Advaxis, Inc. Form S-1 October 22, 2009

File No.	333-

As filed with the Securities and Exchange Commission on October 22, 2009

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM S-1

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

### ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

2836 (Primary Standard Industrial Classification Code Number) 02-0563870 (I.R.S. Employer Identification No.)

Technology Centre of New Jersey 675 US Highway One North Brunswick, New Jersey 08902 (732) 545-1590

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

Mr. Thomas A. Moore Chief Executive Officer Technology Centre of New Jersey 675 US Highway One North Brunswick, New Jersey 08902 (732) 545-1590

(Name, address, including zip code, and telephone number, including area code, of agent for service)

### Copies to:

Robert H. Cohen, Esq. Greenberg Traurig, LLP The MetLife Building 200 Park Avenue New York, New York 10166 Phone: (212) 801-9200

Fax: (212) 801-6400

Approximate date of commencement of proposed sale to the public. From time to time after this Registration Statement becomes effective, as determined by the selling stockholders named in the prospectus contained herein.

If any of the Securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering: "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering: "

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

Large accelerated filer "

Accelerated filer "

Non-accelerated filer "(Do not check if smaller reporting company)

Smaller reporting company x

### CALCULATION OF REGISTRATION FEE

Title of each class of		Proposed maximum	Proposed maximum	
securities to be	Amount to be	offering price per	aggregate offering	Amount of
registered	registered(1)	share	price	registration fee(2)
Common Stock, par value				
\$0.001 per share	33,750,000 shares(3)	\$0.20(4)	\$6,750,000	\$376.65

- (1) In accordance with Rule 416(a) under the Securities Act, the registrant is also registering hereunder an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.
- (2) Pursuant to Rule 429 under the Securities Act of 1933, the prospectus constituting a part of this registration statement also relates to 46,921,250 shares of the Registrant's common stock issuable upon exercise of warrants, which were previously registered under the Registrant's Registration Statement on Form SB-2 (No. 333-147752), for which a filing fee has been previously been paid.
- (3) Represents shares of common stock issuable upon exercise of a warrant at an initial exercise price of \$0.20 per share.

### (4) Calculated pursuant to rule 457(g).

Pursuant to Rule 429 under the Securities Act of 1933, the prospectus included in this Registration Statement is a combined prospectus and also relates to 46,921,250 shares of common stock previously registered and remaining unsold under the Registrant's Registration Statement on Form SB-2 (File No. 333-147752). Accordingly, this Registration Statement, which is a new registration statement, also constitutes Post-Effective Amendment No. 1 to Registration Statement No. 333-147752, which post-effective amendment shall hereafter become effective concurrently with the effectiveness of this Registration Statement and in accordance with Section 8(c) of the

Securities Act of 1933. If securities previously registered under Registration Statement No. 333-147752 are offered and sold before the effective date of this Registration Statement, the amount of previously registered securities so sold will not be included in the prospectus hereunder.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the commission, acting pursuant to section 8(a) may determine.

### **Explanatory Note**

Advaxis, Inc. previously filed a Registration Statement on Form SB-2 (File No. 333-147752) with the U.S. Securities and Exchange Commission (the "SEC") on November 30, 2007, which was declared effective on January 22, 2008 (the "Prior Registration Statement"). The Prior Registration Statement registered up to 109,482,917 shares of our common stock for resale by the selling stockholders named therein, including 50,254,583 shares of our common stock issuable upon the exercise of warrants held by such selling stockholders.

Pursuant to Rule 429 under the Securities Act of 1933, the prospectus included in this Registration Statement is a combined prospectus and also relates to 46,921,250 shares of common stock registered and remaining unsold under the Prior Registration Statement. Accordingly, this Registration Statement, which is a new registration statement, also constitutes Post-Effective Amendment No. 1 to the Prior Registration Statement and is being filed to, among other things; (i) include audited financial statements for our fiscal year ended October 31, 2008 and to reflect additional information disclosed in our Annual Report on Form 10-KSB (the "Annual Report") for our fiscal year ended October 31, 2008, filed with the SEC on January 29, 2009; (ii) include unaudited interim financial statements for our three and nine months ended July 31, 2009 and to reflect additional information disclosed in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K filed with the SEC subsequent to our Annual Report; (iii) convert the Prior Registration Statement from a Registration Statement on Form SB-2 to a Registration Statement on Form S-1; (iv) remove from registration by means of this post-effective amendment an aggregate of 3,333,333 outstanding shares of our common stock which were covered by the Prior Registration Statement, but are no longer required to be registered under the terms of our registration rights agreement with certain of the named selling stockholders; and (v) update the section titled "Selling Stockholders" contained in the prospectus included herein to reflect, among other things, (a) earlier sales or dispositions of our common stock made by certain of the named selling stockholders and (b) the removal from registration of an aggregate of 3,333,333 outstanding shares of our common stock which were covered by the Prior Registration Statement.

Accordingly, this Registration Statement on Form S-1 (i) carries forward from the Prior Registration Statement an aggregate of 46,921,250 shares of our common stock issuable upon the exercise of warrants held by certain of the named selling stockholders and (ii) registers an additional 33,750,000 shares of our common stock which have not previously been registered. All filing fees payable in connection with the initial filing of the Prior Registration Statement were previously paid at the time of the initial filing of the Prior Registration Statement. A registration fee of \$376.65 in respect of the 33,750,000 shares being registered in this Registration Statement on Form S-1 is being paid concurrently with the filing of this Registration Statement on Form S-1.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

### PROSPECTUS, SUBJECT TO COMPLETION, DATED OCTOBER 22, 2009

ADVAXIS, INC.

80,671,250 Shares

Common Stock

This prospectus relates to the resale of up to (i) 33,750,000 shares of our common stock underlying a warrant issued to an affiliate of Optimus Capital Partners, LLC, which we refer to as Optimus, in our September 2009 preferred equity financing and (ii) 46,921,250 shares of our common stock underlying warrants issued in connection with our October 2007 private placement. The shares covered by this prospectus may be sold by the selling stockholders from time to time in the over-the-counter market or other national securities exchange or automated interdealer quotation system on which our common stock is then listed or quoted, through negotiated transactions at negotiated prices or otherwise at market prices prevailing at the time of sale.

Pursuant to registration rights granted by us to the selling stockholders, we are obligated to register the shares to be acquired upon exercise of warrants held by these selling stockholders. The distribution of the shares by the selling stockholders is not subject to any underwriting agreement. We will receive none of the proceeds from the sale of shares by the selling stockholders. The selling stockholders identified in this prospectus will receive the proceeds from the sale of the shares. However, we may receive the proceeds from the exercise of the warrants held by the selling stockholders, if any, to the extent the warrants are not exercised on a cashless basis. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

Our common stock is quoted on the Over-The-Counter Bulletin Board, or OTC Bulletin Board, under the symbol ADXS.OB. On October 21, 2009, the last reported sale price per share for our common stock as reported by the OTC Bulletin Board was \$0.13.

Investing in our common stock involves a high degree of risk. We urge you to carefully consider the "Risk Factors" beginning on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus	is	,	2009
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#### ABOUT THIS PROSPECTUS

You should only rely on the information contained in this prospectus. We have not authorized anyone to give any information or make any representation about this offering that differs from, or adds to, the information in this prospectus or in its documents that are publicly filed with the SEC. Therefore, if anyone does give you different or additional information, you should not rely on it. The delivery of this prospectus does not mean that there have not been any changes in our condition since the date of this prospectus. If you are in a jurisdiction where it is unlawful to offer the securities offered by this prospectus, or if you are a person to whom it is unlawful to direct such activities, then the offer presented by this prospectus does not extend to you. This prospectus speaks only as of its date except where it indicates that another date applies.

Market data and certain industry forecasts used in this prospectus were obtained from market research, publicly available information and industry publications. We believe that these sources are generally reliable, but the accuracy and completeness of such information is not guaranteed. We have not independently verified this information, and we do not make any representation as to the accuracy of such information.

In this prospectus, the terms "we", "us", "our" and "our company" refer to Advaxis, Inc., a Delaware corporation, resulting from the reincorporation of our company from Colorado to Delaware described elsewhere in this prospectus (unless the context references such entity prior to the June 20, 2006 reincorporation from Colorado to Delaware, in which case it refers to the Colorado entity).

The name Advaxis is our trademark. Other trademarks and product names appearing in this prospectus are the property of their respective owners.

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#### PROSPECTUS SUMMARY

This summary highlights some important information from this prospectus, and it may not contain all of the information that is important to you. You should read the following summary together with the more detailed information regarding us and our common stock being sold in this offering, including "Risk Factors" and our financial statements and related notes, included elsewhere in this prospectus.

### Our Company

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

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

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

Product	Indication	Stage
ADXS11-001	Cervical Cancer	Phase I Company sponsored & completed in 2007.
	Cervical Intraepithelial Neoplasia	Phase II Company sponsored study anticipated to commence in January 2010.
	Cervical Cancer	Phase II Company sponsored study anticipated to commence in January 2010 in India. 110 Patients with advanced cervical cancer.
	Cervical Cancer	Phase II The Gynecologic Oncology Group of the National Cancer Institute may conduct a study (timing to be determined).
ADXS31-142	Prostate Cancer	Phase I Company sponsored (timing to be determined).
ADXS31-164	Breast Cancer	Phase I Company sponsored (timing to be determined).

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2008 and July 31, 2009, we had an accumulated deficit of \$17,533,044 and \$17,971,843, respectively, and

shareholders' deficiency of \$839,311 and \$13,639,132, respectively.

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

We intend to continue to devote a substantial portion of our resources to the continued pre-clinical development and optimization of our technology so as to develop it to its full potential and to find appropriate new drug candidates. Specifically, we intend to conduct research relating to developing our Listeria technology using new tumor antigens, and to develop new strains of Listeria, which may lead to additional cancer and infectious disease products, to improve the Listeria platform by developing new Listeria strains that are more suitable as live vaccine vectors, and to continue to develop the use of the Listeria virulence factor LLO as a component of a fusion protein based vaccine. These activities may require significant financial resources, as well as areas of expertise beyond those readily available. In order to provide additional resources and capital, we may enter into research, collaborative or commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including major international pharmaceutical companies or universities.

### Recent Developments

### **Preferred Equity Financing**

On September 24, 2009, we entered into a preferred stock purchase agreement with Optimus, which we refer to as the Optimus purchase agreement, pursuant to which Optimus has agreed to purchase, upon the terms and subject to the conditions set forth therein and described below, up to \$5.0 million of our newly authorized, non-convertible, redeemable Series A preferred stock, which we refer to as our Series A preferred stock, at a price of \$10,000 per share. Under the terms of the Optimus purchase agreement, from time to time until September 24, 2012, in our sole discretion, we may present Optimus with a notice to purchase a specified amount of Series A preferred stock, which Optimus is obligated to purchase on the 10th trading day after the date of the notice, subject to satisfaction of certain closing conditions. We will determine, in our sole discretion, the timing and amount of Series A preferred stock to be purchased by Optimus, and may sell such shares in multiple tranches. Optimus will not be obligated to purchase the Series A preferred stock upon our notice (i) in the event the closing price of our common stock during the nine trading days following delivery of our notice falls below 75% of the closing price on the trading day prior to the date such notice is delivered to Optimus or (ii) to the extent such purchase would result in Optimus and its affiliates beneficially owning more than 9.99% of our outstanding common stock.

