

Advaxis, Inc.  
Form POS AM  
February 16, 2011

File No. 333-168298

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. 1  
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.)
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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  
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North Brunswick, New Jersey 08902  
(732) 545-1590

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

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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:

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

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.

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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.

7,510,038 Shares

Common Stock

This prospectus relates to the resale of up to (i) 3,500,000 shares of our common stock issued to Numoda Capital Innovations, LLC, which we refer to as Numoda Capital, as payment for certain services rendered by one of its affiliates to us and (ii) 4,010,038 shares of our common stock underlying a warrant issued to an affiliate of Optimus Capital Partners, LLC, which we refer to as Optimus, in our Series B preferred equity financing. 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 held by Numoda Capital and the shares to be acquired upon exercise of the warrant held by the affiliate of Optimus. 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 affiliate of Optimus in certain circumstances. 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 \_\_\_\_\_, 2011.

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## ABOUT THIS PROSPECTUS

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

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

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

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

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 with Optimus, which we refer to as the Series B purchase agreement, 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](http://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	<p>A total of 7,510,038 shares of our common stock (1) consisting of:</p> <ul style="list-style-type: none"><li>· 3,500,000 shares of our common stock issued to Numoda Capital as payment for certain services rendered by one of its affiliates to us;</li><li>· 4,010,038 shares of our common stock underlying a warrant issued to an affiliate of Optimus in our Series B preferred equity financing.</li></ul>
Use of proceeds	<p>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. Furthermore, we will not receive cash proceeds from the exercise of the warrants held by the affiliate of Optimus to the extent they are exercised by a promissory note, as permitted by the terms of such warrants.</p>
Risk factors	<p>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.</p>
OTC Bulletin Board market symbol	ADXS.OB

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(1) These shares represent approximately 3.6% 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 2.3% 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 warrant 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.

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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 3,500,000 shares of common stock and 4,010,038 shares of common stock issuable upon exercise of our outstanding warrants, which represents approximately 2.3% 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

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. Furthermore, we will not receive cash proceeds from the exercise of the warrants held by the affiliate of Optimus to the extent they are exercised by a promissory note, as permitted by the terms of such warrants. 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 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, parasitological 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
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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:

ADX11-001 - 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.
- Anticipated Timing: commenced in March 2010 (with patient dosing commencing in June 2010); reporting of low dose portion in late 2011, completion August 2012 or beyond.

Uncertainties:

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

ADX11-001 - Phase II Cervical Cancer Trial Summary Information (India: target enrollment: 110 Patients)

- Cost incurred through October 31, 2010: approximately \$1.4 million.
- Estimated future clinical costs: approximately \$2.3 million.
- Anticipated Timing: start July-August; reporting of survival beginning in late summer 2011, completion August 2012 or beyond.

Additional Uncertainties:

- One or more serious adverse events in these late stage cancer patients enrolled in the trial.



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

- Cost incurred through October 31, 2010: Minimal.

- Estimated future clinical costs: \$500,000 (NCI underwriting costs of \$4.0 million to \$5.0 million).
- Anticipated Timing: The GOG of the NCI has agreed to conduct a study which we expect will commence in 2011.

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on GOG/NCI controlled study; and
  - Delays in the program.

ADXS11-001 - Phase II Cancer of the Head and Neck Trial Summary Information (U.K. CRUK: target enrollment: up to 45 Patients)

- Cost incurred through October 31, 2010: Minimal.
- Estimated future clinical costs: approximately \$50,000 (CRUK to underwrite costs of \$3.0 million to \$4.0 million).
- Anticipated Timing: The CRUK is funding a study of up to 45 patients at 3 UK facilities that we expect will commence in 2011.

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on CRUK controlling the study; and
  - Delays in the program.

ADXS31-142 - GMP Production and Phase I Trial Summary Information (Prostate Cancer: target enrollment: 30 Patients)

- Cost incurred through October 31, 2010: Minimal.
- Estimated future costs: approximately \$3.5 million.
- Anticipated Timing: to be determined.

Additional Uncertainties:

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

ADXS31-164 - Phase I trial Summary Information (Breast or Brain Cancer: target enrollment: 24 Patients)

- Cost incurred through October 31, 2010: Minimal.
- Estimated future costs: to be determined.
- Anticipated Timing: to be determined.

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

Results of Operations

Fiscal Year 2010 Compared to Fiscal Year 2009

Revenue

Revenue increased by approximately \$478,791 to \$508,481 for the year ended October 31, 2010, as compared with \$29,690 for the same period a year ago, as a result of grant revenue received by us.

