Advaxis, Inc. Form POS AM February 16, 2011

File No. 333-162632

As filed with the Securities and Exchange Commission on February 16, 2011

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

POST-EFFECTIVE AMENDMENT NO. 2 TO 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

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 61,428,433 shares of common stock originally registered and remaining unsold under the Registrant's Registration Statement on Form SB-2 (File No. 333-147752). Accordingly, this Registration Statement also constitutes Post-Effective Amendment No. 3 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 S-1 (File No. 333-162632) with the U.S. Securities and Exchange Commission (the "SEC") on October 22, 2009, which was amended and declared effective on November 6, 2009 (the "Existing Registration Statement"). The Existing Registration Statement (i) carried forward the registration of 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 named in a Registration Statement on Form SB-2 (File No. 333-147752) (the "Prior Registration Statement") initially filed with the SEC on November 30, 2007 and declared effective by the SEC on January 22, 2008 and (ii) registered an additional 33,750,000 shares of our common stock issuable upon exercise of certain warrants which had not previously been registered.

The prospectus included in this Registration Statement allows the selling stockholders named in the prospectus (the "Selling Stockholders") to resell, from time to time, up to an aggregate of 61,428,433 shares of our common stock issuable upon the exercise of warrants held by the Selling Stockholders. Such number of shares includes 15,507,183 shares of common stock issuable as a result of antidilution provisions pursuant to Rule 416 of the Securities Act. Accordingly, this Registration Statement constitutes Post-Effective Amendment No. 2 to the Existing Registration Statement and Post-Effective Amendment No. 3 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, 2010 and to reflect additional information disclosed in our Annual Report on Form 10-K (the "Annual Report") for our fiscal year ended October 31, 2010; and (ii) update the section titled "Selling Stockholders" contained in the prospectus included herein to reflect, among other things, earlier sales or dispositions of our common stock made by certain of the named Selling Stockholders and additional shares of common stock issuable as a result of antidilution provisions pursuant to Rule 416 of the Securities Act.

All filing fees payable in connection with the registration of these securities were previously paid.

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 FEBRUARY 16, 2011

ADVAXIS, INC.

61,428,433 Shares

Common Stock

This prospectus relates to the resale of up to 61,428,433 shares of our common stock underlying warrants issued in connection with our October 2007 private placement, which amount includes 15,507,183 shares of common stock issuable as a result of antidilution provisions. 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 February 9, 2011, 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 5.

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, 20 |) | 1 | 1 | |
|------------------------------------|---|---|---|--|
|------------------------------------|---|---|---|--|

TABLE OF CONTENTS

| ABOUT THIS PROSPECTUS | ii |
|---|-----|
| PROSPECTUS SUMMARY | 1 |
| THE OFFERING | 4 |
| RISK FACTORS | 5 |
| SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS | 18 |
| USE OF PROCEEDS | 19 |
| MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS | 19 |
| MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS | 21 |
| DESCRIPTION OF BUSINESS | 31 |
| MANAGEMENT | 50 |
| EXECUTIVE COMPENSATION | 54 |
| STOCK OWNERSHIP | 62 |
| SELLING STOCKHOLDERS | 64 |
| CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS | 68 |
| DESCRIPTION OF OUR CAPITAL STOCK | 68 |
| SHARES ELIGIBLE FOR FUTURE SALE | 73 |
| PLAN OF DISTRIBUTION | 74 |
| LEGAL MATTERS | 76 |
| EXPERTS | 76 |
| INTERESTS OF NAMED EXPERTS AND COUNSEL | 76 |
| WHERE YOU CAN FIND ADDITIONAL INFORMATION | 76 |
| INDEX TO FINANCIAL STATEMENTS | F-1 |

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.

ii

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 immune system to induce antigen-specific anti-tumor immune response involving both innate and adaptive arms of the immune system. In addition, this technology facilitates the immune response by altering tumors to make them more susceptible to immune attack, and increasing the number and maturation of development of specific cells that underlie a strong therapeutic immune response.