The Series A preferred stock is redeemable at our option on or after the fifth anniversary of the date of its issuance. The Series A preferred stock also has a liquidation preference per share equal to the original price per share thereof plus all accrued dividends thereon, and is subject to repurchase by us at Optimus's election under certain circumstances, or following the consummation of certain fundamental transactions by us, at the option of a majority of the holders of the outstanding shares of our Series A preferred stock.

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

- senior to our common stock and any other class or series of preferred stock (other than a class or series of preferred stock that the we intend to cause to be listed for trading or quoted on Nasdaq, NYSE Amex or the New York Stock Exchange); and
- junior to all of our existing and future indebtedness and any class or series of preferred stock that we intend to cause to be listed for trading or quoted on Nasdaq, NYSE Amex or the New York Stock Exchange.

The Optimus purchase agreement further provides that we will pay to Optimus a non-refundable fee of up to \$250,000, \$125,000 of which shall be paid in cash or in stock on or before October 28, 2009, and \$125,000 of which

shall be paid on the closing date of the first tranche (by offset from the gross proceeds of such tranche).

In addition, at the time of execution of the Optimus purchase agreement, we issued to an affiliate of Optimus a three-year warrant to purchase up to 33,750,000 shares of our common stock, at an initial exercise price of \$0.20 per share, subject to adjustment as provided in the warrant. The warrant will become exercisable on the earlier of (i) the date on which a registration statement registering for resale the shares of our common stock issuable upon exercise of the warrant becomes effective and (ii) the first date on which such shares underlying the warrant are eligible for resale without limitation under Rule 144 (assuming a cashless exercise of the warrant). The exercise price of the warrant may be paid (at the option of Optimus) in cash or by Optimus's issuance of a four-year, full-recourse promissory note, bearing interest at 2% per annum, and secured by specified portfolio of assets owned by Optimus. The warrant also provides for cashless exercise if at any time a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale of the shares underlying the warrant. If Optimus fails to acquire and pay for the Series A preferred stock upon delivery of our notice in accordance with the terms of the Optimus purchase agreement (assuming the timely and full satisfaction of all of the conditions set forth therein) and the warrant has not previously been exercised in full, we have the right to demand surrender of the warrant (or any remaining portion thereof) without compensation, and the warrant shall automatically be cancelled.

Our right to deliver a notice to Optimus requiring Optimus to make a purchase, and the obligation of Optimus to accept a notice and to acquire and pay for the Series A preferred stock subject to such notice at a tranche closing, are subject to the satisfaction (or waiver) of certain conditions, which include, among others:

- our common stock must be listed for trading or quoted on the OTC Bulletin Board (or another eligible trading market), and we must be in compliance with all reporting requirements under the Securities Exchange Act of 1934, as amended, in order to maintain such listing;
- either (i) we have a current, valid and effective registration statement covering the resale of all shares underlying the warrant or (ii) all shares underlying the warrant are eligible for resale without limitation under Rule 144 (assuming cashless exercise of the warrant);
- there must not be any material adverse effect with respect to the company since the date we executed the Optimus purchase agreement, other than losses incurred in the ordinary course of business;
  - we must not be in default under any material agreement;
  - ten trading day lock-up agreements, subject to certain extensions, with our senior officers and directors and certain beneficial owners of 10% or more of our outstanding common stock must be effective;
- there must not be any legal restraint prohibiting the transactions contemplated by the Optimus purchase agreement; and
- the aggregate of all shares of our common stock beneficially owned by Optimus and its affiliates must not exceed 9.99% of our outstanding common stock.

### Recent Bridge Financings

On June 18, 2009, we completed a private placement with certain accredited investors pursuant to which we issued (i) senior convertible promissory notes in the aggregate principal face amount of \$1,131,353, for an aggregate net purchase price of \$961,650 and (ii) warrants to purchase 2,404,125 shares of our common stock at an exercise price of \$0.20 per share, subject to adjustments upon the occurrence of certain events. As of October 20, 2009, we completed a portion of a private placement with certain accredited investors pursuant to which we issued (i) junior unsecured convertible promissory notes in the aggregate principal face amount of \$1,058,824, for an aggregate net purchase

price of \$900,000 and (ii) warrants to purchase 2,250,000 shares of our common stock at an exercise price of \$0.20 per share, subject to adjustments upon the occurrence of certain events. We refer to these capital raises as the June 2009 bridge financing and October 2009 bridge financing, respectively. We refer to the notes and warrants issued in the June 2009 bridge financing as the June 2009 bridge motes and June 2009 bridge warrants, respectively, and the notes and warrants issued in the October 2009 bridge financing as the October 2009 bridge motes and October 2009 bridge warrants, respectively.

Each of the June 2009 bridge notes and October 2009 bridge notes were issued with an original issue discount of 15% and are convertible into shares of our common stock as described below. The June 2009 bridge notes mature on December 31, 2009. With respect to the October 2009 bridge notes, \$58,824 of the face amount matures on the later of (i) March 31, 2010 and (ii) the repayment in full or conversion of the June 2009 bridge notes (and any other senior indebtedness), and \$1,000,000 of the face amount matures on the later of (i) April 30, 2010 and (ii) the repayment in full or conversion of the June 2009 bridge notes (and any other senior indebtedness). We may prepay the June 2009 bridge notes and October 2009 bridge notes, in whole or in part, without penalty at any time prior to the respective maturity date.

The indebtedness represented by the October 2009 bridge notes is expressly subordinate to our currently outstanding senior secured indebtedness (including the June 2009 bridge notes), as well as any future senior indebtedness of any kind. We will not make any payments to the holders of the October 2009 bridge notes until the earlier of the repayment in full or conversion of the senior indebtedness.

Each of the June 2009 bridge warrants and October 2009 bridge warrants may be exercised on a cashless basis under certain circumstances.

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

#### Amendment to Moore Notes

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

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

### Grants and Other Developments

As of October 1, 2009, we updated survival data for our Phase I clinical trial of ADXS11-001 in the treatment of advanced, metastatic cervix patients who have failed first line cytotoxic therapy and three of the 13 evaluable patients in the trial, approximately twenty-three percent (23%), are still alive at 1091 days, 1059 days and 960 days, respectively. The trial's median patient survival was 347 days. Of the 15 patients treated in the trial, eight patients (53%) survived at least one year. These figures significantly exceed the median survival rate established by the GOG. The GOG's median survival rate varies between 3.8 and 6.2 months in studies of patients who have failed prior chemotherapy (GOG #127 protocol series) with a 1 year survival of approximately 5%.

On August 19, 2009, the National Institute of Health, which we refer to as the NIH, awarded us a grant for \$210,000 to develop a single bioengineered Lm vaccine to deliver two different antigen-adjuvant proteins. This technology enables a single vaccine to simultaneously attack two separate and distinct tumor targets with a higher level of

potency. Further investigational work is focusing on the use of this dual delivery approach directed against a tumor cell surface marker to kill tumor cells directly plus an anti-angiogenic target that would impair a tumor's ability to grow by simultaneously reducing its blood supply.

On August 19, 2009, we announced our collaboration with investigators with the City of Hope, which we refer to as the CoH. The CoH is a leading biomedical research and treatment center in the development of a vaccine for the treatment of certain forms of leukemia and lymphoma. This collaboration will involve the investigation in the use of our proprietary, live Listeria vaccine technology platform for Leukemia and Lymphoma. The CoH investigators are studying our vaccine directed against the tumor associated antigen WT-1. This molecule is observed to be over-expressed in certain cancers of the blood, such as lymphoma, as well as some solid tumors such as breast, pancreas and brain cancers, which makes it a potential target for a selective immune attack delivered via a Listeria vector designed by us. We also have research relationships with Roswell Park Research Institute for the use of our WT-1 vaccine and with the University of Pittsburgh for the development of vaccines that use the antigens HMW-MAA and IL-13R2.

In July 2009, we were notified that while our grant application filed with Cancer Research-UK, a national philanthropy, for the use of ADXS11-001 in the treatment of head and neck cancer in collaboration with investigators from Aintree Hospital (Liverpool), The Royal Marsden Hospital (London), and at Cardiff University, was well received by the New Agents Committee, it was not prioritized for funding at the present time. With encouragement from CR-UK that grant has been resubmitted and is currently pending.

On June 1, 2009, we received an FDA letter denying our request for Orphan Drug Designation for the use of ADXS11-001 in invasive cervical cancer. The FDA stated their market definition for invasive cervical cancer prevalence (including all those who had been cured) is over the 200,000 person cut-off. As part of our strategy to enhance our development efforts, on July 31, 2009, we filed a request for Fast Track Drug Designation in cervical cancer with the FDA. The FDA could not grant Fast Track Designation based on our initial application but has provided guidance for re-application. We are using this guidance to provide additional information in order to re-apply.

In June 2009, we engaged Numoda Corporation, which we refer to as Numoda, a clinical trial and logistics management company, to oversee Phase II clinical activity with ADXS11-001 for the treatment of invasive cervix cancer in India and to serve as the clinical research organization in our CIN trial in the U.S. Numoda will integrate oversight and logistical functions with the contract laboratories, academic laboratories and statistical groups involved both in the U.S. as well as with the clinical research organization to be selected in India. We estimate the cost of this agreement for both clinical trials to be approximately \$8.0 million through September 2011.

On May 20, 2009, we announced that we applied for a \$2.0 million U.S. Bio-Defense Grant, in collaboration with a healthcare company, to develop an oral formulation of its live Listeria technology for the prevention of influenza. In addition, on May 4, 2009, we announced that we applied for nearly \$5.0 million in Grants in Response to U.S. Department of Defense Solicitation in three separate grant proposals. On April 27, 2009 we announced that we applied for approximately \$1.0 million worth of grants from the NIH.

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

### **Our History**

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 Securities Exchange Act of 1934, as amended. We were a publicly-traded "shell" company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among Advaxis, the stockholders of Advaxis and us. As a result of the Share Exchange, 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 our company from Colorado to Delaware by merging the Colorado entity into our wholly-owned Delaware subsidiary.

# Principal Executive Offices

Our principal executive offices are located at Technology Centre of New Jersey, 675 US Highway One, North Brunswick, New Jersey 08902 and our telephone number is (732) 545-1590. We maintain a website at www.advaxis.com which contains descriptions of our technology, our drugs and the trial status of each drug. The information on our website is not incorporated into this prospectus.

#### THE OFFERING

Shares of common stock offered by us None Shares of common stock which may be sold by A total of 80,671,250 shares of our common stock consisting of: the selling stockholders 33,750,000 shares of our common stock underlying a warrant issued to an affiliate of Optimus in our September 2009 preferred equity financing (1); and 46,921,250 shares of our common stock underlying warrants issued in connection with our October 2007 private placement. Use of proceeds We will not receive any proceeds from the resale of the shares of common stock offered by the selling stockholders, as all of such proceeds will be paid to the selling stockholders. However, we will receive proceeds from the exercise of the warrants held by the selling stockholders, if any, to the extent they are not exercised on a cashless basis. We would receive proceeds of approximately \$16,134,250 from the cash exercise of such warrants, which we expect we would use for general corporate and working capital purposes. Risk factors The purchase of our common stock involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock. OTC Bulletin Board market symbol ADXS.OB (1) These shares represent 29.2% of our currently outstanding shares of common stock (based on 115,638,243 shares of common stock outstanding as of October 1, 2009).