### Research and Development Expenses

Research and development expenses increased by approximately \$2,589,000 to \$4,904,298 for the year ended October 31, 2010 as compared with \$2,315,557 for the same period a year ago. This increase is almost entirely attributable to clinical trial expenses, which increased significantly in the current fiscal year due to our clinical trial activity in the United States and India, initiated during the first fiscal quarter of 2010.

We anticipate a significant increase in research and development expenses as a result of expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, expenses will be incurred in the development of strategic and other relationships required to license manufacture and distribute our product candidates.

### General and Administrative Expenses

General and administrative expenses increased by approximately \$829,000 or 22%, to \$3,530,198 for the year ended October 31, 2010 as compared with \$2,701,133 for the same period a year ago. This is primarily attributable to overall compensation expense being higher in the current fiscal year resulting from additional employees, costs related to a former employee and stock-based non cash compensation resulting from the issuance of 750,000 shares of our common stock pursuant to an executive's employment agreement with us. Overall professional fees also increased in the current year as a result of higher recruiting, legal and accounting fees in fiscal 2010 compared with a year ago. In addition, consulting and travel fees increased in the current fiscal year primarily due to increased efforts by us to present our scientific and business plans. We also recognized approximately \$206,000 in non-cash warrant expense, as compared to \$0 in the prior fiscal year, as a result of additional warrants that were issued to senior and junior bridge note holders in September 2010. All of the above increases were somewhat offset by higher offering expenses in fiscal 2009 that did not repeat in the current fiscal year.

### Interest Expense/Income

In the year ended October 31, 2010, net interest expense increased by approximately \$3 million to \$3,814,863 compared to \$851,008 for the same period a year ago, primarily because in the fiscal year ended October 31, 2010 we recognized both (i) twelve months of interest expense for notes sold during the third and fourth fiscal quarters of 2009 and (ii) partial-year interest expense for notes sold in the fiscal year ended October 31, 2010 whereas in the fiscal year ended October 31, 2009 we only recognized partial-year interest expense for notes sold during the third and fourth fiscal quarters of 2009. Additionally, the debt discount, warrant liabilities and embedded derivatives related to the notes are recorded as a liability on the balance sheet and are amortized to interest expense over the life of the notes. Interest income earned during the year ended October 31, 2010 of approximately \$80,000 was the result of interest earned from the Optimus notes receivable. These notes are classified in the equity section of the balance sheet as a stock subscription receivable.

### Changes in Fair Values

The change in fair value of the common stock warrant liability and embedded derivative liability increased income by approximately \$446,000 for the year ended October 31, 2010 compared to approximately \$5.8 million the same period a year ago. During the fiscal year ended October 31, 2009 we recorded income due to changes in management's assumptions used to calculate the fair value of our warrant and embedded derivative liability. This change in assumption substantially decreased both the number of warrants and related BSM values used in calculating the warrant liability, therefore decreasing the overall warrant and embedded derivative liability at October 31, 2009. For the first nine months of the fiscal year ended October 31, 2010, the BSM values associated with these warrants and embedded derivatives increased resulting from the increase in the price of our common stock, from \$0.135 at October

31, 2009 to \$0.17 at July 31, 2010. However, from July 31 to October 31, 2010, the number of outstanding warrants increased due to a decrease in their exercise price and the BSM values decreased due to a decline in the price of our common stock, resulting in our recording income for the full year.

Potential future increases or decreases in our stock price will result in increased or decreased warrant and embedded derivative liabilities, respectively, on our balance sheet and therefore increased expenses being recognized in our statement of operations in future periods.

For the fiscal year ended October 31, 2010, we recorded income of approximately \$124,000 on the non-cash gain on the early retirement of certain senior and junior bridge notes.

### Income Tax Benefit

For the fiscal year ended October 31, 2010, other income decreased by approximately \$643,000, to approximately \$279,000 as compared to approximately \$922,000 a year ago, primarily due to the fiscal 2009 period NOL being the first time we received funds from the program and so the award covered all prior fiscal years' NOLs from our inception whereas the award for the fiscal year ended October 31, 2010 covered only the current fiscal year's NOL and prior two fiscal years of the research tax credit.

### Liquidity and Capital Resources

Our limited capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2010 and 2009, we had an accumulated deficit of \$27,416,000 and \$16,603,800, respectively, and shareholders' deficiency of \$14,802,631 and \$15,733,328 respectively. Based on our available cash of approximately \$108,000 on October 31, 2010, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail or cease operations in the near future. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2010 included a going concern explanatory paragraph.

