with the closing of the private placement, we sold for \$1,996,667 to CAMOFI Master LDC and CAMHZN Master LDC an aggregate of (i) 10,000,000 shares of Common Stock, (ii) 10,000,000 \$0.20 Warrants, and (iii) 5-year warrants to purchase an additional 3,333,333 shares of Common Stock at a purchase price of \$0.001 per share. Both warrants provide that they may not be exercised if, following the exercise, the holder will be deemed to be the beneficial owner of more than 9.99% of Registrant's outstanding shares of Common Stock.

Pursuant to an advisory agreement dated August 1, 2007 with Centrecourt, Centrecourt provided various strategic advisory services to the Company in consideration thereof. The Company paid Centrecourt \$328,000 in cash and issued 2,483,333 \$0.20 Warrants to Centrecourt, which Centrecourt assigned to the two affiliates.

At the closing of the private placement, we exercised our right under an agreement dated August 23, 2007 with YA Global Investments, L.P. f/k/a Cornell Capital Partners, L.P. ("Yorkville"), to redeem the outstanding \$1,700,000 principal amount of our Secured Convertible Debentures due February 1, 2009 owned by Yorkville, and to acquire from Yorkville warrants expiring February 1, 2011 to purchase an aggregate of 4,500,000 shares of Common Stock. We paid an aggregate of (i) \$2,289,999 to redeem the debentures at the principal amount plus a 20% premium and accrued and unpaid interest, and (ii) \$600,000 to repurchase the warrants.

Plan of Operations

We intend to use a significant portion of the proceeds of the sales described above to conduct a Phase II clinical trial in cervical intraepithelial neoplasia (CIN) using Lovaxin C, one of our lead product candidates in development using our *Listeria* System. We also have used the funds to further expand our clinical, research and development teams to further develop the product candidates and to expand our manufacturing capabilities and strategic activities. Our corporate staff will be responsible for the general and administrative activities.

During the next 12 to 24 months, we anticipate that our strategic focus will be to achieve several objectives described under "Item 1. Description of Business - Strategy" and as follows:

- Present our completed Phase I/II clinical study of Lovaxin C which document the practicability of using this agent safely in the therapeutic treatment of cervical cancer;
- Initiate our Investigational New Drug Application (IND) with the FDA for our Phase II clinical study of Lovaxin C in the therapeutic treatment of CIN;
- Initiate our Phase II clinical study of Lovaxin C in the therapeutic treatment of cervical intraepithelial neoplasia;
- Continue the development work necessary to bring Lovaxin P in the therapeutic treatment of prostate cancer into clinical trials, and initiate that trial;
- Continue the development work necessary to bring Lovaxin B in the therapeutic treatment of breast cancer into clinical trials, and initiate that trial;
- Continue the pre-clinical development of other product candidates, as well as continue research to expand our technology platform; and
 - Initiate strategic and development collaborations with biotechnology and pharmaceutical companies.

The annual cost to maintain our current staff, overhead and preclinical expense is estimated to be in the range of \$2.5 to \$3.0 million in fiscal year 2008. We estimate the cost of our current phase II clinical study in therapeutic treatment of CIN to be in the range of \$3.0 to \$4.0 million for the 12 to 24 month period. Therefore we anticipate our current cash will be adequate to meet our needs through the third fiscal quarter but not over the entire 2008 fiscal year. Our phase II Lovaxin C clinical study is estimated to commence in mid fiscal 2008. We hope to commence the work in prostate and breast cancer in fiscal 2009. The timing and estimated costs of these projects are difficult to predict. In fiscal 2008 our anticipated needs for equipment, personnel and space should not be significant. We do plan on adding a few key employees in fiscal 2008 to address our growing clinical, regulatory and reporting needs.

Overall given the clinical stage of our business our financial needs are driven in large part by the outcomes of clinical trials and preclinical findings. The cost of these clinical trial projects is significant. As a result we will be required to raise additional debt or equity in the near future. If the clinical outcomes are successful and the value of the Company increases it is more than likely we will attempt to accelerate the timing of the required financing and, conversely if the trial or trials aren't successful we may slow our spending and the timing of additional financing will be deferred. While we will attempt to attract a corporate partnership and grants we have not assumed the receipt of any additional financial resources in our cash planning.

For more information about Penn and commitments see "Item 1. Description of Business - Partnerships and agreements - University of Pennsylvania."