#### RISK FACTORS

An investment in our common stock is highly speculative, involves a high degree of risk and should be made only by investors who can afford a complete loss of their investment. You should carefully consider, together with the other matters referred to in this prospectus, the following risk factors before you decide whether to buy our common stock.

Risks Related to our Business

We are a development stage company.

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

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2008 and July 31, 2009, we had an accumulated deficit of \$17,533,044 and \$17,971,843, respectively, and shareholders' deficiency of \$839,311 and \$13,639,132, respectively. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

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

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL tax credit and income earned on investments and grants. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2008 included a going concern explanatory paragraph.

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

We have entered into the Optimus purchase agreement, pursuant to which Optimus has agreed to purchase up to \$5.0 million of our Series A preferred stock from time to time, subject to our ability to effect and maintain an effective registration statement for the shares underlying the warrant issued to an affiliate of Optimus to purchase 33,750,000 shares of common stock, issued in connection with the transaction. Additionally, the Optimus purchase agreement provides that in order to require Optimus to purchase our Series A preferred stock at any time: (i) we must be in compliance with our SEC reporting obligations, (ii) our common stock must be quoted on the OTC Bulletin Board or another eligible trading market, (iii) a material adverse effect relating to, among other things, our results of operations, assets, business or financial condition must not have occurred since September 24, 2009, other than losses incurred in the ordinary course of business, (iv) we must not be in default under any material agreement, and (v) Optimus and its affiliates must not own more than 9.99% of our outstanding common stock, and (vi) we must comply with certain other requirements set forth in the Optimus purchase agreement. If we fail to comply with any of these requirements, Optimus will not be obligated to purchase our Series A preferred stock and we will not receive any

funding from Optimus.

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

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

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

As of July 31, 2009, the face value of our outstanding indebtedness notes was approximately \$2.1 million, of which \$0.9 million is outstanding to our chief executive officer. The total face value of the notes outstanding as of July 31, 2009 is due on or before January 1, 2010. We dedicate a substantial portion of our cash to pay interest and principal on our debt. If we are not able to service our debt, we would need to refinance all or part of that debt, sell assets, borrow more money or sell securities, which we may not be able to do on commercially reasonable terms, or at all.

As of July 31, 2009, \$1.1 million of this indebtedness is secured by substantially all of our assets. The terms of our notes include customary events of default and covenants that restrict our ability to incur additional indebtedness. These restrictions and covenants may prevent us from engaging in transactions that might otherwise be considered beneficial to us. A breach of the provisions of our indebtedness could result in an event of default under our outstanding notes. If an event of default occurs under our notes (after any applicable notice and cure periods), the holders would be entitled to accelerate the repayment of amounts outstanding, plus accrued and unpaid interest. In the event of a default under our senior indebtedness, the holders could also foreclose against the assets securing such obligations. In the event of a foreclosure on all or substantially all of our assets, we may not be able to continue to operate as a going concern.

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

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

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

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

- need to rely on multiple levels of complex financing agreements with outside funding due to the length of the product development cycles and governmental approved protocols associated with the pharmaceutical industry; and
  - dependence upon key personnel including key independent consultants and advisors.

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

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

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

Our research and development expenses are subject to uncertainty.

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

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

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

We outsourced our clinical trials and entered into a contract with Numoda to manage the execution of two Phase II trials for the assessment of our agent ADXS11-001 in the treatment of advanced cervix cancer in women who have failed prior cytotoxic treatment, and in the treatment of CIN, the precursor condition to cervix cancer. We expect to conduct the CIN trial in the U.S. and we expect to conduct the cervix cancer trial in India in association with the

clinical research organization Max Neeman International These trials are scheduled to begin on or about January 2010.

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

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

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

The successful development of biopharmaceuticals is highly uncertain.

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

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

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent

regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict.

We must comply with significant government regulations.

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

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

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

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

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

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the Listeria System, and the proprietary technology of others with which we have entered into licensing

agreements. As of July 31, 2009 we have licensed 21 patents that have been issued and licenses for 24 patents are pending from Penn filed in some of the largest markets in the world. Further, we rely on a combination of trade secrets and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking rights.

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

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

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

Pursuant to an option contained in our existing license agreement with Penn, as amended, we have been in negotiations with Penn since March 2007 to further amend and restate the terms of the license agreement to acquire the rights to use an additional 12 dockets (patentable research agents) under Penn's ownership which, as of July 31, 2009, have generated approximately 22 additional patent applications for Listeria and LLO-based vaccine dockets. As a condition to our exercising this option and entering into an amendment, we must, among other things, pay Penn a mutually agreeable option exercise fee and reimburse Penn for all of its historically accrued patent and licensing expenses relating to these patents (dockets), including their legal and filing fees. As of July 31, 2009, such expenses totaled approximately \$447,000. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn over the form of payment and expect to reach a conclusion at the close of our next financial raise. If we fail to acquire a license to use the additional dockets and patent applications, our patent position may be materially and adversely affected. In addition, as of July 31, 2009, approximately \$315,000 in fees and expense are due and owing to Penn by us under our existing license agreement and other related agreements. While we consider our relationship with Penn to be good, we are in frequent communications over payment of past due invoices and other payables due to our lack of cash. If we fail to reach a mutual agreement, Penn may issue a default notice and we will have 60 days to cure the breach or be subject to the termination of the agreement.

If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future. Additionally, we can provide no assurance that the patents underlying any licenses will

be valid and enforceable. Furthermore, in 2001, an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642. These patent rights are included in the patent rights licensed by us from Penn. GlaxoSmithKline plc, Penn and we expect that the issue will be resolved through a correction of inventorship to add certain GSK inventors, where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

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

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

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

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

Management of our relationships with our collaborators will require:

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

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

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

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

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

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

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

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

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

Our research and development and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials will comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance

policies which include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

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

As of October 1, 2009, we had ten employees. We do not intend to significantly expand our operations and staff unless we get adequate financing. If funded then our new employees may include key managerial, technical, financial, research and development and operations personnel who will not have been fully integrated into our operations. We will be required to expand our operational and financial systems significantly and to expand, train and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate any new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

Risks Related to the Biotechnology / Biopharmaceutical Industry

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

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

capital to us.

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

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

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

The price of our common stock may be volatile.

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

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- · actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock pursuant to the Optimus purchase agreement;
  - general economic conditions and trends;
    - major catastrophic events;
    - sales of large blocks of our stock;
  - significant dilution caused by the anti-dilutive clauses in our financial agreements;
    - departures of key personnel;
  - changes in the regulatory status of our product candidates, including results of our clinical trials;
    - events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
  - regulatory developments in the U.S. and other countries;
- failure of our common stock to be listed or quoted on the Nasdaq Stock Market, NYSE Amex Equities or other national market system;

## changes in accounting principles; and

- discussion of us or our stock price by the financial and scientific press and in online investor communities.
- Inability of the accounting professional to keep up with the complex rules resulting from numerous financial instruments.

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

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

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

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

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

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

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

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

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

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

There is no assurance of an established public trading market.

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

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

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

Because our common stock is not listed for trading on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the U.S. in addition to federal securities law. This regulation covers any primary offering we might attempt and all secondary trading by our stockholders. If we fail to

take appropriate steps to register our common stock or qualify for exemptions for our common stock in certain states or jurisdictions of the U.S., the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

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

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

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

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

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

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

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

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

Our officers and directors, and their affiliates, in the aggregate, beneficially own, as of October 1, 2009, 18.1% of the outstanding shares of our common stock. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders.

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

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

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

We are authorized to issue 500,000,000 shares of our common stock. As of October 1, 2009, we had 115,638,243 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants and options. As of July 31, 2009, we had outstanding options to purchase 17,962,841 shares of our common stock at a weighted exercise price of \$0.16 per share and outstanding warrants to purchase 89,143,801 shares of our common stock, with exercise prices ranging from \$0.18 to \$0.29 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. As of October 1, 2009, the 2004 Stock Option Plan and the 2005 Stock Option Plan have an aggregate of 170,083 shares of common stock available for issuance. In addition, we have granted 11,151,399 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. This prospectus covers 80,671,250 shares of common stock issuable upon exercise of our outstanding warrants, which represents approximately 36% of our outstanding shares of our common stock as of October 1, 2009 on a fully diluted basis. 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, under Rule 144 as currently in effect, a non-affiliate of ours who has beneficially owned shares of our common stock for at least six months is entitled to sell his or her shares without any volume limitations, and an affiliate of ours can sell such number of shares within any three-month period as does not exceed the greater of 1% of the number of shares of our common stock then outstanding, which equaled 1,156,382 shares as of October 1, 2009, or the average weekly trading volume of our common stock on the OTC Bulletin Board during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale. Sales under Rule 144 by our affiliates are also subject to manner-of-sale provisions, notice requirements and the availability of current public information about us.

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

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

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.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. These statements include, but are not limited to:

- statements as to the anticipated timing of clinical studies and other business developments;
  - statements as to the development of new products;
- expectations as to the adequacy of our cash balances to support our operations for specified periods of time and as to the nature and level of cash expenditures; and
- expectations as to the market opportunities for our products, as well as our ability to take advantage of those opportunities.

These statements may be found in the sections of this prospectus titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis and Results of Operations," and "Description of our Business," as well as in this prospectus generally. Actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including all the risks discussed in "Risk Factors" and elsewhere in this prospectus.

In addition, statements that use the terms "can," "continue," "could," "may," "potential," "predicts," "should," "will," "believe "plan," "intend," "estimate," "anticipate," "scheduled" and similar expressions are intended to identify forward-looking statements. All forward-looking statements in this prospectus reflect our current views about future events and are based on assumptions and are subject to risks and uncertainties that could cause our actual results to differ materially from future results expressed or implied by the forward-looking statements. Many of these factors are beyond our ability to control or predict. Forward-looking statements do not guarantee future performance and involve risks and uncertainties. Actual results will differ, and may differ materially, from projected results as a result of certain risks and uncertainties. The risks and uncertainties include, without limitation, those described under "Risk Factors" and those detailed from time to time in our filings with the SEC, and include, among others, the following:

- Our limited operating history and ability to continue as a going concern;
- Our ability to successfully develop and commercialize products based on our therapies and the Listeria System;
- A lengthy approval process and the uncertainty of FDA and other government regulatory requirements may have a material adverse effect on our ability to commercialize our applications;
- •Clinical trials may fail to demonstrate the safety and effectiveness of our applications or therapies, which could have a material adverse effect on our ability to obtain government regulatory approval;
  - The degree and nature of our competition;
  - Our ability to employ and retain qualified employees; and
- The other factors referenced in this prospectus, including, without limitation, under the sections titled "Risk Factors," "Management's Discussion and Analysis and Results of Operations," and "Description of our Business."

These risks are not exhaustive. Other sections of this prospectus may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. These forward-looking statements are made only as of the date of this prospectus. Except for our ongoing obligation to disclose material information as required by federal securities laws, we do not intend to update you concerning any future revisions to any forward-looking statements to reflect events or circumstances occurring after the date of this prospectus.

### **USE OF PROCEEDS**

Other than the cash exercise prices of the warrants, we will not receive any proceeds from the sale of shares of common stock covered by this prospectus by the selling stockholders. If all such warrants covered by this prospectus are exercised for cash, we will receive gross proceeds of approximately \$16,134,250. We intend to use such proceeds for working capital and general corporate purposes. No assurance can be given, however, as to when, if ever, any or all of such warrants will be exercised.

# MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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

	Fiscal 2009				Fiscal 2008				Fiscal 2007			
	High		Low		High		Low		High		Low	
First Quarter (November												
1-January 31)	\$	0.06	\$	0.01	\$	0.20	\$	0.13	\$	0.21	\$	0.14
Second Quarter												
(February 1- April 30)	\$	0.05	\$	0.02	\$	0.15	\$	0.09	\$	0.54	\$	0.15
Third Quarter (May 1 -												
July 31)	\$	0.21	\$	0.04	\$	0.135	\$	0.058	\$	0.36	\$	0.24
Fourth Quarter (August 1 - October 31)	\$	0.19(1)	\$	0.06(1)	\$	0.07	\$	0.03	\$	0.27	\$	0.10

<sup>(1)</sup> Through October 21, 2009.

As of October 1, 2009, there were approximately 100 stockholders of record. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of stockholders of record. Based on information available to us, we believe there are approximately 1,700 non-objecting beneficial owners of our shares of our common stock in addition to the stockholders of record. On October 21, 2009, the last reported sale price per share for our common stock as reported by the OTC Bulletin Board was \$0.13.

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

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

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

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this prospectus 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 prospectus under the heading "Risk Factors". This Management's Discussion and Analysis of Financial Conditions and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus.

#### Overview

Advaxis is a development stage biotechnology company with the intent to develop safe and effective cancer vaccines that utilize multiple mechanisms of immunity. We are developing a live Listeria vaccine technology under license from Penn which can be engineered to secrete a variety of different protein sequences containing tumor-specific antigens leading to the development of a variety of different products. We believe this vaccine technology is capable of stimulating the body's immune system to process and recognize the antigen that has a therapeutic effect upon cancer. We believe that this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers, infectious diseases and auto-immune disorders.

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

We have no customers. Since our inception in 2002, we have focused our development efforts upon understanding our technology and establishing a product development pipeline that incorporates this technology in the therapeutic cancer vaccines area targeting cervical, prostate, breast, and a pre cancerous indication of CIN. Although no products have been commercialized to date, research and development and investment continues to be placed behind the pipeline and the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entail risk and expense. We anticipate that our ongoing operational costs will increase significantly when we begin several of our clinical trials.

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

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

We expect our future sources of liquidity to be primarily debt and equity capital raised from investors, as well as licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties. Of the grants applied for, there is \$5,809,571 still outstanding, which could net us up to \$4,662,860 in funding strategic research (the award of one

grant will exclude us from receiving a similar one that we've applied for) and clinical programs, excluding the NIH grant that we were awarded in August 2009. In addition, we have applied for the New Jersey NOL program for our tax losses in fiscal year 2008 as well as the Research Tax Credit Program for the first time this year.

If additional capital were raised through the sale of equity or convertible debt securities, the issuance of such securities would result in additional dilution to our existing stockholders. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. Any sale of our common stock at its current price will trigger a significant dilution due to the ratchets in the warrant agreements, debt agreements and the security purchase agreement for the October 17, 2007 raise.

#### Plan of Operations

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

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

- Raise funding to pursue our U.S. based Phase II clinical study of ADXS11-001 in the therapeutic treatment of CIN and our Indian based Phase II study in late stage cervical cancer;
- Continue to execute our two Phase II clinical studies of ADXS11-001 in the therapeutic treatment of CIN and late-stage cervical cancer managed by our clinical partner Numoda;
- Continue to work on our grant from the NIH awarded in August 2009 for \$210,000 to develop a single bioengineered Listeria monocytogenes (Lm) vaccine to deliver two different antigen-adjuvant proteins.
- Follow up on the status of our grant applications with the NIH for \$948,000 and the U.S. Department of Defense Solicitation for up to \$3.5 million.
- Continue to focus working with government funded or subsidized research in the U.S. in the treatment of cervical cancer;
  - Continue to work with our strategic and development collaborations with academic laboratories;
- Continue the development work necessary to bring ADXS31-142 in the therapeutic treatment of prostate cancer into clinical trials, and initiate that trial provided that funding is available;
- Continue the development work necessary to bring ADXS31-164 in the therapeutic treatment of breast cancer into clinical trials, and initiate that trial when and if funding is available; and
- Continue the pre-clinical development of other product candidates, as well as continue research to expand our technology platform.

Our projected annual staff, overhead and preclinical expenses are estimated to be approximately \$4.1 million starting in fiscal year beginning November 1, 2009. The cost of our Phase II clinical studies in therapeutic treatment of CIN and late stage cancer of the cervix is estimated to be approximately \$8.0 million over the estimated 30 month period of the trial. Therefore we must raise additional funds in order to fund the entire Phase II CIN trial. Our Phase II ADXS11-001 clinical studies are estimated to commence in January 2010. If we can raise additional funds we intend to commence the clinical work in prostate cancer by late 2010 or beyond and breast cancer by 2011 or beyond. The

timing and estimated costs of these projects are difficult to predict and depends on factors such as our ability to raise funds and enter into a corporate partnership. In the fiscal year ending October 31, 2009 our anticipated needs for additional equipment, personnel and space should not be significant.

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

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

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

- Cost incurred to date: approximately \$1.1 million
- Estimated future clinical costs: \$5.7 million to \$6.0 million
- Anticipated Timing: start January 2010; completion August 2012 or beyond

#### Uncertainties:

- The FDA (or relevant foreign regulatory authority) may place the project on clinical hold or stop the project;
  - One or more serious adverse events in otherwise healthy patients enrolled in the trial;
    - Difficulty in recruiting patients;
      - Delays in the program;
      - Material cash flows; and
- Anticipated Timing: Unknown at this stage and dependent upon successful trials, adequate fund raising, entering a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

ADXS11-001 - Phase II Cancer of the Cervix Trial Summary Information (India: 110 Patients)

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

#### Additional Uncertainties:

• One or more serious adverse events in these late stage cancer patients enrolled in the trial; and

Difficulty in recruiting patients especially in a new country.

ADXS11-001 - Phase II Cancer of the Cervix Trial Summary Information (U.S. GOG/NCI: 63 Patients)

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

#### Additional Uncertainties:

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

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

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

Additional Uncertainties:

- New agent; and
- FDA (or foreign regulatory authority) may not approve the study.

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

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

Additional Uncertainties: See ADXS31-164 (see prior Uncertainties)

#### **Results of Operations**

Nine months ended July 31, 2009 period compared to the nine months ended July 31, 2008

Revenue. Our revenue decreased by \$73,773, or over 100%, to a negative \$5,369 for the nine months ended July 31, 2009 ("Fiscal 2009 Period") as compared with \$68,404 for the nine months ended July 31, 2008 ("Fiscal 2008 Period") due to a grant from the State of New Jersey received in the Fiscal 2008 Quarter not being repeated in Fiscal 2009 Quarter combined with the State request to refund certain grant money received on a prior grant.

Research and Development Expenses. Research and development expenses decreased by \$1,042,126 or 52%, to \$962,198 for the Fiscal 2009 Period as compared with \$2,004,324 for the Fiscal 2008 Period, principally attributable to the following:

- •Clinical trial expenses decreased by \$187,512, or 67%, to \$94,013 from \$281,525 primarily due to the close out of our Phase I trial in the Fiscal 2008 Period which more than off set the one-half month of start-up cost of our Phase II cervical cancer study in India in the Fiscal 2009 Period.
  - Wages, options and lab costs decreased by \$171,571 or 19% to \$718,850 from \$888,212 principally due to the recording of the full years bonus accrual in Fiscal 2008 that was reversed in Fiscal 2009 Period or \$242,385. No bonus accrual was recorded nor paid in Fiscal 2009 Period. Overall the lab costs were lower due to the priority given to the lower cost of grant and publication writing. These lower costs were partially offset by \$107,624 higher option expense relating to new grants in Fiscal 2009 Period and \$40,930 in wages primarily due to the new hire of the Executive Director, Product Development in March 2008.
- Consulting expenses increased by \$11,829, or 12%, to \$107,709 from \$95,880, principally due to higher option expense of \$30,835 recorded in Fiscal 2009 Period relating to new grants as compared to a credit to option expense of \$36,922 due to the true up of unvested option expense recorded in prior Fiscal periods. This resulted in a \$67,757 increase, overall, of option expense which was offset in part by the lower effort required to prepare the IND filing for the FDA or \$56,928 in the Fiscal 2009 Period compared to the same period last year.
- Subcontracted research expenses decreased by \$121,023, or 100%, to \$0 from \$121,023 reflecting the completion of the project prior to Fiscal 2009 Period performed by Dr. Paterson at Penn, pursuant to a sponsored research agreement ongoing in the Fiscal 2008 Period.
- Manufacturing expenses decreased by \$547,208, to \$41,626 from \$588,834, or 93% resulting from the completion of our clinical supply program for the upcoming CIN trial prior to Fiscal 2009 Period compared to the manufacturing program in the Fiscal 2008.
- •Toxicology study expenses decreased by \$26,640, to \$0 or 100% due the completion in Fiscal 2008 Period of our toxicology study by Pharm Olam in connection with our ADXS111-001 product candidates in anticipation of clinical studies in 2008.

General and Administrative Expenses. General and administrative expenses decreased by \$308,424, or 13%, to \$2,041,016 for the Fiscal 2009 Period as compared with \$2,349,439 for the Fiscal 2008 Period primarily attributable to the following:

- Wages, Options and benefit expenses decreased by \$113,876, or 12% to \$828,290 from \$942,166 principally due to the reversal of a nine month bonus accrual in Fiscal 2009 Period or \$79,039 that was recorded as expense in Fiscal 2008 Period (no bonus accrual was recorded nor paid in Fiscal 2009 Period) and no stock was issued in Fiscal 2009 Period compared to \$71,250 worth of stock was issued to the CEO per his employment agreement in Fiscal 2008 Period. These lower expenses were partially offset by higher option expense of \$45,975 primarily due to new stock options granted in Fiscal 2009 Period resulting in a \$105,112 expense partially offset by lower option expenses recorded in Fiscal 2009 Period due to the nine months vesting of the CEO's options in Fiscal 2008 Period compared to two months of vesting of his options in the Fiscal 2009 Period.
- Consulting fees decreased by \$272,769, or 73%, to \$99,150 from \$371,919. This decrease was primarily attributed to a one-time payment in settlement of Mr. Appel's (our previous President & CEO) employment agreement of \$130,000 recorded in the Fiscal 2008 Period. The consulting expenses were also \$180,571 lower due to reduced financial advisor fees in Fiscal 2009 Period compared to \$200,571 recorded in the Fiscal 2008 Period primarily due to the close of the offering on October 17, 2007. These lower fees were partially offset by \$50,000 fees recorded for the Sage Group in Fiscal 2009 Period for seeking corporate partnerships that did not occur in Fiscal 2008 Period.
- Offering expenses increased by \$302,505 to \$335,633 from \$33,128. The offering expenses of \$351,973 recorded included in Fiscal 2009 Period or an increase of \$318,845 consists of legal costs in preparation for financial raises and SEC filings that did not occur in Fiscal 2008 Period, partially offset by non-cash warrants expense.
- An increase in legal, accounting, professional and public relations expenses of \$77,121, or 18%, to \$516,521 from \$439,400, primarily as a result of a higher overall legal, patent expenses of \$114,049 partially offset by lower accounting, Public relations and tax preparation fees in Fiscal 2009 Period than in the Fiscal 2008 Period.
- Amortization of intangibles and depreciation of fixed assets increased by \$3,090, or 4%, to \$81,860 from \$78,770 primarily due to an increase in fixed assets and intangibles in the Fiscal 2009 Period compared to the Fiscal 2008 Period.
- Analysis Research cost decreased by \$117,990 or 100%, to \$0 from \$117,990 due to a one time report and business analysis report in the Fiscal 2008 Period not repeated in Fiscal 2009 Period.
- Recruiting fees for the Executive Director of Product Development in Fiscal 2008 Period was \$63,395 and there was no such expense in Fiscal 2009 Period.
- Overall occupancy and conference related expenses decreased by \$123,110 or 41% to \$179,561 from \$302,672. Conference and dues and subscription expenses have decreased by \$89,044 in the Fiscal 2009 Period due to lower participation in cancer conferences. In addition lower travel related to the reduced conferences attendance amounted to a decrease of \$21,061 in the Fiscal 2009 Period than incurred in Fiscal 2008 Period.