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

Pursuant to the Series B purchase agreement, Optimus has agreed to purchase, upon the terms and subject to the conditions set forth therein and described below, up to \$7.5 million of our newly authorized, non-convertible, redeemable Series B preferred stock at a price of \$10,000 per share. Under the terms of the Series B purchase agreement we may from time to time until July 19, 2013, present Optimus with a notice to purchase a specified amount of Series B preferred stock. Subject to satisfaction of certain closing conditions, Optimus is obligated to purchase such shares of Series B preferred stock on the 10th trading day after the date of the notice. We will determine, in our sole discretion, the timing and amount of Series B preferred stock to be purchased by Optimus, and may sell such shares in multiple tranches. Optimus will not be obligated to purchase the Series B preferred stock upon our notice (i) in the event the closing price of our common stock during the nine trading days following delivery of our notice falls below 75% of the closing price on the trading day prior to the date such notice is delivered to Optimus or (ii) to the extent such purchase would result in Optimus and its affiliates beneficially owning more than 9.99% of our outstanding common stock.

As of October 31, 2010, we had issued and sold 289 shares of Series B preferred stock to Optimus pursuant to the terms of the Series B purchase agreement. We received net proceeds of \$2,545,000 from this transaction. The aggregate purchase price for the Series B preferred stock was \$2.89 million. As of October 31, 2010, under the terms of the Series B purchase Agreement, Optimus remained obligated, from time to time until July 19, 2013, to purchase up to an additional 461 shares of Series B preferred stock at a purchase price of \$10,000 per share upon notice from us to Optimus, if certain conditions set forth in the Series B purchase agreement are satisfied. Among these conditions, we must have a sufficient number of registered shares underlying a warrant issued to an affiliate of Optimus. We 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 Series B preferred equity financing, an affiliate of Optimus was granted on July 19, 2010 a warrant to purchase up to 40,500,000 shares of our common stock at an exercise price of \$0.25 to be adjusted in connection with the draw down of each tranche. On August 13, 2010, the draw down date of the first tranche of Series B preferred stock, the affiliate of Optimus exercised a portion of the warrant to purchase 9,847,059 shares of common stock at an adjusted exercise price of \$0.17 per share. On September 28, 2010, the draw down date of the second tranche of Series B preferred stock, the affiliate of Optimus exercised a portion of the warrant to purchase 14,850,000 shares of common stock at an exercise price of \$0.15 per share. As permitted by the terms of such warrant, the aggregate exercise price of \$3,901,500 for the first tranche and second tranche, received by us is payable pursuant to four year full recourse promissory notes each bearing interest at the rate of 2% per year. As of October 31, 2010, 15,802,941 warrants remained outstanding.

On September 24, 2009, we entered into a preferred stock purchase agreement with Optimus, which we refer to as the Series A purchase agreement, pursuant to which Optimus agreed to purchase, upon the terms and subject to the conditions set forth therein, up to \$5.0 million of Series A preferred stock at a price of \$10,000 per share. As of May 13, 2010, all 500 shares of Series A preferred stock were issued and sold to Optimus. On July 19, 2010, we issued 500 shares of Series B preferred stock to Optimus, which we refer to as the Series B exchange shares, in exchange for the 500 shares of Series A preferred stock so that all shares of our preferred stock held or subsequently purchased by Optimus under the Series B purchase agreement would be redeemable upon substantially identical terms. In connection with the Series A preferred equity financing, an affiliate of Optimus was granted on September 24, 2009 a warrant to purchase up to 33,750,000 shares of our common stock at an exercise price of \$0.20 to be adjusted in connection with the draw down of each tranche. On January 11, 2010, the draw down date of the first tranche, the affiliate of Optimus exercised a portion of the warrant to purchase 11,563,000 shares of common stock at an adjusted exercise price of \$0.17 per share. On March 29, 2010, the draw down date of the second tranche, the affiliate of Optimus exercised a portion of the warrant to purchase 14,580,000 shares of common stock at an exercise price of \$0.20 per share. On May 13, 2010, the draw down date of the final tranche, the affiliate of Optimus exercised the remainder of the warrant to purchase 7,607,000 shares of common stock at an adjusted exercise price of \$0.18 per share. In each case, we agreed with Optimus and its affiliate to waive certain terms and conditions in the Series A purchase agreement and the warrant in order to permit the affiliate of Optimus to exercise the warrant at such adjusted exercise prices prior to the closing of the purchase of the Series A preferred stock and acquire beneficial ownership of more than 4.99% of our common stock on the date of each exercise. As permitted by the terms of such warrant, the aggregate exercise prices of \$1,965,710, \$2,916,000 and \$1,369,260 for the first tranche, second tranche and final tranche, respectively, received by us is payable pursuant to three separate four year full recourse promissory notes each bearing interest at the rate of 2% per year. In addition, in connection with the draw down of the final tranche, we issued an additional warrant to an affiliate of Optimus to purchase up to 2,818,000 shares of common stock at an exercise price of \$0.18 per share, subject to customary anti-dilution adjustments (the exercise price of which may also be paid at the option of the affiliate of Optimus in cash or by its issuance of a promissory note on the same terms as the foregoing promissory notes). The foregoing promissory notes are not due or payable at any time that (a) we are in default of under the Series A preferred stock purchase agreement, any loan agreement or other material agreement or (b) there are any Series B exchange shares issued or outstanding.

