

Advaxis, Inc.  
Form S-1/A  
December 12, 2012

**File No. 333-185357**

**As filed with the Securities and Exchange Commission on December 12, 2012**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**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	2836	02-0563870
(State or other jurisdiction	(Primary Standard Industrial	(I.R.S.
of incorporation or organization)	Classification Code Number)	Employer
		Identification
		No.)

**305 College Road East**

**Princeton, New Jersey 08540**

**(609) 452-9813**

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

**Mr. Thomas A. Moore**

**Chief Executive Officer**

**305 College Road East**

**Princeton, New Jersey 08540**

**(609) 452-9813**

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

*Copies to:*

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**200 Park Avenue**

**New York, New York 10166**

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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 stockholder 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:

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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.**

**The information in this prospectus is not complete and may be changed. The selling stockholder 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 DECEMBER 12, 2012***

**ADVAXIS, INC.**

**115,000,000 Shares**

**Common Stock**

This prospectus relates to the disposition from time to time of up to 115,000,000 shares of our common stock, which are held or may be held by the selling shareholder named in this prospectus. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling shareholder.

The selling shareholder identified in this prospectus may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We provide more information about how the selling shareholder may sell its shares of common stock in the section entitled "Plan of Distribution" beginning on page 76 of this prospectus. We will not be paying any underwriting discounts or commissions in connection with any offering of common stock under this prospectus.

Our common stock is quoted on the Over-The-Counter Bulletin Board, or OTC Bulletin Board, under the symbol ADXS.OB. On December 6, 2012, the last reported sale price per share for our common stock as reported by the OTC Bulletin Board was \$0.04.

**Investing in our common stock involves a high degree of risk. We urge you to carefully consider the "Risk Factors" beginning on page 2.**

*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 \_\_\_\_\_.

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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 immunotherapies for cancer and infectious diseases. These immunotherapies are based on a platform technology under exclusive license from the University of Pennsylvania, which we refer to as Penn, that utilizes live attenuated *Listeria monocytogenes*, which we refer to as *Listeria* or *Lm*, bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains use a fragment of the protein listeriolysin (LLO), fused to a tumor associated antigen (TAA) or other antigen of interest. We believe these *Lm*-LLO agents redirect the potent immune response to *Lm* which is inherent in humans, to the TAA or antigen of interest. The immune response to a live, metabolically competent pathogen is much more complex than the response to a synthetic or organic molecule and may enable a more comprehensive therapeutic outcome than current treatment modalities. We believe this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers and infectious diseases.

The discoveries that underlie this innovative technology are based upon the work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn. *Lm*-LLO based immunotherapies stimulate the immune system to induce antigen-specific anti-tumor immune responses involving both innate and adaptive arms of the immune system. In addition, this technology facilitates the immune response by altering the microenvironment of tumors to make them more susceptible to immune attack.

We have focused our initial development efforts on therapeutic immunotherapies targeting HPV-associated diseases: cervical intraepithelial neoplasia, which we refer to as CIN 2/3, recurrent or refractory cervical cancer, and head and neck cancer. In addition we have developed immunotherapies for prostate cancer, and HER2 expressing cancers (such as breast, gastric, bladder, brain, pancreatic and ovarian cancer). Our lead drug candidates in clinical development are as follows:

Immunotherapy	Indication	Stage
ADX5-HPV	Cervical Cancer	<b>Phase 1</b> Company sponsored & completed in 2007 with 15 patients.

	Cervical Intraepithelial Neoplasia	<b>Phase 2</b> Company sponsored study, initiated in March 2010 in the US. The Company completed enrollment of the low-dose cohort in September 2011 (41 patients) and in June 2012 (40 patients) in the mid-dose cohort.
	Cervical Cancer	<b>Phase 2</b> Company sponsored study initiated in November 2010 in India in 110 patients with recurrent or refractory cervical cancer. The Company completed enrollment (110 patients) in May 2012.
	Cervical Cancer	<b>Phase 2</b> The Gynecologic Oncology Group (GOG) of the National Cancer Institute is conducting a study in 67 patients with recurrent or refractory cervical cancer which is currently open to enrollment. As of October 3, 2012, 6 out of 67 patients have been enrolled in the safety run-in phase.
	Head & Neck Cancer	<b>Phase 1</b> The Cancer Research UK (CRUK) is funding a study of 27 patients with head & neck cancer at 3 UK sites. As of October 3, 2012, 6 patients have been enrolled.
ADX-PSA	Prostate Cancer	<b>Phase 1</b> Company sponsored (timing to be determined).
ADX-HER2	HER2 Expressing Cancer	<b>Phase 1</b> Company sponsored (timing to be determined).
ADX-HER2	Canine Osteosarcoma	<b>Phase 1</b> Company sponsored study, initiated in July 2011 in the US. As of October 3, 2012, 2 dogs have been dosed.