Other Income (expense). Other income increased by \$1,562,883 to \$1,603,605 in income for Fiscal 2009 Period from income of \$40,722 for the Fiscal 2008 Period. In Fiscal Period 2009 the Net change in fair value of common stock warrant liability and embedded liability resulted in income of \$2,014,220 due to a lower fair market value on July 31, 2009 compared to June 18, 2009, while this transaction did not incur in Fiscal Period 2008. During the Fiscal 2009 and the Fiscal 2008 Periods, we recorded interest expense of \$410,615 and \$5,705, respectively, primarily related to interest accrued on our outstanding notes including accreted interest on the of \$316,623 on the value of the warrant

and embedded derivative liabilities. Interest earned on investments for the Fiscal 2009 and Fiscal 2008 Periods amounted to \$0\$ and \$46,427, respectively

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

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

Fiscal Year 2008 Compared to Fiscal Year 2007

Revenue. Our revenue decreased by \$88,465, or 57%, from \$154,201 during the fiscal 2007 period to \$65,736 as compared with the fiscal 2008 period primarily due to the decreased grant money of \$133,850 received from the NCI in the fiscal 2007 period not repeated in the fiscal 2008 period partially offset by the increased grant money received from the State of New Jersey in the fiscal 2008 period as compared to the fiscal 2007 period.

Research and Development Expenses. Research and development expenses increased by \$353,744, or 17%, from \$2,128,096 for the fiscal 2007 period to \$2,481,840 for the fiscal 2008 period, principally attributable to the following:

Clinical trial expenses decreased by \$117,014, or 29%, from \$401,783 to \$284,769 due to our higher clinical trial activity in the fiscal 2007 period compared to the close out phase in the fiscal 2008 period.

Wages, options and lab costs increased by \$309,756, or 37%, from \$832,757 to \$1,142,513 principally due to our expanded research & development efforts, the hiring of an Executive Director of Product Development, a wage increase on November 1, 2007 and an increase in bonuses.

IND development consulting expenses increased by \$7,512 or 4%, from \$174,960 to \$182,472 primarily due to the submission cost of our IND in Fiscal 2008 period compared to Fiscal period 2007.

Subcontracted research expenses decreased by \$128,062, or 43%, from \$300,535 to \$172,473 primarily reflecting the decreased subcontract work performed by Dr. Paterson at Penn, pursuant to our sponsored research agreement in the fiscal 2008 period compared to the same period last year.

Manufacturing expenses increased by \$319,194 or 90%, from \$353,780 to \$672,974 as a result of the ongoing clinical supply program for our upcoming Phase II trial in fiscal 2008 period compared to the manufacturing program in the fiscal 2007 period.

Toxicology study expenses decreased by \$37,640, or 59%, from \$64,280 to \$26,640 due to expenses incurred in the fiscal 2007 period as a result of a toxicology study by Pharm Olam in connection with our ADXS11-001 product candidates in anticipation of clinical studies in 2008.

We anticipate a continued increase in research and development expenses as a result of the start-up of our Phase II CIN trial and other costs. Additionally, we expect expenses to be incurred in the development of strategic and other relationships required if the licensing, manufacture and distribution of our product candidates are ultimately undertaken.

General and Administrative Expenses. General and administrative expenses increased by \$406,586, or 15%, from \$2,629,094 for the fiscal 2007 period to \$3,035,680 for the fiscal 2008 period, primarily attributable to the following:

Wages, Options and benefit expenses increased by \$369,991, or 44%, from \$835,935 to \$1,205,926 primarily due to the increase of our Chief Executive Officer's base pay by \$100,000 and stock compensation of \$71,250 per his employment agreement, overall higher wages of \$47,000 for employees, increased board compensation of \$45,000 and benefits due to a wage increase on November 1, 2007.

Consulting fees and expenses decreased by \$370,618, or 46%, from \$798,536 to \$427,918. This decrease was primarily attributed to an amendment to Mr. Appel's (LVEP) consulting agreement in the fiscal 2007 period partially offset by a settlement agreement in the fiscal 2008 period which resulted in: (i) a decrease of \$251,269 in option expense recorded primarily due to an amendment of Mr. Appel's consulting agreement compared to no option expense recorded in the fiscal 2008 period; (ii) a decrease of \$200,000 primarily due to the issuance to Mr. Appel of two million shares in the fiscal 2007 period also due to the amendment, (iii) a net decrease of \$256,747 in Mr. Appel's consulting expenses recorded in the fiscal 2008 period compared to the fiscal 2007 period and (iv) a decrease of \$41,667 in Mr. Appel's bonus accrual in the fiscal 2007 period partially offset by (v) his \$130,000 settlement payment in cash in the fiscal 2008 period along with a \$14,615 payment in shares of our common stock. Mr. Appel's net decreases (i-v) were partially offset by the increase in other consulting expenses due to higher financial advisor fees of \$234,450 recorded in the fiscal 2008 periods versus the fees for other consultants in the fiscal 2007 period.

Legal, accounting, professional, tax preparation and public relations expenses increased by \$46,555, or 9%, from \$517,810 to \$564,365, primarily as a result of higher patent, tax preparation and accounting expenses partially offset by lower legal and public relations costs due to fewer security filings in the fiscal 2008 period versus the fiscal 2007 period.

Recruiting fees for the Executive Director of Product Development increased by \$62,295 from \$1,100 in the fiscal 2007 period to \$63,395 in the fiscal 2008 period.

Analyst research cost increased by \$101,708 from \$240 in fiscal 2007 period to \$101,948 in fiscal 2008 period. This increase primarily consists of \$55,240 in warrant expense recorded based on the Black-Scholes calculation with the balance in cost for fees, cash payment of \$40,000 and printing expense.

Offering expense increased by \$49,744 from \$3,774 to \$53,518 due primarily to penalty expense of \$31,778 paid in our common stock recorded during the fiscal 2008 period due to the delay of effectiveness of the registration statement on Form SB-2, File No. 333-147752.

Overall costs for occupancy, dues, subscriptions and travel in the fiscal 2008 period increased by \$26,718 or 11%, from \$247,304 to \$274,022 primarily due to increased travel and related expense for scientific and investor conferences compared to the fiscal 2007 period.

Amortization of intangibles and depreciation of fixed assets increased by \$111,256 or 129%, from \$86,089 to \$197,345 primarily due to the companies decision to discontinue our use of its Trademark and write-off if its intangible assets \$91,453 and increase in fixed assets and intangibles in the fiscal 2008 period compared to the fiscal 2007 period.

Overall conference expenses and investor conferences in fiscal 2008 period increased by \$8,938 or 6%, from \$138,306 to \$147,244.

Other Income (expense). Other Income (expense) decreased by \$2,113,170 from income of \$2,148,536 for the fiscal 2007 period to income of \$35,366 income for the fiscal 2008 period.

During the years ended October 31, 2008 and 2007 we recorded interest expense \$11,263 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, 2008 and 2007 we recorded interest income of \$46,629 and \$63,406, respectively, earned on investments. During the years ended October 31, 2008 and 2007 we recorded changes due to the fair market value of common stock warrants and embedded derivative as a \$0 and \$1,159,846 gain, respectively. 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. There were no gains or losses recorded as of October 31, 2008 due to the extinguishments in the fiscal 2007 period. Due to the eliminations of the convertible debenture in the fiscal 2007 period, 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. There were no gains on retirement in the fiscal 2008 period.

### Liquidity and Capital Resources

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL tax credit and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2008 and July 31, 2009, we had an accumulated deficit of \$17,533,044 and \$17,971,843, respectively, and shareholders' deficiency of \$839,311 and \$13,639,132, respectively. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail or cease operations in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2008 included a going concern explanatory paragraph.

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

Pursuant to the Optimus purchase agreement, Optimus has agreed to purchase, upon the terms and subject to the conditions set forth therein and described below, up to \$5.0 million of our newly authorized, non-convertible, redeemable Series A preferred stock at a price of \$10,000 per share. Under the terms of the purchase agreement, from time to time until September 24, 2012, in our sole discretion, we may present Optimus with a notice to purchase a specified amount of Series A preferred stock, which Optimus is obligated to purchase on the 10th trading day after the date of the notice, subject to satisfaction of certain closing conditions (including our ability to effect and maintain an effective registration statement for the shares underlying the warrant to purchase 33,750,000 shares of common stock, issued to an affiliate of Optimus in connection with the transaction). We will determine, in our sole discretion, the timing and amount of Series A preferred stock to be purchased by Optimus, and may sell such shares in multiple tranches. Optimus will not be obligated to purchase the Series A preferred stock upon our notice (i) in the event the closing price of our common stock during the nine trading days following delivery of our notice falls below 75% of the closing price on the trading day prior to the date such notice is delivered to Optimus or (ii) to the extent such purchase would result in Optimus and its affiliates beneficially owning more than 9.99% of our outstanding common stock.

On June 18, 2009, we completed the June 2009 bridge financing. The June 2009 bridge financing was a private placement with certain accredited investors pursuant to which we issued (i) senior convertible promissory notes in the aggregate principal face amount of \$1,131,353, for an aggregate net purchase price of \$961,650 and (ii) warrants to purchase 2,404,125 shares of our common stock at an exercise price of \$0.20 per share, subject to adjustments upon the occurrence of certain events. As of October 20, 2009, we completed a portion of the October 2009 bridge financing. The October 2009 bridge financing was a private placement with certain accredited investors pursuant to which we issued (i) junior unsecured convertible promissory notes in the aggregate principal face amount of \$1,058,824, for an aggregate net purchase price of \$900,000 and (ii) warrants to purchase 2,250,000 shares of our common stock at an exercise price of \$0.20 per share, subject to adjustments upon the occurrence of certain events.

Each of the June 2009 bridge notes and October 2009 bridge notes were issued with an original issue discount of 15% and are convertible into shares of our common stock as described below. The June 2009 bridge notes mature on December 31, 2009. With respect to the October 2009 bridge notes, \$58,824 of the face amount matures on the later of (i) March 31, 2010 and (ii) the repayment in full or conversion of the June 2009 bridge notes (and any other senior indebtedness), and \$1,000,000 of the face amount matures on the later of (i) April 30, 2010 and (ii) the repayment in full or conversion of the June 2009 bridge notes (and any other senior indebtedness). We may prepay the June 2009 bridge notes and October 2009 bridge notes, in whole or in part, without penalty at any time prior to the respective maturity date.