On June 18, 2009, we completed the senior bridge financing. The senior bridge financing was a private placement with certain accredited investors pursuant to which we issued (i) senior bridge notes in the aggregate principal face amount of \$1,131,353, for an aggregate net purchase price of \$961,650 and (ii) senior bridge warrants to purchase 2,404,125 shares of our common stock at an exercise price of \$0.20 per share (prior to giving effect to anti-dilution adjustments which have subsequently reduced the exercise price to \$0.15 per share), subject to adjustments upon the occurrence of certain events. Each of the senior bridge notes were issued with an original issue discount of 15% and were convertible into shares of our common stock in certain circumstances. The senior bridge notes had an initial maturity date of December 31, 2009. During January and February 2010, we repaid \$834,852 of the \$1,131,353 in face value of our senior bridge notes. In addition, holders of the remaining \$296,501 of our senior bridge notes agreed



to extend the maturity dates from December 31, 2009 to periods into February and March 2010. We have agreed to issue additional consideration, including warrants to senior bridge note holders, all of whom agreed to extend the maturity period beyond December 31, 2009. As of October 31, 2010, approximately \$89,000 remained outstanding under the senior bridge notes.

During the twelve months ended October 31, 2010, we issued to certain accredited investors (i) junior bridge notes in the aggregate principal face amount of approximately \$1,462,000 for an aggregate net purchase price of approximately \$1,255,000 and (ii) warrants to purchase 3,270,955 shares of our common stock, which we refer to as junior bridge warrants, at original exercise prices ranging from \$0.17 to \$0.25 per share, subject to adjustments upon the occurrence of certain events. These junior bridge notes were issued with original issue discounts ranging from 6% to 18% and are convertible into shares of our common stock. These junior bridge notes mature on or before May 31, 2011.

As a result of anti-dilution provisions in the senior bridge warrants, certain of the junior bridge warrants and the warrants issued in connection with the equity financings completed in October 2007 being triggered by the tranche take down under the Series B purchase agreement in September 2010, we agreed to issue an additional 616,136 warrants to the senior bridge note investors and certain of the junior bridge note investors at an exercise price of \$0.15 per share and agreed to reduce the exercise price of the warrants held by such senior and junior bridge note investors to \$0.15 per share (formerly ranging from \$0.17 to \$0.25 per share).

During the twelve months ended October 31, 2010, the company repaid a total of approximately \$1,542,000 in principal value of junior bridge notes and converted \$2,420,000 in principal value of junior bridge notes into 14,237,489 shares of our common stock. At October 31, 2010, approximately \$777,000 in principal value of junior bridge notes remained outstanding and is classified as a current liability on the balance sheet. The indebtedness represented by these junior bridge notes is expressly subordinate to our currently outstanding senior secured indebtedness (approximately \$89,000 of senior bridge notes at October 31, 2010).

As a result of anti-dilution protection provisions contained in certain of our outstanding warrants, we (i) reduced the exercise price from \$0.20 to \$0.17 per share in January 2010 and further reduced the exercise price from \$0.17 to \$0.15 per share in September 2010 with respect to substantially all the warrants to purchase shares of our common stock and (ii) correspondingly adjusted the amount of warrant shares issuable such that approximately 11.4 million additional warrant shares are issuable related to the January 2010 repricing and approximately 10.4 million additional warrant shares are issuable related to the September 2010 repricing. As of October 31, 2010, approximately 87.3 million warrant shares are currently exercisable at \$0.15 per share.