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, 2011 and July 31, 2012, we had an accumulated deficit of \$35,531,740 and \$45,611,368, respectively and shareholders' deficiency of \$12,279,713 and \$4,999,243, respectively.

To date, we have outsourced many functions of drug development including manufacturing and clinical trials management. Accordingly, the expenses of these outsourced services account for a significant amount of our accumulated loss. We cannot predict when, if ever, any of our immunotherapies 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 immunotherapies, with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures.

We intend to continue devoting a substantial portion of our resources to the continued pre-clinical development and optimization of our platform technology so as to develop it to its full potential and to further identify appropriate new drug candidates. Specifically, we intend to conduct research relating to developing the next generations of our *Lm*-LLO based immunotherapies using new antigens of interest; improving the *Lm*-LLO based platform technology by developing new strains of *Listeria* which may be more suitable as live vaccine vectors; and continuing to develop the use of the LLO as a component of a fusion protein based immunotherapy. 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**

### ***Equity Enhancement Program***

On October 26, 2012, we entered into a Common Stock Purchase Agreement, which we refer to as the Purchase Agreement, with Hanover Holdings I, LLC, a New York limited liability company, which we refer to as Hanover, whereby we may, subject to certain customary conditions, pursuant to a financing arrangement that is sometimes referred to as a committed equity line financing facility, which we refer to this prospectus as the Equity Enhancement Program, require Hanover to purchase up to \$10.0 million of shares of our common stock over the 24-month term following the effectiveness of the resale registration statement described below. Over the 24-month term following the effectiveness of the resale registration statement, we generally have the right, but not the obligation, to direct Hanover to periodically purchase shares of our common stock in specific amounts under certain conditions at our sole discretion. The purchase price for such shares of common stock will be the higher of (i) the minimum price, which we refer to as the Floor Price, set forth in our notice electing to effect such issuance, which we refer to as the Draw Down Notice, and (ii) 90% of the arithmetic average of the five lowest closing sale prices of the common stock during the applicable ten trading day pricing period (or, if less, the arithmetic average of all trading days with closing sale prices in excess of the Floor Price), subject to adjustment upon an alternative transaction. Each trading day with a closing sale price less than the Floor Price is excluded from the calculation of the purchase price and automatically reduces the number of trading days in the applicable pricing period.

In consideration for Hanover's execution and delivery of the Purchase Agreement, in connection with the execution and delivery of the Purchase Agreement, we have issued Hanover 3,500,000 shares of our common stock, which we refer to as the Commitment Fee Shares. We have also agreed to issue Hanover up to 1,800,000 additional shares of our common stock, which we refer to as the Maintenance Fee Shares, during any full calendar quarter during the term of the Purchase Agreement, if no shares of common stock have been purchased or sold because we did not deliver a Draw Down Notice to Hanover. The number of Maintenance Fee Shares to be delivered to Hanover, from time to time, with respect to any calendar quarter, will be equal to approximately \$15,000 worth of shares of common stock at a 10% discount to market.

The Purchase Agreement provides for indemnification of Hanover and its affiliates in the event that Hanover incurs losses, liabilities, obligations, claims, contingencies, damages, costs and expenses related to a breach by us of any of our representations and warranties under the Purchase Agreement or the other related transaction documents or any action instituted against Hanover or its affiliates due to the transactions contemplated by the Purchase Agreement or other transaction documents, subject to certain limitations.

In connection with the Purchase Agreement, on October 26, 2012, we entered into a registration rights agreement with Hanover, which we refer to as the Registration Rights Agreement, pursuant to which we granted to Hanover certain registration rights related to the Commitment Fee Shares, the Maintenance Fee Shares, and the shares issuable under the Purchase Agreement, which we refer to as the Registrable Securities. Under the Registration Rights Agreement, we agreed to prepare and file with the SEC one or more registration statements for the purpose of registering the resale of the Registrable Securities. We agreed to file the initial registration statement with the SEC within 12 calendar days of the Purchase Agreement and to use our commercially reasonable efforts to cause such registration statement to be declared effective within 90 calendar days of the Purchase Agreement (120 calendar days if the registration statement is reviewed by the SEC).