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

| Product | Indication | Stage |
|------------|------------------------------------|---|
| ADXS11-001 | Cervical Cancer | Phase I Company sponsored & completed in 2007. |
| | Cervical Intraepithelial Neoplasia | Phase II Company sponsored study, commenced in March 2010 (with patient dosing commencing in June 2010). |
| | Cervical Cancer | Phase II Company sponsored study initiated in November 2010 in India. 110 Patients with advanced cervical cancer. |
| | Cervical Cancer | Phase II The Gynecologic Oncology Group of the National Cancer Institute has agreed to conduct a study which we expect will commence in early 2011. |
| | Head & Neck Cancer | Phase I The Cancer Research UK (CRUK) is funding a study of up to 45 patients at 3 UK facilities that we expect will commence in early 2011. |
| ADXS31-142 | Prostate Cancer | Phase I Company sponsored (timing to be determined). |

ADXS31-164 Breast Cancer Phase I Company sponsored (timing to be determined).

ADXS31-164 Canine Osteosarcoma Phase 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, 2010, we had an accumulated deficit of \$27,416,000 and shareholders' deficiency of \$14,802,631.

To date, we have outsourced many functions of drug development including manufacturing and clinical trials management. Accordingly, the expenses of these outsourced services account for a significant amount of our accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or approved by the 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, 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.

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

Series B Preferred Equity Financing

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

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

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

Recent Bridge Financings

From November 1, 2010 through November 10, 2010 we issued to certain accredited investors (i) junior unsecured convertible promissory notes in the aggregate principal face amount of \$431,579, for an aggregate net purchase price of \$410,000 and (ii) warrants to purchase 1,025,000 shares of our common stock at an exercise price of \$0.17 per share, subject to adjustments upon the occurrence of certain events. These notes were issued with an original issue discount of 5% and are convertible into shares of our common stock. These notes mature in 60 days from their date of issue. From November 1, 2010 through November 5, 2010 we also issued to certain accredited investors (i) junior unsecured convertible promissory notes in the aggregate principal face amount of \$500,000, for an aggregate net purchase price of \$425,000 and (ii) warrants to purchase 2,062,500 shares of our common stock at an exercise price of \$0.17 per share, subject to adjustments upon the occurrence of certain events. These notes were issued with an original issue discount of 15% and are convertible into shares of our common stock. These notes mature on or before August 31, 2011. The indebtedness represented by these notes is expressly subordinate to our currently outstanding senior secured indebtedness (including the senior convertible promissory notes issued in June 2009, which we refer to as the senior bridge notes), as well as any future senior indebtedness of any kind. We will not make any payments to the holders of these notes until the earlier of the repayment in full or conversion of the senior indebtedness.

During November 2010 the Company repaid four junior bridge notes issued during fiscal 2010 in the aggregate principal amount of \$187,582. With respect to all the senior bridge notes and all of the junior unsecured convertible promissory notes issued from June 2009 through January 27, 2011, each of which we refer to as a junior bridge note and collectively as the junior bridge notes, an aggregate principal amount of \$1,874,100 remains outstanding.

During January and February 2011, we issued to certain accredited investors, junior bridge notes in the aggregate principal face amount of \$452,941, for an aggregate net purchase price of \$395,000 and (ii) warrants to purchase an aggregate of 1,642,500 shares of our common stock, each at an exercise price of \$0.15 per share, subject to adjustments upon the occurrence of certain events. These junior bridge notes were issued with original issue discounts ranging from 5% to 15% and are convertible into shares of our common stock. These junior bridge notes have maturity dates ranging from 90 days to nine months from their date of issue.

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 became 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 the selling stockholders

A total of 61,428,433 shares of our common stock (1) underlying warrants issued in connection with our October 2007 private placement, which amount includes 15,507,183 shares of common stock issuable as a result of antidilution provisions.