On September 22, 2008 we entered into a note purchase agreement with our Chief Executive Officer, Thomas A. Moore, pursuant to which we agreed to sell to Mr. Moore, from time to time, Moore Notes, which we refer to as the Moore Agreement. The Moore Notes have been amended from time to time. During 2010, we agreed to amend the terms of the Moore Notes such that Mr. Moore may elect, at his option, to receive accumulated interest thereon (of which we paid \$130,000 on March 17, 2010) and that we will begin to make installment payments on the outstanding principal beginning on April 15, 2010 (of which \$250,000 was paid during the year ended October 31, 2010); provided, however, that the balance of the principal will be repaid in full as a result of either (i) consummation of our next equity financing resulting in gross proceeds to the company of at least \$6.0 million or (ii) default by the company as defined under the terms of the Moore Agreement. As of October 31, 2010, the company was not in default under the terms of the Moore Agreement. Additionally, we agreed to retain \$200,000 of the repayment amount for investment in our next equity financing (Mr. Moore exchanged debt with the principal amount of \$200,000 into 1,176,471 shares of our common stock in May 2010).

The Moore Notes bear interest at a rate of 12% per annum and may be prepaid in whole or in part at our option without penalty at any time prior to maturity. As of October 31, 2010, approximately \$600,000 in Moore Notes were outstanding and payable to Mr. Moore.

In October 2010, we received an IRS grant under the Qualified Therapeutic Discovery Program for approximately \$245,000. We plan to sell our Net Operating Losses and research tax credits for the 2009 fiscal year under the same State of New Jersey NOL Transfer Program for small business.

#### Off-Balance Sheet Arrangements

As of October 31, 2010, we had no off-balance sheet arrangements, other than our lease for space. There were no changes in significant contractual obligations during the year ended October 31, 2010.

#### Critical Accounting Estimates

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

- It requires assumption to be made that were uncertain at the time the estimate was made, and

- Changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

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

**Share-Based Payment.** We record compensation expense associated with stock options in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 718, Stock Compensation (formerly, FASB Statement 123R). We adopted the modified prospective transition method provided under SFAS No. 123R. Under this transition method, compensation expense associated with stock options recognized in the first quarter of fiscal year 2007, and in subsequent quarters, includes expense related to the remaining unvested portion of all stock option awards granted prior to April 1, 2006, the estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123.

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

If factors change and we employ different assumptions in the application of ASC 718 in future periods, the compensation expense that we record under ASC 718 relative to new grants may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option-pricing models to estimate share-based compensation under ASC 718. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Employee stock options may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements.

#### Warrants.

Warrants were issued in connection with the equity financings completed in October 2007, the sale of preferred stock and the issuance of our senior and junior bridge notes. At October 31, 2010, we estimated the fair value of the outstanding instruments using the Black-Scholes valuation model, which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term and the closing price of our common stock. Changes in assumptions used to estimate the fair value of these derivative instruments could result in a material change in the fair value of the instruments. We believe the assumptions used to estimate the fair values of the warrants are reasonable.

As of October 31, 2010, we had outstanding warrants to purchase 103,139,628 shares of our common stock (adjusted for anti-dilution provisions to-date) including approximately 87 million warrants with an exercise price of \$0.15 per share. These warrants include 15,802,941 warrants owned by Optimus as part of the Series B purchase agreement.

New Accounting Pronouncements

In April 2010, FASB issued Accounting Standards Update (ASU) 2010-17, Revenue Recognition—Milestone Method (Topic 605) - Milestone Method of Revenue Recognition - a consensus of the FASB Emerging Issues Task Force. This ASU provides guidance to vendors on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted.

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

## DESCRIPTION OF BUSINESS

## General

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

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

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

Product	Indication	Stage
ADXS11-001	Cervical Cancer	Phase I Company sponsored & completed in 2007.
	Cervical Intraepithelial Neoplasia	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 FDA. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies, including conducting clinical trials for our product candidates, with no certainty that our products will become commercially viable or profitable as a result of these expenditures.

## Strategy

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

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

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

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

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

Given our expertise in genetically modifying Listeria to create vaccines for many different diseases, our longer term strategy will be to license the commercial development of ADXS11-001 for the indications of CIN, cervical and head and neck cancers, and other HPV related diseases. On a global basis, these indications are extremely large and will require one or more significant partners. We do not intend to engage in commercial development beyond Phase II without entering into one or more partnerships or a license agreement.