We also agreed, among other things, to indemnify Hanover from certain liabilities and fees and expenses of Hanover incident to our obligations under the Registration Rights Agreement, including certain liabilities under the Securities Act. Hanover has agreed to indemnify us and hold harmless each of our directors, officers and persons who control us against certain liabilities that may be based upon written information furnished by Hanover to us for inclusion in a registration statement pursuant to the Registration Rights Agreement, including certain liabilities under the Securities Act of 1933, as amended.

For a more detailed description of the Equity Enhancement Program see "Equity Enhancement Program" on page 17 below.

### ***Private Placements of Convertible Notes to Hanover***

On September 19, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500 for a purchase price of \$132,500, which we refer to as the September 2012 Hanover PIPE Note. On October 19, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500, for a purchase price of \$132,500, which we refer to as the October 2012 Hanover PIPE Note, which, together with the September 2012 Hanover PIPE Note we refer to as the Initial Hanover PIPE Notes.

On December 6, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which we refer to as the Hanover December 2012 Note. The Hanover December 2012 Note bears interest at a rate of 12% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of such Hanover December 2012 Note. The Hanover December 2012 Note is convertible into shares of our common stock at a conversion price of \$0.03 per share. On December 5, Hanover exchanged the Initial Hanover PIPE Notes for convertible notes in the form of the Hanover December 2012 Note in all material respects (other than date of issuance, exchange date, the maturity date of May 19, 2012 solely with respect to the Exchanged Hanover PIPE Note issued in exchange for the Hanover September 2012 PIPE Note and the maturity date of June 19, 2013 solely with respect to the Exchanged Hanover PIPE Note issued in exchange for the Hanover October 2012 PIPE Note) that also are convertible into shares of our common stock at a conversion price of \$0.03 per share, which we refer to as the Exchanged Hanover PIPE Notes. Each of the Hanover December 2012 Note and the Exchanged Hanover PIPE Notes are subject to limitations on conversion if after giving effect to such conversion Hanover would beneficially own more than 4.99% of our common stock.

### ***Other Hanover Related Transactions***

In October 2012, pursuant to the terms of various Assignment Agreements, which we refer to as the Assignment Agreements, Magna Group, LLC, an affiliate of Hanover, which we refer to as Magna, acquired \$400,075.88 in aggregate principal amount of our outstanding convertible notes from certain third parties and entered into agreements to acquire an additional \$340,522.90 in aggregate principal amount of our outstanding convertible notes from other third parties. Pursuant to the terms of such Assignment Agreements, we delivered two convertible notes to Magna in an aggregate principal amount of \$740,598.74, in anticipation of the closing of all of the transactions contemplated by such Assignment Agreements. On October 25, 2012, the convertible note in the aggregate principal amount of \$617,722.92 previously delivered to Magna was exchanged for a new convertible note in the aggregate principal amount of \$400,075.77, convertible into shares of common stock, which we refer to as the First Magna Exchange Note, to reflect such portion of the convertible notes actually issued as of October 25, 2012 pursuant to the Assignment Agreements, and the remaining convertible note in the aggregate principal amount of \$122,875.82 previously delivered to Magna was returned to us and cancelled. Prior to the date of this filing, the First Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On November 14, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$58,823.53, convertible into shares of common stock, which we refer to as the Second Magna Exchange Note. The Second Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Second Magna Exchange Note. Prior to the date of this filing, the Second Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On November 23, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$111,111.11, convertible into shares of common stock, which we refer to as the Third Magna Exchange Note. The Third Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Third Magna Exchange Note. Prior to the date of this filing, the Third Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On December 6, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$170,588.22, convertible into shares of common stock, which we refer to as the Fourth Magna Exchange Note. The Fourth Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Fourth Magna Exchange Note. Prior to the date of this filing, the Fourth Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

### ***Warrants – 2007 Private Placement***

On October 17, 2012, warrants to purchase 15,869,507 shares of our common stock expired unexercised. As of December 6, 2012, we have warrants to purchase 164,896,321 shares of our common stock outstanding.