Accounting Policies; Impact of Growth

Below is a brief description of basic accounting principles which we have adopted in determining our recognition of expenses, as well as a brief description of the effects that our management believes that our anticipated growth will have on our revenues and expenses in the 12 months ended October 31, 2008.

Revenues. We do not anticipate that we will record any material revenues during at least the twelve months ending October 31, 2008. When we recognize revenues, we anticipate that they will be principally grants and licensing fees.

Expenses. We recorded operating expenses for the years ended October 31, 2005, 2006 and 2007 of \$2,395,328, \$3,481,226 and \$4,757,190, respectively.

The preparation of financial statements in accordance with GAAP involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ substantially from these estimates. Significant estimates include the fair value and recoverability of the carrying value of intangible assets (trade marks, patents and licenses) the fair value of options, the fair value of embedded conversion features, warrants, recognition of on-going clinical trial, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policy involves significant estimates and judgment. We amortize trademark, license and patent costs over their estimated useful lives. We may be required to adjust these lives based on advances in science and competitor actions. We review the recorded amounts of trademarks, licenses and patents at each period end to determine if their carrying amount is still recoverable based on expectations regarding potential licensing of the intangibles or sales of related products. Such an assessment, in the future, may result in a conclusion that the assets are impaired, with a corresponding charge against earnings.

In accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, revenue from license fees and grants is recognized when the following criteria are met; persuasive evidence an arrangement exists, services have been rendered, the contract price is fixed or determinable, and collectability is reasonably assured. In licensing arrangements, delivery does not occur for revenue recognition purposes until the license term begins. Nonrefundable upfront fees received in exchange for products delivered or services performed that do not represent the culmination of a separate earnings process will be deferred and recognized over the term of the agreement using the straight-line method or another method if it better represents the timing and pattern of performance.

For revenue contracts that contain multiple elements, we will determine whether the contract includes multiple units of accounting in accordance with EITF No. 00-21, Revenue Arrangements with Multiple Deliverables. Under that guidance, revenue arrangements with multiple deliverables are divided into separate units of accounting if the

delivered item has value to the customer on a standalone basis and there is objective and reliable evidence of the fair value of the undelivered item.

Research and Development. During the years ended October 31, 2005, 2006 and 2007, we recorded research and development expenses of \$1,175,536, \$1,404,164 and \$2,128,096, respectively. Such expenses were principally comprised of manufacturing scale up and process development, license fees, sponsored research, clinical trial and consulting expenses. We recognize research and development expenses as incurred.

Commencing with the year ending October 31, 2008, we anticipate that our research and development expenses will increase as a result of our expanded development and commercialization efforts related to clinical trials, product development, and development of strategic and other relationships required ultimately for the licensing, manufacture and distribution of our product candidates. We regard four of our product candidates as major research and development projects. The timing, costs and uncertainties of those projects are as follows:

Lovaxin C - Phase I/II & II trial Summary Information (Cervical Cancer & CIN)

Cost incurred to date: approximately \$2,350,000

Estimated future costs: \$150,000 Phase I and \$3,000,000 - \$4,000,000 Phase II

Anticipated completion date of Phase II: Fiscal year 2009

Uncertainties:

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

One or more serious adverse events in patients enrolled in the trial

difficulty in recruiting patients

delays in the program

Commencement of material cash flows:

Unknown at this stage and dependent upon a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

Lovaxin P - Pre Clinical and Phase I Trial Summary Information (Prostate Cancer)

Cost incurred to date: \$150,000

Estimated future costs: \$1,500,000

Anticipated completion dates: fourth quarter of fiscal 2009 or beyond

Risks and uncertainties:

Obtaining favorable animal data

Proving low toxicity in animals

Manufacturing scale up to GMP level

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

The occurrence of a severe or life threatening adverse event in a patient

Delays in the program

Lovaxin B - Phase I trial Summary Information (Breast Cancer)

- Cost incurred to date: \$450,000
- Estimated future costs: \$2,000,000
- Anticipate completion dates: Fiscal 2010 or beyond

Risks and uncertainties: See Lovaxin in P (above)

Commencement of material cash flows:

· Unknown at this stage, dependent upon a licensing deal or to a marketing collaboration subject to regulatory approval to market and sell the product.