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

## Background



Cancer

Cancer is the second largest cause of death in the U.S., exceeded only by heart disease. The cost of treating cancer patients in 2008 was estimated to be \$228.1 billion in healthcare costs and another \$188 billion in indirect costs resulting from morbidity and lost productivity (source: Facts & Figures 2009, American Cancer Society). The American Cancer Society's most recent estimates for newly diagnosed cervical cancer in the U.S. in 2010 was 12,200 and numbers for newly diagnosed CIN are approximately about 250,000 patients per year based on 3.5 million abnormal Pap smears (source: Jones HW, Cancer 1995;76:1914-18; Jones BA and Davey, Arch Pathol Lab Med 2000; 124:672-81). Overall predicted incidence and mortality rates for 2009 are set forth below:

US Cancer Rates (2009 Estimated)

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

Cancer Incidence and Mortality Rates\* by Site, Race, and Ethnicity, US, 2001-2005

Incidence	White	African American and Pacific Islander	Asian American and Alaska Native	American Indian Native	Hispanic/Latino
<b>All sites</b>					
Male	551.4	651.5	354.0	336.6	419.4
Female	423.6	398.9	287.8	296.4	317.8
Breast (female)	130.6	117.5	89.6	75.0	90.1
<b>Colon &amp; rectum</b>					
Male	58.9	71.2	48.0	46.0	47.3
Female	43.2	54.5	35.4	41.2	32.8
<b>Kidney &amp; renal pelvis</b>					
Male	18.8	21.3	9.1	19.5	17.4
Female	9.5	10.1	4.6	12.7	9.6
<b>Liver &amp; bile duct</b>					
Male	8.2	13.2	21.7	14.4	15.0
Female	2.9	4.0	8.3	6.3	5.8
<b>Lung &amp; bronchus</b>					
Male	79.3	107.6	53.9	54.3	44.2
Female	54.9	54.6	28.0	39.7	25.4
<b>Prostate</b>	156.7	248.5	93.8	73.3	138.0
<b>Stomach</b>					
Male	10.0	17.4	18.6	16.8	15.5
Female	4.7	8.9	10.5	7.7	9.5
<b>Uterine cervix</b>	8.2	10.8	8.0	6.9	13.2

Mortality	White	African American and Pacific Islander	Asian American and Alaska Native	American Indian Native	Hispanic/Latino
<b>All sites</b>					
Male	230.7	313.0	138.8	190.0	159.0
Female	159.2	186.7	95.9	142.0	105.2
Breast (female)	24.4	33.5	12.6	17.1	15.8
<b>Colon &amp; rectum</b>					
Male	22.1	31.8	14.4	20.5	16.5
Female	15.3	22.4	10.2	14.2	10.8
<b>Kidney &amp; renal pelvis</b>					
Male	6.2	6.1	2.4	9.3	5.3
Female	2.8	2.7	1.2	4.3	2.4
<b>Liver &amp; bile duct</b>					
Male	6.7	10.3	15.2	10.6	11.1
Female	2.9	3.9	6.6	6.6	5.1
<b>Lung &amp; bronchus</b>					
Male	71.3	93.1	37.5	50.2	35.1
Female	42.0	39.9	18.5	33.8	14.6
<b>Prostate</b>	24.6	59.4	11.0	21.1	20.6
<b>Stomach</b>					
Male	5.0	11.5	10.1	9.9	8.7

Female	2.5	5.5	5.9	5.2	4.9
Uterine cervix	2.3	4.7	2.2	3.7	3.2

\* Per 100,000, age adjusted to the 2000 US standard population. † Data based on Contract Health Service Delivery Areas (CHSDA), 624 counties comprising 54% of the US American Indian/Alaska Native population. ‡ Persons of Hispanic/Latino origin may be of any race. § Data unavailable from the Alaska Native Registry and Kentucky. ¶ Data unavailable from Minnesota, New Hampshire, and North Dakota.

Source: Ries LAG, Melbert D, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2005, National Cancer Institute, Bethesda, MD, [seer.cancer.gov/csr/1975\\_2005/](http://seer.cancer.gov/csr/1975_2005/), 2008.