The indebtedness represented by the October 2009 bridge notes is expressly subordinate to our currently outstanding senior secured indebtedness (including the June 2009 bridge notes), as well as any future senior indebtedness of any kind. We will not make any payments to the holders of the October 2009 bridge notes until the earlier of the repayment in full or conversion of the senior indebtedness.

Each of the June 2009 bridge warrants and October 2009 bridge warrants may be exercised on a cashless basis under certain circumstances.

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

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

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

The Moore Notes bear interest at a rate of 12% per annum, compounded quarterly, and may be prepaid in whole or in part at our option without penalty at any time prior to maturity. In consideration of Mr. Moore's agreement to purchase the Moore Notes, we agreed that concurrently with an equity financing resulting in gross proceeds to us of at least \$6.0 million, we will issue to Mr. Moore a warrant to purchase our common stock, which will entitle Mr. Moore to purchase a number of shares of our common stock equal to one share per \$1.00 invested by Mr. Moore in the purchase of the Moore Notes. The terms of these warrants were subsequently modified by the Board based on the terms of the June 2009 bridge financing increasing the number of warrants from one warrant per dollar invested to two and one half (2 ½) warrants. The final terms are anticipated to contain the same terms and conditions as warrants issued to investors in the subsequent financing. As of July 31, 2009, \$947,985 in notes were outstanding and payable to Mr. Moore.

On June 15, 2009, the Moore Notes were amended to increase the amounts available pursuant to the Moore Agreement from \$800,000 to \$950,000 and change the maturity date of the Notes from June 15, 2009 to the earlier of January 1, 2010 or our next equity financing resulting in gross proceeds to us of at least \$6.0 million. Also the Moore Notes were amended as per the agreement to include the same warrant provision per dollar invested as the subsequent bridge note agreement or two and one-half (2½) warrants per one dollar invested instead of one warrant.

On October 17, 2007, we issued and sold to institutional and accredited investors (i) 49,228,334 shares of our common stock and (ii) five-year warrants to purchase 36,921,250 shares of our common stock exercisable at \$0.20 per share, which we refer to as the "\$0.20 warrants", in a private placement that resulted in gross proceeds to us of \$7,384,235. We refer to this private placement as the "October 2007 private placement". Pursuant to the related placement agency agreement with Carter Securities, LLC, we paid the placement agent \$354,439 in cash commissions and reimbursement of expenses and issued to it 2,949,333 warrants with an exercise price of \$0.20. Our offering expenses, including legal fees, amounted to \$165,250.

Concurrently with the closing of the October 2007 private placement, we issued and sold to CAMOFI Master LDC and CAMHZN Master LDC (i) 10,000,000 shares of our common stock, (ii) \$0.20 warrants to purchase 10,000,000 shares of our common stock and (iii) five-year warrants to purchase 3,333,333 shares of our common stock exercisable at \$0.001 per share, which we refer to as the \$0.001 warrants, in a private placement that resulted in gross proceeds to us of \$1,996,667. Neither the \$0.20 warrants nor the \$0.001 warrants may be exercised if, following the exercise, the holder will be deemed to be the beneficial owner of more than 4.99% of our outstanding shares of our common stock (unless such holder provides us with 61 days' notice of the holders waiver of such provisions). In May 2009 all of the 3,333,333 warrants that were purchased for \$0.149 per warrant with an exercise price of \$0.001 were exercised on a cashless basis and 3,299,999 common shares were issued.

Each of CAMOFI Master LDC and CAMHZN Master LDC are affiliates of our financial advisor, Centrecourt Asset Management, which we refer to as Centrecourt. Pursuant to a consulting agreement between us and Centrecourt dated August 1, 2007, we paid Centrecourt \$328,000 in cash and issued to it 2,483,333 warrants at an exercise price of \$0.20, for strategic advisory services provided to us. Centrecourt transferred the \$0.20 warrants to CAMOFI Master LDC and CAMHZN Master LDC.

In connection with the closing of the October 2007 private placement, we exercised our right under an agreement dated August 23, 2007 with YA Global Investments, L.P., which we refer to as Yorkville and f/k/a Cornell Capital Partners, L.P., to (i) redeem the outstanding \$1.7 million principal amount of our secured convertible debentures due February 1, 2009 held by Yorkville and (ii) repurchase from Yorkville warrants to purchase an aggregate of 4,500,000 shares of our common stock that would have expired on February 1, 2011. The secured convertible debentures bore interest at 6% per annum and were convertible into shares of our common stock at a price equal to the lesser of (i) \$0.287 per share or (ii) 95% of the lowest volume weighted average price of our common stock, or VWAP, during the 30 trading days immediately preceding the date of conversion. Of the warrants that we repurchased, 4,200,000 were

exercisable at \$0.287 per share and 300,000 were exercisable at \$0.344 per share. We paid an aggregate of (i) \$2,289,999 to redeem the secured convertible debentures at the principal amount plus a 20% premium and accrued and unpaid interest, and (ii) \$600,000 to repurchase their warrants.

On August 24, 2007, we issued and sold an aggregate of \$600,000 in principal amount of 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 Mr. Moore. Mr. Moore purchased notes in the aggregate purchase amount of \$400,000 and received warrants to purchase 100,000 shares of our common stock. The promissory notes, and accrued but unpaid interest thereon, are convertible at the option of the holders into shares of our common stock upon the closing of a subsequent financing in which we raise \$3.0 million or more in gross proceeds. The conversion rate will be the greater of the price at which the equity securities issued in the subsequent financing are sold or the per share price of the last reported trade of our common stock on the market on which our common stock is then listed, as quoted by Bloomberg LP. The promissory notes may prepaid at any time prior to conversion. Mr. Moore converted his \$400,000 note into 2,665,667 shares of our common stock and warrants to purchase 2,000,000 shares of our common stock at \$0.20 per share based on the terms of the private placement that closed on October 17, 2007. Mr. Moore received an interest payment of \$7,101 in cash. The other two note holders also converted the principal amount of their notes into shares of common stock and received interest in cash. This note was extinguished in full on October 17, 2007.

In a letter dated November 13, 2008 from the New Jersey Economic Development Authority we were notified that our application for the New Jersey Technology Tax Certificate Transfer Program was approved. Through the State of New Jersey Program for small businesses, we received a net cash amount of \$922,020 on December 12, 2008 from the sale of our state net operating losses through December 31, 2007 of \$1,084,729. We intend to apply for additional benefits under the program including the sale of research tax credits.

#### **Off-Balance Sheet Arrangements**

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

#### **Critical Accounting Estimates**

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

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

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

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

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

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

Warrants were issued in connection with various financings throughout our history. As of July 31, 2009, we began estimating the fair value of these instruments using the Black-Scholes model, which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term and the closing price of our common stock. Changes in assumptions used to estimate the fair value of these derivative instruments could result in a material change in the fair value of the instruments. We believe the assumptions outlined below used to estimate the fair values of the warrants are reasonable. Accounting for all outstanding warrants related to our determination that all of the outstanding warrants were reclassified as liabilities due the fact that the conversion feature on the June 2009 bridge notes could require us to issue shares in excess of its authorized amount. All outstanding warrants have been recorded as a liability effective June 18, 2009, based on their fair value calculated using the Black-Scholes-Merton valuation model and the following assumptions: First we estimated the probability of three different outcomes (i) that we would be able to meet the QEF at the current warrant price of \$0.20 per share, (ii) the QEF price would be \$0.15 per share and trigger a 10% discount and (iii) not meet the QEF ("Non-QEF Pricing") and trigger an effective per share conversion price equal to 50% of the VWAP per share of the Common Stock over the five (5) consecutive trading days immediately preceding the third business day prior to the Maturity Date. We estimated that there was an equal probability for each scenario. The fair value of the warrant liability under each outcome was determined and then averaged the outcomes to estimate the warrant value of \$13,036,087 at June 18, 2009.

In accounting for the June 2009 bridge notes' embedded conversion feature and warrants described above we considered the guidance contained in EITF 00-19, "Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In, a Company's Own Common Stock," and SFAS 133 "Accounting for Derivative Instruments and Hedging Activities." In accordance with the guidance provided in EITF 05-2 in order to clarify provisions of EITF 00-19, we determined that the conversion feature in the June 2009 bridge notes represented an embedded derivative since the debenture is convertible into a variable number of shares based upon a conversion formula which could require us to issue shares in excess of its authorized amount. The convertible debentures are not considered "conventional" convertible debt under EITF 00-19 and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability.

As of July 31, 2009, we had outstanding warrants to purchase 89,143,801 shares of our common stock (adjusted for anti-dilution provision to-date) with exercise prices ranges from \$0.187 to \$0.287 per share (adjusted for anti-dilution provision to-date). These warrants include 2,404,125 warrants issued to June 2009 bridge notes at an exercise price of \$0.20 per warrant. Most of the warrants include anti-dilutive provisions that can trigger an adjustment to the number and price of the warrants outstanding resulting from certain future equity transactions issued below their exercise price. The Moore Notes also include warrants not issued but could be issued base on contingent conditions. See Note 6 Derivative Instruments in the quarterly footnotes for a discussion on warrants.

**New Accounting Pronouncements** 

In June 2008, the Financial Accounting Standards Board, or FASB, ratified Emerging Issues Task Force (EITF) Issue No 07-5, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock" (EITF 07-5). EITF 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature indexed to the entities own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which is our first quarter of fiscal 2010. Many of the warrants issued by us contain a strike price adjustment feature, which upon adoption of EITF 07-5, may result in the instruments no longer being considered indexed to our own stock. Accordingly, adoption of EITF 07-5 may change the current classification (from equity to liability) and the related accounting for many warrants outstanding at that date, even though we now record warrants and the embedded derivative as a liability under the guidance contained in EITF 00-19, "Accounting for Derivative Financial Instrument Indexed to and Potentially Settled In a Company's Own Common Stock," and SFAS 133 "Accounting for Derivative Instruments and Hedging Activities". In accordance with the guidance provided in EITF 05-2 in order to clarify provisions of EITF 00-19, we determined that the conversion feature in the June 2009 bridge notes represented an embedded derivative since the debenture is convertible into a variable number of shares based upon a conversion formula which could require us to issue shares in excess of its authorized amount. The convertible debentures are not considered "conventional" convertible debt under EITF 00-19 and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability. We are currently evaluating the impact the adoption of EITF 07-5 may have on our financial position, results of operation, or cash flows.

In May 2009, FASB issued Statement of Financial Accounting Standards No. 165, Subsequent Events ("SFAS 165"), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 also requires entities to disclose the date through which subsequent events were evaluated as well as the rational as to why the date was selected. SFAS 165 is effective for interim and annual periods ended after June 15, 2009. We have adopted the provisions of SFAS 165. We have evaluated subsequent events through the date of issuance of the July 31, 2009 financial statements, September 23, 2009, and updated their review through October 22, 2009.