General and Administrative Expenses. During the years ended October 31, 2005, 2006 and 2007, we recorded general and administrative expenses of \$1,219,792, \$2,077,062 and \$2,629,094, respectively. General and administrative costs primarily include the salaries and expenses for executive, consultants, finance, facilities, insurances, accounting and legal assistance, as well as other corporate and administrative functions that serve to support Advaxis' current and our future operations and provide an infrastructure to support this anticipated future growth. For the year ending October 31, 2008 and beyond, we anticipate that our general and administrative costs will increase significantly due to the increased compliance requirements, including, without limitation, legal, accounting, and insurance expenses, to comply with periodic reporting and other regulations applicable to public companies.

Other Income (Expense). During the years ended October 31, 2005, 2006 and 2007 we recorded interest expense (\$7,307), (\$437,299) and (\$607,193), respectively. Interest expense, relates primarily to our then outstanding secured convertible debenture commencing at the closing dates of our Two Tranche Private Placement on February 2 and March 8, 2006 extinguished on October 17, 2007. During the years ended October 31, 2005, 2006 and 2007 we recorded interest income of \$43,978, \$90,899 and \$63,407, respectively, earned on investments. As of October 17, 2007, the extinguishment date, the changes due to the fair market value of common stock warrants and embedded derivative was recorded as a \$1,159,846 gain compared to a \$(2,802,078) loss recorded as of October 31, 2006. Due to the eliminations of the convertible debenture, we also recorded a gain on extinguishment of the Debenture of \$1,212,510 in addition to \$319,967 gain on retirement of a note with Penn totaling \$1,532,477. For fiscal 2008, we anticipate minimal interest expense and increased interest income due to the elimination of the convertible debenture and additional cash investment.

Recently Issued Accounting Pronouncements.

In July 2006, the FASB issued FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes (an interpretation of FASB Statement No. 109)" ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in tax positions and requires that companies recognize in their financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The Company will be required to adopt the provisions of FIN 48 beginning in fiscal 2008, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings as well as requiring additional disclosures. The Company does not expect the adoption of FIN 48 to have a material impact on its financial reporting.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement*. This statement does not require any new fair value measurement, but it provides guidance on how to measure fair value under other accounting pronouncements. SFAS No. 157 also establishes a fair value hierarchy to classify the source of information used in fair value measurements. The hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad categories. This standard is effective for the Company beginning in fiscal 2009. The Company is currently evaluating the impact of this pronouncement on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. The election to measure the financial instrument at fair value is made on an instrument-by-instrument basis for the entire instrument, with few exceptions, and is irreversible. SFAS No. 159 is effective for the Company beginning in the fiscal year ending October 31, 2009. The Company is currently evaluating

the impact of this pronouncement on its financial statements.

Results of Operations

Year Ended October 31, 2007 Compared to the Year Ended October 31, 2006

Revenue. Our revenue decreased by \$277,760, or 64%, from \$431,961 for the year ended October 31, 2006 to \$154,201 for the year ended October 31, 2007 primarily due to the completion of the HER-2 SBIR, FUSION and FLAIR grants in fiscal 2006 partially offset by a new grant and the continuation of a State of New Jersey grant.

Research and Development Expenses. Research and development expenses increased by \$723,932, or 52%, from \$1,404,164 for the twelve months ended October 31, 2006 to \$2,128,096 for the twelve months ended October 31, 2007. This increase was principally attributable to the following:

- Clinical trial expenses decreased \$20,132, or 5%, from \$421,915 to \$401,783 due to the higher start-up expenses of our clinical trial in March 2006 partially offset by the lower expenses incurred at the end of the trial in fiscal 2007.
- Wages, salaries and related lab costs increased by \$183,650, or 31%, from \$600,329 to \$783,979 principally due to adding one research and development staff at the end of fiscal 2006 and a higher bonus payment in fiscal 2007.
- IND/NDA and developmental consulting expenses increased \$130,466 or 293% from \$44,494 to \$174,960 primarily due to costs related to the preparation to file an IND and establishing the Phase II clinical trial protocol.
- Subcontracted expenses increased by \$51,220, or 21%, from \$249,315 to \$300,535 reflecting the additional subcontract work performed by Dr. Paterson, pursuant to certain grants.
- Manufacturing expenses increased \$327,625, or 1253%, from \$26,155 to \$353,780; primarily the result of the fiscal 2007 manufacturing program in anticipation of the Lovaxin C Phase II clinical trial planned in fiscal 2008.
- Toxicology study expenses increased \$30,722, or 92%, from \$33,558 to \$64,280; principally as a result of the initiation of additional toxicology studies by Pharm Olam in connection with our Lovaxin C clinical trial in anticipation of our IND filing in fiscal 2008.