### ***French Note***

On September 27, 2012, in a private placement pursuant to a note purchase agreement, we issued our employee Christine French a convertible promissory note in the aggregate principal amount of \$25,000 for a purchase price of \$25,000, which we refer to as the French Note. The French Note bears interest at a rate of 12% per annum, compounding annually. The French Note is convertible into shares of our common stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The French Note matures one month from its issuance date. Additionally, Ms. French will receive a warrant, which we refer to as the French Warrant, to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the French Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The French Warrant may be exercised on a cashless basis under certain circumstances. The French Note and the French Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Ms. French be entitled to convert any portion of the French Note or French Warrant to the extent that after such conversion or exercise, as applicable, Ms. French (together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. On December 7, 2012, Ms. French agreed to extend the maturity date of the French Note to December 31, 2012.

### ***Paterson Note***

On September 25, 2012, in a private placement pursuant to a note purchase agreement, we issued our affiliate Dr. Yvonne Paterson a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which we refer to as the Paterson Note. The Paterson Note bears interest at a rate of 12% per annum, compounding annually. The Paterson Note is convertible into shares of our common stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Paterson Note matures one month from its issuance date. Additionally, Dr. Paterson will receive a warrant, which we refer to as the Paterson Warrant, to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the Patterson Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The Paterson Warrant may be exercised on a cashless basis under certain circumstances. The Paterson Note and the Paterson Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Paterson be entitled to convert any portion of the Paterson Note or Paterson Warrant to the extent that after such conversion or exercise, as applicable, Dr. Paterson



(together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. On December 7, 2012, Dr. Paterson agreed to extend the maturity date of the Paterson Note to December 31, 2012.

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### *Asher Notes*

On September 11, 2012, in a private placement pursuant to a note purchase agreement, we issued Asher Enterprises, Inc, which we refer to as Asher, a convertible promissory note in the aggregate principal amount of \$103,500 for a purchase price of \$100,000, which we refer to as the September Asher Note. The September Asher Note bears interest at a rate of 8% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the September Asher Note. The September Asher Note is convertible into shares of our common stock at a conversion price equal to 61% of the arithmetic average of the five lowest closing trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The September Asher Note matures on June 13, 2013, nine months from its issuance date. The September Asher Note may be converted by Asher, at its option, in whole or in part. The September Asher Note includes a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the September Asher Note to the extent that after such conversion Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

On November 12, 2012, in a private placement pursuant to a note purchase agreement, we issued Asher a convertible promissory note in the aggregate principal amount of \$153,500 for a purchase price of \$153,500, which we refer to as the November Asher Note. The November Asher Note bears interest at a rate of 8% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the November Asher Note. The November Asher Note is convertible into shares of our common stock at a conversion price equal to 65% of the arithmetic average of the four lowest closing trading prices for the common stock during the 20 trading day period ending on the latest complete trading day prior to the applicable conversion date. The November Asher Note matures on August 14, 2013, nine months from its issuance date. The November Asher Note may be converted by Asher, at its option, in whole or in part. The November Asher Note includes a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the November Asher Note to the extent that after such conversion Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

### *August 2012 Note*

On August 27, 2012, in a private placement pursuant to a note purchase agreement, we issued JMJ Financial a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which we refer to as the August 2012 Note. The August 2012 Note is initially convertible at a per share conversion price equal to \$0.15. In addition, if the August 2012 Note is converted after November 30, 2012 and the market price of our common stock is less than \$0.16 per share on the date of conversion, then the conversion price shall equal 95% of the arithmetic average of the three lowest closing trading prices for the common stock during the 15 trading day period ending on the latest complete trading day prior to the applicable conversion date. The August 2012 Note matures on August 29, 2013. To the extent JMJ Financial does not elect to convert the August 2012 Note as described above, the principal amount and interest of such note shall be payable in cash at maturity. The August 2012 Note may be converted by JMJ Financial, at its option, in whole or in part. The August 2012 Note includes a limitation on

conversion, which provides that at no time will MJM Financial be entitled to convert any portion of the August 2012 Note to the extent that after such conversion MJM Financial (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. Pursuant to the terms of the August 2012 Note, we agreed to register up to 3,250,000 shares of our common stock which may be issuable upon conversion of the August 2012 Note with the SEC. These shares were registered on August 31, 2012.

***MJM August 2012 Settlement Agreement***

On August 27, 2012, we entered into a settlement agreement with MJM Financial pursuant to which we issued to MJM Financial 4,076,923 shares of our common stock for the mutual release of any claims held by our company or MJM Financial relating to our failure to file the registration statement related to the May 2012 issuance of 4,000,000 shares of our common stock to MJM Financial and have the registration statement declared effective by certain prescribed deadlines.