In July 2009, FASB issued SFAS No. 168, "FASB Accounting Standards Codification TM and the Hierarchy of Generally Accepted Accounting Principles" — a replacement of FASB Statement No. 162 ("SFAS 168"). With the issuance of SFAS 168, the FASB Standards Codification, or the Codification, becomes the single source of authoritative U.S. accounting and reporting standards applicable for all non-governmental entities, with the exception of guidance issued by the Securities and Exchange Commission. The Codification does not change current U.S. GAAP, but changes the referencing of financial standards and is intended to simplify user access to authoritative U.S. GAAP, by providing all the authoritative literature related to a particular topic in one place. The Codification is effective for interim and annual periods ended after September 15, 2009. At that time, all references made to U.S. GAAP will use the new Codification numbering system prescribed by the FASB. The adoption of SFAS No. 168 will result in the change of disclosures to reflect the new codification references, but otherwise we do not expect it to have any effect on its financial statements.

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

#### **DESCRIPTION OF BUSINESS**

#### General

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

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

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

Product ADXS11-001	Indication Cervical Cancer	Stage Phase I Company sponsored & completed in 2007.			
	Cervical Intraepithelial Neoplasia	Phase II Company sponsored study anticipated to commence in January 2010.			
	Cervical Cancer	Phase II Company sponsored study anticipated to commence in January 2010 in India. 110 Patients with advanced cervical cancer.			
	Cervical Cancer	Phase II The Gynecologic Oncology Group of the National Cancer Institute may conduct a study (timing to be determined).			
ADXS31-142	Prostate Cancer	Phase I Company sponsored (timing to be determined).			
ADXS31-164	Breast Cancer	Phase I Company sponsored (timing to be determined).			

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2008 and July 31, 2009, we had an accumulated deficit of \$17,533,044 and \$17,971,843, respectively, and shareholders' deficiency of \$839,311 and \$13,639,132, respectively.

To date, we have outsourced many functions of drug development including; manufacturing, and clinical trials management. Accordingly, the expenses of these outsourced services account for a significant amount of our

accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or approved by the FDA. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies, including conducting clinical trials for our product candidates, with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

### Strategy

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

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

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

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

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

# Background

### Cancer

Cancer is the second largest cause of death in the U.S., exceeded only by heart disease. The cost of treating cancer patients in 2007 was estimated to be \$219.2 billion in healthcare costs and another \$18.2 billion in indirect costs resulting from morbidity and lost productivity (source: Facts & Figures 2008, American Cancer Society). The American Cancer Society's most recent estimates for newly diagnosed cervical cancer in the U.S. in 2009 was 11,270 and numbers for newly diagnosed CIN are approximately about 250,000 patients per year based on 3.5 million abnormal Pap smears (source: Jones HW, Cancer 1995:76:1914-18; Jones BA and Davey, Arch Pathol Lab Med 2000; 124:672-81). Overall predicted incidence and mortality rates for 2009 are set forth below:

### Immune System and Normal Antigen Processing

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

### Innate Immunity:

Innate immunity is the first step in the recognition of a foreign antigen, and underlies an adaptive (antigen specific) response by lymphocytes. This non-specific response by the immune system results in the release of various soluble mediators of immune response such as cytokines, chemokines and other molecules.

Exogenous pathway of Adaptive Immunity (Class II pathway):

Proteins and foreign molecules ingested by Antigen Processing Cells, or APCs, 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+) called helper T-cells that produce induce a proliferation of helper T cells that assist in the maturation of cytotoxic T-lymphocytes. This system is called the exogenous pathway, since it is the prototypical response to an exogenous antigen like bacteria. (Listeria generated MHC-2 responses are directed at the activation of helper T cell activation, as Listeria tends not to stimulate antibody formation.)

Endogenous pathway of Adaptive Immunity (Class I pathway):

There exists another adaptive immune pathway, called the endogenous pathway. In this system, unusual proteins created within the cytoplasm of the APC (as opposed to within he digestive phagosome), are 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 needed for elimination of virus-infected or cancerous cells.

Listeria based vaccines are unique for many reasons, one of which is that unlike viral vectors, DNA or peptide antigens or other vaccines, Listeria stimulates all of the above mechanisms of immune action. We use a bioengineered form of Listeria to activate the immune system to treat cancer, infectious diseases, or allergic syndromes. Our technology allows the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by utilizing a number of 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 monocytogenes (Lm) is a bacterium well known to medical science because it can cause an infection in humans. Listeria is a pathogen that causes food poisoning, typically in the very old, the very young, people who are either immunocompromised or who eat a large quantity of the microbe as can occur in spoiled dairy products. It is not laterally transmitted from person to person. As Lm is in the soil and thus found on leafy vegetables, in meat and dairy products, and is a common microbe in our environment we are exposed to it constantly. Most people ingest Listeria without being aware of it, but in high quantities or in immune suppressed people Listeria can cause various clinical conditions, including sepsis, meningitis and placental infections in pregnant women. This is rare, and fortunately, many common antibiotics can kill and sterilize Listeria.

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.

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

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

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

Figs 8-10. A certain percentage of bacteria 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 the Advaxis technology. Inside the lysosome, Listeria produces listeriolysin-O, or 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 to the proteosome for digestion, which terminates its action and provides fragments that then go to the endoplasmic reticulum, where it is processed just like a protein antigen in the endogenous pathway to generate MHC-1 complexes.

This mechanism is used by Listeria to its benefit because the actions of LLO enable the bacteria to avoid digestion in the lysosome and escape to the cytosol where they can multiply and spread and then be neutralized so that it does not kill the host cell. Advaxis is using a technology that co-opts this mechanism by creating a protein that is comprised of the cancer antigen fused to a non-hemolytic portion of the LLO molecule that contains the PEST sequence. This serves to route the molecule for accelerated proteolytic degradation which accelerates both the rate of antigen breakdown and the amount of antigen fragments available for incorporation in to MHC-1 complexes, thus increasing the stimulus to activate cytotoxic T cells against a tumor specific antigen. Further, because LLO is a primary virulence factor for Lm and thus is a molecule to which humans have evolved a strong immune response, using a non-hemolytic fragment of LLO (which is thus safe) fused to an antigen, Advaxis vaccines secrete an antigen and an adjuvant in a single molecule.

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

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

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

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

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

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

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

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

- 1. Very strong innate immune response
- 2. Stimulates inordinately strong killer Tregs response
  - 3. Stimulates helper Tregs

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

# Research and Development Program

### Overview

We use genetically engineered and highly attenuated Listeria monocytogenes as a therapeutic agent. We start with an attenuated strain of Listeria, and then add to this bacterium multiple copies of a plasmid that encodes a fusion protein sequence that includes a fragment of the LLO molecule joined to the tumor antigen of interest. This protein is secreted by the Listeria inside the antigen processing cells, and other cells that Listeria infects which then results in the immune response as discussed above.

We can use different tumor, infectious disease, or other antigens in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, ADXS11-001, uses a HPV 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.

### Partnerships and Agreements

# University of Pennsylvania

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

This license, unless sooner terminated in accordance with its terms, terminates upon the later (a) expiration of the last to expire Penn patent rights; or (b) twenty years after the effective date of the license. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to raise capital, 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 4.7% of our common stock outstanding on a fully-diluted basis. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments

based on net sales and percentages of sublicense fees and certain commercial milestones. Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of \$525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which we are not expecting to begin paying within the next five years). In addition, under the license, we are obligated to pay an annual maintenance fee on December 31, in 2008, 2009, 2010, 2011 and 2012 and each December 31st thereafter for the remainder of the term of the agreement of \$50,000, \$70,000, \$100,000, \$100,000 and \$100,000, respectively until the first commercial sale of a Penn licensed product. Overall the amended and restated agreement payment terms reflect lower near term requirements but the savings are offset by higher long term milestone payments for the initiation of a Phase III clinical trial and the regulatory approval for the first Penn Licensed Product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

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

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

Pursuant to an option contained in our existing license agreement with Penn, as amended, we have been in negotiations with Penn since March 2007 to further amend and restate the terms of the license agreement to acquire the rights to use an additional 12 dockets (patentable research agents) under Penn's ownership which, as of July 31, 2009, have generated approximately 22 additional patent applications for Listeria and LLO-based vaccine dockets. "Docket number" or "case number" refers to a subject on which a patent application or applications are filed. A docket number or case number can contain several applications, which are usually related applications. Related applications are sometimes assigned to more than one docket number, for example if the inventor list is not identical. As a condition to our exercising this option and entering into an amendment, we must, among other things, pay Penn a mutually agreeable option exercise fee and reimburse Penn for all of its historically accrued patent and licensing expenses relating to these patents (dockets), including their legal and filing fees. As of July 31, 2009, such expenses totaled approximately \$447,000. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn over the form of payment and expect to reach a conclusion at the close of our next financial raise. If we fail to acquire a license to use the additional dockets and patent applications, our patent position may be materially and adversely affected. In addition, as of July 31, 2009, approximately \$315,000 in fees and expense are due and owing to Penn by us under our existing license agreement and other related agreements. While we consider our relationship with Penn to be good, we are in frequent communications over payment of past due invoices and other payables due to our lack of cash. If we fail to reach a mutual agreement, Penn may issue a default notice and we will have 60 days to cure the breach or be subject to the termination of the agreement.

Strategically we 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 the management of our company or in our decisions with respect to exploitation of the patent portfolio, except that Dr. Paterson is the Chairperson of our Scientific Advisory Board.

### Dr. Yvonne Paterson

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

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

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

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

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

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

The Sage Group

On January 7, 2009 we signed an Agreement with The Sage Group, which we refer to as Sage, in a program to commercialize our vaccines. They are health-care strategy consultants and are based in New Jersey. Their Agreement is for \$5,000 per month starting in January through April 2009 and \$10,000 per month from May 1 through February 2010 plus 5% of the deal, if completed in the first 24 months, 2 1/2% in the twelve months thereafter.

Dr. David Filer

On January 7, 2005 we entered into a consulting agreement with Dr. David Filer, a biotech consultant. The Agreement provides that Dr. Filer spends three days per month assisting us with our development efforts, reviewing our scientific, technical and business data and materials and introducing us to industry analysts, institutional investor collaborators and strategic partners. In 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 exercisable at \$0.20 per warrant as consideration for his assistance in the raise on October 17, 2007 as well a his advisory services and assistance. This agreement is cancelable with 90 days advance notice.

Freemind Group LLC

We have entered into an agreement with Freemind Group LLC, which we refer to as 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 ranging from \$5,000-7,000 depending on the type of grant application submitted. Freemind has extensive experience in accessing public financing opportunities and the resources of 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 ADXS11-001 for cervical dysplasia. We have paid Freemind as of October 31, 2008, fees aggregating \$29,500. We currently have no future plans to use Freemind and have been successfully writing our own grants.

# University of California

On March 14, 2004 we entered into a nonexclusive license and bailment agreement with the Regents of the UCLA to commercially develop products using the XFL7 strain of Listeria monoctyogenes in humans and animals. The agreement is effective for a period of 15 years and is renewable by mutual consent of the parties. Advaxis paid UCLA an initial licensee fee and continues to pay annual maintenance fees for the 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, which we refer to as Cobra, for the purpose of manufacturing our cervical cancer vaccine ADXS11-001. Cobra has extensive experience in manufacturing gene therapy products for investigational studies. Cobra is a full service manufacturing organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotech industry. These services include the Good Manufacturing Practices, or 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 outstanding fees for manufacturing in exchange for future royalties from the sales of ADXS11-001 at the rate of 1.5% of net sales, with royalty payments not to exceed \$2.0 million.