American Cancer Society, Surveillance and Health Policy Research, 2009

### Immune System and Normal Antigen Processing

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

#### Innate Immunity:

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

#### Exogenous pathway of Adaptive Immunity (Class II pathway):

Proteins and foreign molecules ingested by Antigen Presenting Cells, or APCs, are broken down inside digestive vacuoles into small pieces, and the pieces are combined with proteins called Class 2 MHC (for Major Histocompatibility Complex) in a part of the cell called the endoplasmic reticulum. The MHC-peptide, termed and MHC-2 complex from the Class 2 (or exogenous) pathway, migrates to the cell surface where it interacts with certain classes of lymphocytes (CD4+) called helper T-cells that support the function of cytotoxic T-lymphocytes (killer T cells). This interaction renders CD4+ cells antigen specific, and they express their function whenever they encounter the antigen to which they've been activated. This system is called the exogenous pathway, since it is the prototypical response to an antigen from outside of the cell, like bacteria.

Endogenous pathway of Adaptive Immunity (Class I pathway):

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

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

Listeria based vaccines are unique for many reasons, one of which is that unlike viral vectors, DNA or peptide antigens or other vaccines, Listeria stimulates all of the above mechanisms of immune action. We use a bioengineered form of Listeria to activate the immune system to treat cancer, infectious diseases, or allergic syndromes. Our technology allows the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by utilizing a number of biological characteristics of the Listeria bacteria and Advaxis proprietary antigen-fusion protein technology to stimulate multiple therapeutic immune mechanisms simultaneously in an integrated and coordinated manner.

Mechanism of Action

Listeria monocytogenes (Lm) is a bacterium well known to medical science because it can cause an infection in humans. Listeria is a rare, but serious, cause food poisoning, typically in the very old, the very young, people who are either immunocompromised or who eat a large quantity of the microbe as can occur in spoiled food. It is not laterally transmitted from person to person. As Lm is in the soil and thus found on leafy vegetables, in meat and dairy products, and is a common microbe in our environment, we are exposed to it constantly. Most people ingest Listeria without being aware of it, but in high quantities or in immune suppressed people Listeria can cause various clinical conditions, including sepsis, meningitis and placental infections in pregnant women. This is rare, and fortunately, many common antibiotics can kill and sterilize Listeria. Advaxis has a number of strains of Listeria that are bioengineered for use as a human vaccine vector. These vaccines are highly attenuated, which means they are much less pathogenic. Advaxis vaccines are between 10,000 and 100,000 times weaker (and less able to cause disease) than wild type Listeria.

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

APCs are scavenging cells in the body that circulate looking for foreign invaders. When they find one, they ingest it, break it down, and provide the fragments as molecular targets for the immune system to attack. In this way they are the cells that direct a specific immune response, and Listeria has the ability to infect them. Because Listeria infects APC, and our vaccines secrete biologically active molecules from within APC, our live attenuated Lm vaccines have the ability to direct an immune attack in a way no other therapy can.

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

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

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

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

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

Other mechanisms that Advaxis vaccines employ include *Listeria*'s ability to increase the synthesis of myeloid cells such as APCs and macrophages, and to stimulate the maturation of immature myeloid cells to increase the number of available activated immune cells that underlie a cancer-killing response. Immature myeloid cells actually inhibit the immune system and *Listeria* removes this inhibition within the actual tumor. Also, *Listeria* and LLO both stimulate the synthesis, release, and expression of various chemicals which stimulate a therapeutic immune response. These chemicals are called cytokines, chemokines and co-stimulatory molecules. By doing this, not only are immune cells activated to kill cancers and clear them from the body, but local environments within tumors are created that support and facilitate a therapeutic response.

Finally, in a manner that appears to be unique to Advaxis live attenuated *Listeria* vaccines: they can reduce the number and function of immunosuppressive cells that tumors recruit to protect them from therapeutic immune attack. Over the past few years it has become known that the reason many previous immunologic cancer treatments have failed is that although they were able to strongly activate the immune system, they were rendered ineffective by endogenous sources of immune inhibition within the tumors themselves. Advaxis has either published scientific papers or presented data at scientific meetings about the ability of our vaccines to reduce the number of regulatory T cells (Tregs) and Myeloid Derived Suppressor Cells (MDSC); and that MDSC which remain are less immunosuppressive. This renders tumors susceptible to immune attack. The ability to reduce the effect of immunosuppressive cells within tumors is currently under clinical investigation by other companies and is believed to be a significant mechanism of achieving a therapeutic response.

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

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

It should also be noted that the live *Listeria* vaccines Advaxis creates are attenuated from 10,000 to 100,000 times in order that they will not cause disease themselves. The strains of *Listeria* that we use are cleared by animals such as SCID mice or IFN-gamma knockout mice that lack adaptive immune responses and are thus profoundly immuno-compromised.