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. If all such remaining warrants covered by this prospectus are exercised for cash at the current exercise price, we would receive proceeds of approximately \$9.2 million 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 approximately 29.2% of our currently outstanding shares of common stock (based on 210,645,862 shares of common stock outstanding as of January 27, 2011). These shares also represent approximately 18.4% of our currently outstanding shares of common stock (based on 333,202,511 shares of common stock outstanding as of January 27, 2011 on a fully diluted basis).

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, 2010, we had an accumulated deficit of \$27,416,000 and shareholders' deficiency of \$14,802,631. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

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

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL and Research tax credits and income earned on investments and grants. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2010 included a going concern explanatory paragraph.

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

We have entered into the Series B purchase agreement, pursuant to which Optimus has agreed to purchase up to \$7.5 million of our Series B preferred stock from time to time, subject to our ability to effect and maintain an effective registration statement for the shares underlying the warrant issued to an affiliate of Optimus to purchase up to 40,500,000 shares of common stock, issued in connection with the transaction. As of January 27, 2011, Optimus had purchased an aggregate of 422 shares of Series B preferred stock and remains obligated, from time to time until July 19, 2013, to purchase up to an additional 328 shares of Series B preferred stock, for an aggregate purchase price of \$3,280,000, upon notice from us to Optimus, if certain conditions set forth in the Series B purchase agreement are satisfied, including among things that: (i) we must be in compliance with our SEC reporting obligations, (ii) our common stock must be quoted on the OTC Bulletin Board or another eligible trading market, (iii) a material adverse effect relating to, among other things, our results of operations, assets, business or financial condition must not have occurred since July 19, 2010, other than losses incurred in the ordinary course of business, (iv) we must not be in default under any material agreement, (v) Optimus and its affiliates must not own more than 9.99% of our outstanding common stock, and (vi) we must comply with certain other requirements set forth in the Series B purchase

agreement. If we fail to comply with any of these requirements, Optimus will not be obligated to purchase our Series B preferred stock and we will not receive any funding from Optimus. Moreover, if we exercise our option to require Optimus to purchase our Series B preferred stock, and our common stock has a closing price of less than \$0.15 per share on the trading day immediately preceding our delivery of the exercise notice, we may trigger at closing certain anti-dilution protection provisions in certain outstanding warrants that would result in an adjustment to the number and price of certain outstanding warrants.

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

In connection with our Series B preferred equity financing, we issued to an affiliate of Optimus a three-year warrant to purchase up to 40,500,000 shares of our common stock, at an initial exercise price of \$0.25 per share. The warrant provides that on each tranche notice date under the Series B purchase agreement, (i) that portion of the warrant equal to 135% of the tranche amount will vest and become exercisable (and such vested portion may be exercised at any time during the exercise period on or after such tranche notice date) and (ii) the exercise price will be adjusted to the closing sale price of a share of our common stock on such tranche notice date. We are not permitted to deliver a tranche notice under the Series B purchase agreement and require Optimus to purchase shares of Series B preferred stock if the number of registered shares underlying the warrant is insufficient to cover the portion of the warrant that will vest and become exercisable in connection with such tranche notice. We currently have 4,010,038 registered shares underlying the warrant available under our prospectus and will likely need to register additional warrants shares in order to require Optimus to purchase the remaining 328 shares of Series B preferred stock. We cannot assure you that we will be able to timely effect and maintain a registration statement for any such additional warrant shares so as to permit us to require Optimus to purchase the remaining \$3,280,000 of Series B preferred stock under the Series B purchase agreement.

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

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

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

As of December 31, 2010, our total outstanding indebtedness was approximately \$2.1 million, which included the face value of all our outstanding senior bridge notes and junior bridge notes in the amount of approximately \$1.5 million, a note outstanding to BioAdvance in the amount of \$40,000 and the note outstanding to our chief executive officer in the amount of approximately \$0.6 million. The total face value of these notes outstanding as of December 31, 2010 is due on or before August 31, 2011. We dedicate a substantial portion of our cash to pay interest and principal on our debt. If we are not able to service our debt, we would need to refinance all or part of that debt, sell assets, borrow more money or sell securities, which we may not be able to do on commercially reasonable terms, or at all. In addition, our failure to timely repay (or extend) amounts due and owing under our outstanding senior bridge notes and the junior bridge notes issued in October 2009 may trigger the anti-dilution protection provisions in substantially all of our warrants (other than the warrants issued to the affiliate of Optimus and to certain bridge note holders), in which case holders of our common stock will experience significant additional dilution.