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

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

### LVEP Management, LLC

We entered into a consulting agreement with LVEP Management, LLC, which we refer to as LVEP, dated as of January 19, 2005, and amended on April 15, 2005, and October 31, 2005, pursuant to which Mr. Appel served as our Chief Executive Officer, Chief Financial Officer and Secretary 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 stockholder. Pursuant to an amendment dated December 15, 2006. Mr. Appel resigned as our President and Chief Executive Officer and Secretary as of December 15, 2006, but remains as a member of our board of directors and remained as a consultant to us until December 15, 2007. The consulting agreement terminated on December 15, 2008. Mr. Appel devoted 50% of his time over the first twelve months of the consulting period to support us. Also as

a consultant, he was paid at a rate of \$22,500 per month in addition to benefits as provided to other company officers. He received severance payments over an additional twelve months at a rate of \$10,416.67 per month and was reimbursed for family health care. All his stock options became fully vested on December 15, 2006. 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.

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

### Pharm-Olam International Ltd.

In April 2005, we entered into a consulting agreement with Pharm-Olam International Ltd., which we refer to as POI, whereby POI is to execute and manage our Phase I clinical trial in ADXS11-001 for a fee of \$430,000 plus reimbursement of certain expenses 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. On February 20, 2008, we approved change order 2 reflecting changes in the study for \$175,000 in additional service fees for a total contractual service fee of \$697,000. As of October 31, 2008 we have paid \$440,650 toward the \$697,000 portion of the agreement. In total the pass-through expenses (\$119,346), patient cost (\$135,272) and service fees totaled \$951,618.

# The Investor Relations Group, Inc.

We entered into an agreement with The Investor Relations Group, Inc., which we refer to as IRG, whereby IRG was retained to serve as an investor relations and public relations consultant. In consideration for performing its services, IRG was paid \$10,000 per month plus out of pocket expenses, and 200,000 shares of our common stock. On December 1, 2008, we terminated this agreement.

### Biologics Consulting Group, Inc.

On June 1, 2006 we entered into an agreement with Biologics Consulting Group, Inc., which we refer to as BCG, and on June 11, 2007, we entered into an amendment No. 1 to provide biologics regulatory consulting services to us, on an as needed basis, in support of the IND submission to the FDA. The tasks to be performed under this Agreement will be agreed to in advance by us and BCG. The term of the amendment No. 1 was from June 1, 2007 to June 1, 2008. In April 2009 we entered into Amendment No. 2 which set June 1, 2008 as the effective date and amended the term from June 1, 2006 through June 1, 2010.

### Numoda Corporation

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

#### MediVector, Inc.

In May 2007, we entered into a Master Service Agreement with MediVector, Inc., which we refer to as MI, covering three projects to serve in clinical study planning, management and execution for our upcoming Phase II clinical study. We paid MI \$71,000 for its services. In early 2008 we terminated all agreements.

#### Patents and Licenses

Dr. Paterson and Penn have invested significant resources and time in developing a broad base of intellectual property around the cancer vaccine platform technology to which on July 1, 2002 we entered into a 20-year exclusive worldwide license and a right to grant sublicenses pursuant to our license agreement with Penn. As of July 31, 2009 Penn has 17 issued and 18 pending patents in the U.S. and other large countries including Japan, and the European Union, through the Patent Cooperation Treaty system pursuant to which we have an exclusive license to exploit the patents. While Penn holds 10 additional patents and patent applications in smaller countries, we have decided not to continue them for economic reasons. We believe that these patents will allow us to take a lead in the U.S. in the field of Listeria-based therapy.

### **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 GlaxoSmithKline plc, which we refer to as GSK, Penn and us that the issue will be resolved through: (1) a correction of inventorship to add certain GSK inventors, (2) where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and (3) a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above.

Pursuant to our existing license with Penn, we had an option to license from Penn any new future invention conceived by either Dr. Yvonne Paterson or by Dr. Fred Frankel in the vaccine area that expired on June 17, 2009. Under our license agreement with Penn, we expanded our intellectual property base and gained access to inventions. Although the option exercise period formally expired in June 2009, we remain in negotiations with Penn to obtain additional patent licenses. Further, our previous consulting agreement with Dr. Paterson provided, among other things, that, to the extent that Dr. Paterson's consulting work resulted in new inventions, such inventions were assigned to Penn, and we have access to those inventions under license agreements to be negotiated. This agreement is currently being revised as of October 1, 2009.

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

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

Based on searches of publicly available databases, we do not believe that Anza or any other third party owns any published Listeria patents or has any issued patent claims that might materially and adversely affect our ability to

operate our business as currently contemplated in the field of recombinant Listeria monocytogenes. Additionally, our proprietary position that is the issued patents and licenses for pending applications restricts anyone from using plasmid based Listeria constructs, or those that are bioengineered to deliver antigens fused to LLO, ActA, or fragments of LLO or ActA.

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

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

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

### Governmental Regulation

### The Drug Development Process

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

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

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

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

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

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

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

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

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

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

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

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

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

### Other Regulations

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

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

### Manufacturing

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

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

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

### Competition

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

some of which have completed numerous clinical trials.

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

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

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

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

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

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

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

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

# Scientific Advisory Board

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

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

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

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

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

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

Research Foundation at the University of Cincinnati in 1986. He completed his Post Doctoral Fellowship in the Department of Pathology at Penn in 1989, under the direction of Dr. Mark Greene. At that time he joined the Faculty at the Wistar Institute in Philadelphia. He was recruited back to Penn in 1994. He is currently an Associate Professor with Tenure in the Department of Pathology, and he is the Associate Chair of the Gene Therapy and Vaccines Graduate Program at Penn. Of relevance during his career he has worked extensively in the areas of molecular immunology, the development of vaccines and vaccine technology for infectious diseases and in the area of molecular oncology and immune therapy. His laboratory is considered one of the founders of the field of DNA vaccines as his group not only was the first to report on the use of this technology for vaccines against HIV, but was also the first group to advance DNA vaccine technology to clinical evaluation. In addition he has worked on the identification of novel approaches to inhibit HIV infection by targeting the accessory gene functions of the virus. Dr. Weiner has authored over 260 articles in peer reviewed journals and is the author of over 28 awarded U.S. patents as well as their international counterparts. He has served and still serves on many national and international review boards and panels including the NIH Study section, WHO advisory panels, the National Institute for Biological Standards and Control, Department of Veterans Affairs Scientific Review Panel, as well as the FDA Advisory panel - Center for Biologics Evaluation and Research, and Adult AIDS Clinical Trial Group, among others. He also serves or has served in an advisory capacity to several Biotechnology and Pharmaceutical Companies. Dr. Weiner has, through training of young people in his laboratory, advanced over 35 undergraduate scientists to Medical School or Doctoral Programs and has trained 28 Post Doctoral Fellows and 7 Doctoral Candidates as well as served on fourteen Doctoral Student Committees.

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

# **Employees**

As of October 1, 2009, we had ten full time employees. Of these employees, nine employees hold the following degrees: one MD/JD, one MD/PhD, three PhD's, one MS & three BS's, four serve in the research area, two serve in the clinical/regulatory development area and four serve in the general and administration area.

We do not anticipate any significant increase in 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.

### **Description of Property**

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

### **Legal Proceedings**

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.

#### **MANAGEMENT**

Executive Officers, Directors and Key Employees

The following are our executive officers and directors and their respective ages and positions as of October 1, 2009:

Name	Age	Position
Thomas A. Moore	58	Chief Executive Officer and Chairman of our Board of Directors
Dr. James Patton	51	Director
Roni A. Appel	42	Director
Dr. Thomas McKearn	60	Director
Richard Berman	67	Director
John Rothman, Ph.D.	61	Executive Vice President of Clinical and Scientific Operations
Fredrick D. Cobb	62	Vice President, Finance and Principal Financial Officer
Christopher C. Duignan	34	Senior Vice President of Finance

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

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

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

Roni A. Appel. Mr. Appel has served as a member of our board of directors since November 2004. He was President and Chief Executive Officer from January 1, 2006 and Secretary and Chief Financial Officer from November 2004, until he resigned as our Chief Financial Officer on September 7, 2006 and as our President, Chief Executive Officer and Secretary on December 15, 2006. He has provided consulting services to us through LVEP Management, LLC, since January 19, 2005. From 1999 to 2004, he has been a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1998 he was an attorney and completed his MBA at Columbia University.

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

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

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

Fredrick D. Cobb. Mr. Cobb joined our company in February 2006 as the Vice President of Finance and on September 7, 2006 was appointed Principal Financial Officer (PFO) and Assistant Secretary. He was the PFO and Corporate Controller for Metaphore Pharmaceuticals Inc., a private company, from June 2004 to December 2005 and PFO and Corporate Controller at the public company Emisphere Technologies, Inc. from 2001 until 2004. Prior thereto he served as Vice President and Chief Financial Officer at MetaMorphix, Inc. from 1997 to 2000. Formerly Mr. Cobb served as Group Director of Bristol Myers-Squibb Science and Technology Group, where he had a twelve-year career in senior financial roles. Mr. Cobb received an M.S. in Accounting from Seton Hall University in 1997 and holds a B.S. degree in Management from Cornell University.

Christopher C. Duignan. Mr. Duignan joined our company in September 2009 as the Senior Vice President of Finance. He was the Chief Financial Officer of Enliven Marketing Technologies Corporation from November 2006 until the company was sold in October 2008. Mr. Duignan worked for Enliven Marketing Technologies Corporation from January 2002 to November 2008, during which time he served as Assistant Controller, Controller, Chief Accounting Officer, and Chief Financial Officer. Prior to Enliven Marketing Technologies Corporation, Mr. Duignan worked at PricewaterhouseCoopers LLP from September 1997 to October 2001 in their technology group within the

audit practice. At PricewaterhouseCoopers LLP, Mr. Duignan's client base consisted of publicly traded technology companies as well as start-ups. Mr. Duignan received a B.S. in Accounting from Fairfield University in 1997 and is a Certified Public Accountant.

#### **Board of Directors**

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

### Committees of the Board of Directors

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

#### **Audit Committee**

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

The audit committee is responsible for the following:

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

### **Compensation Committee**

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

### Nominating and Corporate Governance Committee

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

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

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

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

### **EXECUTIVE COMPENSATION**

# **Summary Compensation Table**

The following table sets forth the information as to compensation paid to or earned by our Chief Executive Officer and our two other most highly compensated executive officers during the fiscal years ended October 31, 2007 and 2008. These individuals are referred to in this prospectus as our named executive officers. As none of our named executive officers received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal years ended October 31, 2007 and 2008, we have omitted those columns from the table.

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s) (1)	Option Award(s)	All Other Compensation	Total
Thomas A. Moore, CEO and	2008	\$ 352,692	\$ -\$	S —	\$ 156,364	4 \$ 27,626(2) \$	536.682
Chairman	2007	220,769	_	172,500	129,813	3 23,976(2)	547,058
Dr. John Rothman, Executive VP of Science & Operations	2008 2007	255,000 173,923	55,000 45,000	23,378(3) 44,497(5)	25,092 23,128		386,332 314,045
Fredrick D. Cobb, VP Finance	2008 2007	182,923 144,731	40,000 28,000	15,585(6) 22,353(8)	19,977 13,863		265,621 218,305

<sup>(1)</sup> The amounts shown in this column represents the compensation expense incurred by us for the fiscal year in accordance with FAS 123(R) using the assumptions described under "Share-Based Compensation Expense" in Note 2 to our financial statements included elsewhere in this prospectus.