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

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

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

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

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

## Research and Development Program

### Overview

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

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

We can use different tumor, infectious disease, or other antigens in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, ADXS11-001, uses a HPV derived antigen that is present in cervical cancers. ADXS31-162 uses Her2/neu, an antigen found in many breast cancer and melanoma cells, to induce an immune response that should be useful in treating these conditions. ADXS31-142 is directed against PSA, and antigen of importance in prostate cancer.

## Partnerships and Agreements

### University of Pennsylvania

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

This license, unless sooner terminated in accordance with its terms, terminates upon the later (a) expiration of the last to expire Penn patent rights; or (b) twenty years after the effective date of the license. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to raise capital and pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our common stock which currently represents approximately 0.2% of our common stock outstanding on a fully-diluted basis. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of \$525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which we are not expecting to begin paying within the next five years). In addition, under the license, we are obligated to pay an annual maintenance fee of \$100,000 on December 31, 2010, 2011 and 2012 and each December 31st thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. Overall the amended and restated agreement payment terms reflect lower near term requirements but the savings are offset by higher long term milestone payments for the initiation of a Phase III clinical trial and the regulatory approval for the first Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

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

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

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

Strategically we intend to maintain our relationship with Dr. Paterson and Penn to generate new intellectual property and to exploit all existing intellectual property covered by the license.

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

Dr. Yvonne Paterson

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

Consulting Agreement. On January 28, 2005 we entered into a consulting agreement with Dr. Paterson, which expired on January 31, 2009. Dr. Paterson has advised us on an exclusive basis on various issues related to our technology, manufacturing issues, establishing our lab, knowledge transfer, and our long-term research and development program. Pursuant to the expired agreement, Dr. Paterson received \$7,000 per month. Upon the closing of an additional \$9.0 million in equity capital, Dr. Paterson's rates would have increased to \$9,000 per month. Also, under the prior Agreement, on February 1, 2005, she received options to purchase 400,000 shares of our common stock at an exercise price of \$0.287 per share which are now fully vested. In total she holds 704,365 shares of our common stock and 569,048 fully vested options to purchase shares of our common stock.

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

Cancer Research UK

On February 9, 2010, we announced that Cancer Research UK (CRUK), the UK organization dedicated to cancer research, has agreed to fund the cost of a clinical trial to investigate the use of ADXS11-001, our lead vaccine candidate, for the treatment of head and neck cancer. This sponsored clinical trial will investigate the safety and efficacy of ADXS11-001 in head and neck cancer patients who have previously failed treatment with surgery, radiotherapy and chemotherapy – alone or in combination. We will provide the vaccines, with all other associated costs to be funded by CRUK. The study is to be conducted at Aintree Hospital at the University of Liverpool, The Royal Marsden Hospital in London, and Cardiff Hospital at the University of Wales. At such time, enrollment officials anticipate recruiting a maximum of 45 patients.

National Cancer Institute Gynecologic Oncology Group

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

On November 1, 2010 we entered into a Collaborative Research and Development Agreement (CRADA) with the Vaccine Section of National Cancer Institute for the development of live attenuated Listeria vaccines for the treatment

of cancer. We will provide all live Listeria vaccines. NCI will use different in vitro and in vivo models to elucidate the effect of our live attenuated Listeria vaccines on many different types of immune cells, and will investigate the mechanisms by which live Listeria vaccines reduce cancer induced immune inhibition that protects tumors from immune attack. We and NCI will use the results of this work to enhance the anti-tumor effects of live Listeria vaccines as therapeutic agents for the treatment of cancer and as therapeutic immune adjuvants that alter the tumor milieu which will enable them to be used with other modalities of cancer treatment. The cost of the CRADA is \$150,000 annually and the length of the agreement is three years.

#### University of British Columbia

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

#### The Sage Group

We are party to a consulting agreement with The Sage Group, a health-care strategy consultant assisting us with a program to commercialize our vaccines. The initial agreement was entered into in January 2009 and subsequently amended on July 22, 2009. Pursuant to the terms of agreement, as amended, we have agreed to pay Sage (i) \$5,000 per month (which we began paying in January 2009) until an aggregate of \$120,000 has been paid to Sage under the consulting agreement and (ii) a 5% commission for certain transactions if completed in the first 24 months of the term of the agreement, reduced to 2% if completed in the 12 months thereafter. The Sage Group has been paid approximately \$56,000 through October 31, 2010.

#### Recipharm AB (formerly Cobra Biomanufacturing PLC)