General and Administrative Expenses. General and administrative expenses increased by \$552,032, or 27%, from \$2,077,062 for the year ended October 31, 2006 to \$2,629,094 for the year ended October 31, 2007, primarily attributable to the following:

- Wages, option expense and benefits increased by \$453,409 or 119% from \$382,526 to \$835,935 primarily due to hiring a CEO in fiscal 2007 previously filled by a consultant (LVEP) these costs did not occur in the fiscal 2006.
- All other costs increased by \$84,319 or 24% from \$354,042 to \$438,361 primarily due to higher depreciation expense, insurance, accounting and other operating costs.
- Consulting fees and related expenses decreased by \$86,813, or 104%, from \$885,349 for the twelve months ended October 31, 2006 to \$798,536 for the same period in 2007 arising from a lower bonus expense and consulting fees primarily for LVEP (prior Chief Executive Officer) and consultants partially offset by a \$251,269 increase in option expense due to accelerated vesting of the previous CEO options (LVEP).
- A decrease in legal fees and public relations expenses of \$23,666, or 5%, from \$441,621 for the twelve-months ended October 31, 2006 to \$417,955 for the same period in 2007, primarily as a result of lower legal costs.
- Conference expenses increased by \$124,779 or 922% from \$13,527 to \$138,306 due to increased fund raising activities and communication efforts.

Other Income (expense). Other Income (expense) improved by \$5,297,014 from (\$3,148,478) recorded as expense for the twelve months ended October 31, 2006 to \$2,148,536 recorded as income for the twelve months ended October 31, 2007. The breakdown is as follows:

- Interest income earned on investments decreased by \$27,492 in fiscal year 2007 from \$90,899 in fiscal year 2006 to \$63,407 in 2007.
- Gain on Note Retirements in the fiscal year 2007 totaled \$1,532,477 compared to no gain recorded in fiscal 2006. There were two gains; the first was a gain due to the amendment and restatement of a license agreement that involved a note with Penn of \$319,967 which was forgiven as well as a gain recorded on the early extinguishment of the Debentures with Cornell Partners of \$1,212,510. In the case of the debentures, the reacquisition price was less than the net carrying value and therefore a gain on extinguishment was recorded.
- Change in fair value of common stock warrants & embedded derivatives recorded in fiscal 2007 improved by \$3,961,924 from an expense recorded in fiscal 2006 of (\$2,802,078) to income of \$1,159,846 in fiscal year 2007. This change primarily resulted from this early extinguishment of the debenture on October 17, 2007 and a decrease in fair value as recorded in fiscal 2007 compared to fiscal 2006.
- Interest expense increased by \$169,894, or 39% from fiscal year 2006 of (\$437,299) to (\$607,193) for fiscal year 2007. Interest expense, relates primarily to our then outstanding secured convertible debenture that commenced at the closing dates of February 2 and March 8, 2006 and were extinguished on October 17, 2007.

No provision for income taxes was made for the year ended October 31, 2006 or 2007 due to significant tax losses during and prior to such periods.

Year Ended October 31, 2006 Compared to the Year Ended October 31, 2005

Revenue. Our revenue decreased by \$120,907, or 22%, from \$552,868 for the year ended October 31, 2005 to \$431,961 for the year ended October 31, 2006 primarily due to the decrease in the FLAIR grant money received by the Company.

Research and Development Expenses. Research and development expenses increased by \$228,628, or 19%, from \$1,175,536 for the twelve months ended October 31, 2005 to \$1,404,164 for the twelve months ended October 31, 2006. This increase was principally attributable to the following:

- Clinical trial expenses increased \$328,389, or 351%, from \$93,525 to \$421,915 due to the start-up of our clinical trial in March 2006.
- Wages, salaries and related lab costs increased by \$409,542, or 215%, from \$190,804 to \$600,329 principally due to our expanded research and development staffing in early 2006.
- Subcontracted expenses increased by \$107,949, or 76.3%, from \$141,366 to \$249,315 reflecting the additional subcontract work performed by Dr. Paterson at Penn, pursuant to certain grants.
- Manufacturing expenses decreased \$383,387, or 93.6%, from \$409,542 to \$26,155; the result of the fiscal 2005 manufacturing program in anticipation of the Lovaxin C for toxicology and clinical trials required in early 2006.
- Toxicology study expenses decreased \$259,548, or 88.6%, from \$293,105 to \$33,558; principally as a result of the initiation in the earlier period of toxicology studies by Pharm Olam in connection with our Lovaxin C product candidates in anticipation of the clinical studies in 2006.