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

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

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

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

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

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

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

Our research and development expenses are subject to uncertainty.

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

- competition from companies that have substantially greater assets and financial resources than we have;
 - need for acceptance of products;

- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of the product development cycles and governmental approved protocols associated with the pharmaceutical industry; and

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

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

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

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

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

The successful development of biopharmaceuticals is highly uncertain.

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

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

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

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

agreements.

As of January 27, 2011 we have 32 patents that have been issued and licenses for 33 patent applications that are pending (including the 23 patent applications obtained in May 2010). We have licensed most of these patents and applications from Penn and we have obtained the rights to all future patent applications originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel. 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 are also aware of Aduro Biotech, a company comprised in part of former Cerus and Anza employees that has recently formed to investigate Listeria vaccines. 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 cannot be appealed. The granted claims, the subject matter of which was discovered by Dr. Yvonne Paterson, scientific founder of Advaxis, are directed to the method of preparation and composition of matter of recombinant bacteria expressing tumor antigens for treatment of patients with cancer. Based on searches of publicly available databases, we do not believe that Anza, Aduro or any other third party owns any published Listeria patents or has any issued patent claims that might materially and adversely affect our ability to operate our business as currently contemplated in the field of recombinant Listeria monocytogenes. Additionally, our proprietary position that is the issued patents and licenses for pending applications restricts anyone from using plasmid based Listeria constructs, or those that are bioengineered to deliver antigens fused to LLO, ActA, or fragments of LLO or ActA.

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.

Pursuant to the terms of our Second Amendment Agreement with Penn, as amended, we have acquired exclusive licenses for an additional 23 patent applications related to our proprietary Listeria vaccine technology. However, as of January 27, 2011, we still owed Penn approximately \$212,000 in patent expenses and \$0 in sponsored research agreement fees.

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, which we refer to as GSK, Penn and we expect that the issue will be resolved through a correction of inventorship to add certain GSK inventors, where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

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

We do not intend to create facilities to manufacture our products and therefore are dependent upon third parties to do so. We currently have an agreement with Cobra Manufacturing for production of our immunotherapies and vaccines for research and development and testing purposes. Our reliance on third parties for the manufacture of our products

creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to replace the development of our product candidates, our clinical testing program may not be able to go forward and our entire business plan could fail.

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

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

Management of our relationships with our collaborators will require:

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

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

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

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

- decreased demand for our product candidates;
 - damage to our reputation;

- withdrawal of clinical trial participants;
 - costs of related litigation;
- substantial monetary awards to patients or other claimants;

- loss of revenues;
- the inability to commercialize product candidates; and
- increased difficulty in raising required additional funds in the private and public capital markets.

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

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

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

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

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

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

As of January 27, 2011, we had 11 employees, all of which were full time employees. We do not intend to significantly expand our operations and staff unless we get adequate financing. If we receive such funding 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.

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. 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. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical and chemical companies, including Aduro Biotech, Antigenics Inc., Avi BioPharma, Inc., Biomura Inc., Biovest International, Biosante Pharmaceuticals Inc., Dendreon Corporation, Pharmexa-Epimmune Inc., Genzyme Corp., Progenics Pharmaceuticals Inc. and Vical Incorporated each of which is pursuing cancer vaccines.

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 Series B 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.

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 Series B 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 and fiscal year ended October 31, 2009, we were unable to file our respective quarterly report on Form 10-Q and annual report on Form 10-K in a timely manner, but we were able to make the filings and cure our compliance deficiencies 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 in the past, and may be ineffective again in the future, and failure to improve them at such time 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 internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past. We have taken steps to improve our disclosure controls and procedures and our internal control over financial reporting, and as of October 31, 2010, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures and internal control over financial reporting were effective. However, there is no assurance that our disclosure controls and procedures will remain effective or that there will be no material weaknesses in our internal control over financial reporting in the future. Additionally, as a result of the historical material weaknesses in our internal control over financial reporting and the historical ineffectiveness of our disclosure controls and procedures, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

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.

As of January 27, 2011, our officers and directors and their affiliates, in the aggregate, beneficially own approximately 13.4% 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, any merger, consolidation or sale of all or substantially all of our assets, an increase in the number of shares authorized for issuance under our stock option plans, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders.

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

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

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

We are authorized to issue 500,000,000 shares of our common stock. As of January 27, 2011, we had 210,645,862 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants and options. As of October 31, 2010, we had outstanding options to purchase 26,467,424 shares of our common stock at a weighted average exercise price of approximately \$0.16 per share and outstanding warrants to purchase 87,336,687 shares of our common stock (excluding Optimus warrants in the amount of 15,802,941), with exercise prices ranging from \$0.15 to \$0.29 per share. Pursuant to our 2004, 2005 and 2009 Stock Option Plans, we have 2,381,525, 5,600,000 and 20,000,000 shares of common stock reserved respectively, for issuance under the plans. In addition, as of January 27, 2011, we have 62,500, 505,333 and 590,268 of these options available for issuance under the 2004, 2005 and 2009 Stock Option Plans, respectively. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Moreover, the above-mentioned warrants to purchase our common stock are subject to "full ratchet" anti-dilution protection upon certain equity issuances below \$0.15 per share (as may be further adjusted).

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 61,428,433 shares of common stock issuable upon exercise of our outstanding warrants, which represents approximately 18.4% of our outstanding shares of our common stock as of January 27, 2011 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 approximately 2,106,459 shares as of January 27, 2011, 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 Amended and Restated Certification of Incorporation provides for the authorization of 5,000,000 shares of "blank check" preferred stock. Pursuant to our Amended and Restated 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 cash dividends.

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. Any future determination as to the payment of cash 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.

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 remaining warrants covered by this prospectus are exercised for cash at the current exercise price, we would receive proceeds of approximately \$9.2 million from the cash exercise of such warrants, which we expect we would use for general corporate and working capital 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 2011 | | | | Fiscal 2010 | | | | Fiscal 2009 | | | |
|------------------------------------|-------------|----------|----------|----------|-------------|------|-----|------|-------------|------|-----|------|
| | High | | Low | | High | | Low | | High | | Low | |
| First Quarter (November 1-January | | 0.46 | . | 0.11 | Φ. | 0.40 | 4 | 0.00 | Φ. | 0.06 | 4 | 0.01 |
| 31) | \$ | 0.16 | \$ | 0.11 | \$ | 0.19 | \$ | 0.02 | \$ | 0.06 | \$ | 0.01 |
| Second Quarter | | | | | | | | | | | | |
| (February 1- April 30) | \$ | 0.15 (1) | \$ | 0.13 (1) | \$ | 0.26 | \$ | 0.12 | \$ | 0.05 | \$ | 0.02 |
| Third Quarter (May 1 - | | | | | | | | | | | | |
| July 31) | \$ | - | \$ | - | \$ | 0.25 | \$ | 0.17 | \$ | 0.21 | \$ | 0.04 |
| Fourth Quarter (August 1 - October | | | | | | | | | | | | |
| 31) | \$ | - | \$ | - | \$ | 0.19 | \$ | 0.10 | \$ | 0.19 | \$ | 0.06 |

⁽¹⁾ Through February 9, 2011

As of January 27, 2011, there were approximately 87 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

3,500 beneficial owners of our shares of our common stock in addition to the stockholders of record. On February 9, 2011, 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 cash 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 B preferred stock will be entitled to receive dividends, which will accrue in shares of Series B 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 B preferred stock or upon the liquidation, dissolution or winding up of our company. The Series B 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 Series A preferred stock or 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);
 - pari passu with any outstanding shares of our Series A preferred stock (none of which are issued and outstanding as of the date hereof); 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.