General and Administrative Expenses. General and administrative expenses increased by \$857,270, or 70.3%, from \$1,219,792 for the year ended October 31, 2005 to \$2,077,062 for the year ended October 31, 2006, primarily attributable to the following:

- Consulting fees and related expenses increased by \$580,197, or 190%, from \$305,153 for the twelve months ended October 31, 2005 to \$885,349 for the same period in 2006 arising from a higher bonus expense, stock expense, consulting fees and the fair value of options primarily for the Chief Executive Officer(s) and consultants.
- An increase in legal fees and public relations expenses of \$391,611, or 364%, from \$107,370 for the twelve-months ended October 31, 2005 to \$498,611 for the same period in 2006, primarily as a result of an increase in the costs arising from being publicly held.
- A decrease in offering and analyst expenses of \$132,498 incurred in fiscal 2005 while none were incurred in 2006.

Other Income (expense). Other Income (expense) increased by (\$3,185,149) from income of \$36,671 for the twelve months ended October 31, 2005 to (\$3,148,478) recorded as expense for the twelve months ended October 31, 2006. During the years ended October 31, 2005 and 2006 we recorded interest expense of (\$7,307), and (\$437,299) respectively. Interest expense, relates primarily to our outstanding secured convertible debenture commencing at the closing dates on February 2 and March 8, 2006. Interest earned on investments amounted to \$43,978 and \$90,899, respectively. In the year ended October 31, 2006 there is a net change of (\$2,802,078) in fair value of common stock warrants and embedded derivative liabilities in expense (non-cash item) as of October 31, 2006 compared to the original value for the secured convertible debenture.

No provision for income taxes was made for the year ended October 31, 2005 or 2006 due to significant tax losses during and prior to such periods.

Liquidity and capital resources

At October 31, 2005, 2006 and 2007, our cash was \$2,075,206, \$2,761,166 and \$4,041,984 we had working capital of \$1,365,742, \$1,254,651 and \$3,069,172, respectively.

To date, our principal source of liquidity has been cash provided by private placements of our securities. Some of these offerings have been structured so as to be exempt from the prospectus delivery requirements under the Securities Act. Principal uses of our cash have been to support research and development, clinical study, financing and working capital. We anticipate these uses will continue to be our principal uses in the future.

On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation through the Share Exchange. The transaction was accounted for as a recapitalization. Accordingly, the historical financial statements of Advaxis are our financial statements for reporting purposes. Advaxis, Inc has changed its fiscal year to the year ended October 31st and as a result is providing herein its audited financial statements for the years ended October 31, 2006 and 2007.

Although we believe that the net proceeds received by us from the October 17, 2007 private placement will be sufficient to finance our currently planned operations through the third fiscal quarter 2008, they will not be sufficient to meet the full fiscal year 2008 nor our longer-term cash requirements or our cash requirements for the commercialization of any of our existing or future product candidates. We will be required to sell equity or debt securities or to enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, The Company has suffered losses that raise substantial doubt about its ability to continue as a going concern, The financial statement do not include any adjustments that might result from the outcome of this uncertainty.

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

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

We expect our future sources of liquidity to be primarily equity capital raised from investors, as well as licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties.

On November 12, 2004, we sold to accredited investors at a closing of the first tranche of the Three Tranche Private Placement 117 Units at \$25,000 per unit for an aggregate purchase price of \$2,925,000. Each Unit is comprised of (i) 87,108 shares of our common stock and (ii) a five-year warrant to purchase 87,108 shares of our common stock at an exercise price of \$0.40 per share. At the initial closing, the accredited investors received an aggregate of 10,191,638 shares of common stock and warrants to purchase 10,191,638 shares of common stock. In addition, on November 12, 2004, \$595,000 aggregate principal amount of outstanding convertible promissory notes including accrued interest, were converted into units on the same terms as those upon which the Units sold, accordingly, an aggregate of 2,136,441 shares of common stock and additional warrants to purchase 2,136,441 shares of common stock.