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 this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers, infectious diseases and auto-immune disorders.

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

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

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

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

We expect our future sources of liquidity to be primarily debt and equity capital raised from investors, as well as licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties. In August 2009, we received an NIH grant for \$210,739 for the development of a dual vector capable of attacking two immunologic targets

simultaneously. In October 2010, we received notice that the company was awarded an IRS grant under the Qualified Therapeutic Discovery Program for approximately \$245,000. This amount was included in grant revenue for the year ending October 31, 2010. We received the funds in November 2010.

On January 15, 2010 we received \$278,978 from the New Jersey Economic Development Authority. Under the State of New Jersey NOL Transfer Program for small business we received this cash amount from the sale of our State Net Operating Losses through December 31, 2008 and our research tax credit for fiscal years 2007 and 2008. We plan to sell our Net Operating Losses and research tax credits for the 2009 fiscal year under the same State of New Jersey Program for small business.

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 or issuance of rights to acquire our common stock below \$0.15 per share (as may be further adjusted) will trigger a significant dilution due to the anti-dilution protection provisions in certain of our outstanding warrants and debt instruments.

Plan of Operations

If we are successful in our financing plans we intend to use the majority of the proceeds to complete our two Phase II trials of ADXS11-001, our initial Listeria construct targeting diseases caused by the Human Papilloma Virus, which we refer to as HPV. One trial is a 120 patient U.S. study in CIN, and the other trial is a 110 patient Indian study in highly advanced cervical cancer. We also anticipate using the funds to further our preclinical and clinical, research and development efforts in developing product candidates in prostate cancer, breast and brain cancer and for general and administrative activities.

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

- Complete our two Phase II clinical studies of ADXS11-001 in the therapeutic treatment of CIN and late-stage cervical cancer;
- Begin an additional Phase II clinical trial of our ADXS11-001 candidate in the treatment of advanced cervical cancer with the Gynecologic Oncology Group, which we refer to as the GOG, largely underwritten by the NCI;
- Continue to focus on our collaboration with the CRUK to carry out our Phase I/II clinical trial of our ADXS11-001 candidate in the treatment of head and neck cancer entirely underwritten by the CRUK;
- Continue to support our Collaborative Research and Development Agreement with the U.S. Department of Homeland Security to develop vaccines for the protection of our food supply;
 - Continue to execute our Canine Osteosarcoma Study with Penn with relevance to human adolescents;
- To support our new Collaborative Research and Development Agreement with the NCI to understand the mechanisms of action of attenuated Listeria vaccines, to develop new vaccines, and to advance them to clinical testing;
- Continue to further our structured collaboration with the University of British Columbia on innovative uses of Listeria constructs in infectious disease, parasitical disease and neonatal immunity;
- Continue to develop strategic and development collaborations with academic laboratories and potential commercial partners;
- 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, brain and other cancers into clinical trials, and initiate that trial when and if funding is available; and

•

Continue the preclinical development of other product candidates, as well as continue research to expand our technology platform.

Our projected annual staff, overhead, laboratory and nonclinical expenses are estimated to be approximately \$4.1 million starting in fiscal year beginning November 1, 2010. The cost of our Phase II clinical studies in therapeutic treatment of CIN and late stage cervical cancer is estimated to be approximately \$11.2 million over the estimated 30 month period of the trial. While approximately \$4 million has already been paid towards these costs, we must raise additional funds in order to complete the Phase II trials. If we can raise additional funds we intend to commence the clinical work in prostate cancer by late 2011 and breast and brain cancer by late 2011. The timing and estimated costs of these projects are difficult to predict.

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 defer the timing of additional financing. 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.: target enrollment: 120 Patients)

- Cost incurred through October 31, 2010: approximately \$2.8 million.
 - Estimated future clinical costs: approximately \$4.7 million.