On December 8, 2004, we sold to accredited investors at the closing of the second tranche 8 units for an aggregate purchase price of \$200,000 and the investors received an aggregate of 696,864 shares of common stock and additional warrants to purchase 696,864 shares of Common Stock.

On January 4, 2005, we sold to accredited investors at a third tranche 5.12 Units for an aggregate purchase price of \$128,000, 445,993 shares of common stock and additional warrants to purchase 445,993 shares of Common Stock were issued.

Pursuant to the terms of a investment banking agreement, dated March 19, 2004, by and between us and Sunrise Securities, Corp. ("Sunrise" or the "Placement Agent"), we issued to the Placement Agent and its designees an aggregate of 2,283,445 shares of common stock and warrants to purchase up to an aggregate of 2,666,900 shares of common

stock. The securities were issued along with a cash fee of \$50,530 in consideration for the services of Sunrise, as our placement agent in the Private Placement.

On January 12, 2005, we sold an accredited investor at a closing the third tranche 44 units for an aggregate purchase price of \$1,100,000 and therefore an aggregate of 3,832,752 shares of common stock and warrants to purchase 3,832,752 shares of common stock.

Pursuant to a Securities Purchase Agreement dated February 2, 2006 and March 8, 2006 we sold to Cornell \$3,000,000 principal amount of our 6% Secured Convertible Debentures due February 1, 2009 (the "Debentures") at face amount (before commissions and related fees of \$260,000), along with five year A Warrants to purchase 4,200,000 shares of common stock at the price of \$0.287 per share and five year B Warrants to purchase 300,000 shares of common stock at a price of \$0.3444 per share.

The 6% per annum interest due at maturity was charged to expense. The investment-banking fee paid to Yorkville Advisors in connection with the Debentures in the amount of \$240,000 was charged, in view its relationship with Cornell, as additional interest expense over the three-year term of the Debentures. The remaining transaction fees of \$20,000 was capitalized.

The Company calculated the fair value of the embedded conversion of the Company's above mentioned warrants to be recorded as a warrant liability at the end of the fiscal year 2006. As a result of this calculation at the end of October 31, 2006 included in the Statement of Operations for the Company is a \$2,802,078 non-cash expense in the establishment of the liabilities related to the warrants and embedded conversion feature for the entire year. Upon full satisfaction of the Debentures (whether through its repayment or conversion to equity), the fair value of the remaining warrants on that date will be reclassified to equity.

On October 17, 2007, pursuant to a Securities Purchase Agreement, we completed a private placement resulting in \$7,384,235 in gross proceeds, pursuant to which we sold 49,228,334 shares of common stock at a purchase price of \$0.15 per share solely to institutional and accredited investors and warrants to purchase 36,921,250 additional shares at a purchase price of \$0.20 per share. Each investor received a five-year warrant to purchase an amount of shares of common stock that equals 75% of the number of shares of common stock purchased by such investor in the offering. Concurrent with the closing of the private placement, we sold for \$1,996,666 to CAMOFI Master LDC and CAMHZN Master LDC an aggregate of (i) 10,000,000 shares of Common Stock, (ii) 10,000,000 \$0.20 Warrants, and (iii) 5-year warrants to purchase an additional 3,333,333 shares of Common Stock at a purchase price of \$0.001 per share. Both warrants provide that they may not be exercised if, following the exercise, the holder will be deemed to be the beneficial owner of more than 9.99% of Registrant's outstanding shares of Common Stock.

Pursuant to an advisory agreement dated August 1, 2007 with Centrecourt, Centrecourt provided various strategic advisory services to the Company in consideration thereof. Registrant paid Centrecourt \$328,000 in cash and issued 2,483,333 \$0.20 Warrants to Centrecourt, which Centrecourt assigned to the two affiliates.

At the closing of the private placement, we exercised our right under an agreement dated August 23, 2007 with YA Global Investments, L.P. f/k/a Cornell Capital Partners, L.P. ("Yorkville"), to redeem the outstanding \$1,700,000 principal amount of our Secured Convertible Debentures due February 1, 2009 owned by Yorkville, and to acquire from Yorkville warrants expiring February 1, 2011 to purchase an aggregate of 4,500,000 shares of Common Stock. We paid an aggregate of (i) \$2,289,999 to redeem the debentures at the principal amount plus a 20% premium and accrued and unpaid interest, and (ii) \$600,000 to repurchase the warrants. As a result the Company recorded a gain on re