***Amendment to Certificate of Incorporation***

On August 16, 2012, we filed a certificate of amendment to our amended and restated certificate of incorporation with the Delaware Secretary of State to increase the total number of authorized shares of capital stock available for issuance from 505,000,000, consisting of 500,000,000 shares of our common stock and 5,000,000 shares of “blank check” preferred stock, to 1,005,000,000, consisting of 1,000,000,000 shares of our common stock and 5,000,000 shares of “blank check” preferred stock. The certificate of amendment became effective upon filing.

*Patton Note*

On August 2, 2012, in a private placement pursuant to a note purchase agreement, we issued Dr. James Patton, a member of our board of directors, a convertible promissory note, which we refer to as the Patton Note, in the principal amount of \$66,667 for a purchase price of \$50,000. The Patton Note was issued with an original issue discount of 25%. Dr. Patton paid \$0.75 for each \$1.00 of principal amount of the Patton Note purchased. The Patton Note is convertible into shares of our common stock at a per share conversion price equal to \$0.025287. Additionally, Dr. Patton received a warrant, which we refer to as the Patton Warrant, to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the Patton Note at an exercise price of \$0.025287 per share. The Patton Note matures on August 2, 2013. We may redeem the Patton Note under certain circumstances. The Patton Warrant is exercisable at any time on or before August 2, 2017. The Patton Warrant may be exercised on a cashless basis under certain circumstances. The Patton Note and the Patton Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Patton be entitled to convert any portion of the Patton Note or Patton Warrant to the extent that after such conversion or exercise, as applicable, Dr. Patton (together with his affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

## **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. Our date of inception, for financial statement purposes, is March 1, 2002. Our statements of income and cash flows disclose our accumulated losses and net cash increases (decreases), respectively since inception.

## **Principal Executive Offices**

Our principal executive offices are located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. 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 stockholder	The selling shareholder named in this prospectus may offer and sell up to 115,000,000 shares of our common stock <sup>(1)</sup> .
Use of proceeds	We will not receive any proceeds from the resale of the shares of common stock offered by the selling stockholder as all of such proceeds will be paid to the selling stockholder.
Risk factors	The purchase of our common stock involves a high degree of risk. You should carefully review and consider the “Risk Factors” section of this prospectus for a discussion of factors to consider

before  
deciding to  
invest in  
shares of our  
common  
stock.

OTC Bulletin Board market symbol

ADXS.OB

(1) These shares represent approximately 27.1% of our currently outstanding shares of common stock (based on 423,827,618 shares of common stock outstanding as of December 6, 2012). These shares also represent approximately 16.3% of our currently outstanding shares of common stock (based on 706,730,213 shares of common stock outstanding as of December 6, 2012) on a fully diluted basis.

1



## **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 development stage biotechnology 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, 2011 and July 31, 2012, we had an accumulated deficit of \$35,531,740 and \$45,611,368, respectively and shareholders' deficiency of \$12,279,713 and \$4,999,243, respectively. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our immunotherapies 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, 2011 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 and if the average closing sale price of our common stock on each tranche notice date is less than \$0.15 per share, 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, as amended.***

On July 19, 2010, we entered into a Series B preferred stock purchase agreement, which we refer to as the Series B purchase agreement, with Optimus Capital Partners, LLC, which we refer to as Optimus, which was subsequently amended on April 4, 2011. Pursuant to the Series B purchase agreement, Optimus remains obligated to purchase \$2.84 million of our non-convertible, redeemable Series B preferred stock, which we refer to as our Series B preferred stock, at a price of \$10,000 per share from time to time, subject to our ability to effect and maintain an effective registration statement for the remaining 25,610,038 shares underlying the warrants issued to an affiliate of Optimus in connection with the transaction. As of December 6, 2012, Optimus had purchased an aggregate of 466 shares of Series B preferred stock and remains obligated, from time to time until July 19, 2013, to purchase up to an additional 284 shares of Series B preferred stock, for an aggregate purchase price of \$2,840,000, upon notice from us to Optimus, if certain conditions set forth in the Series B purchase agreement, as amended, are satisfied, including among other things that: (i) we must be in compliance with our SEC reporting obligations, (ii) our common stock must be quoted on an 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, as amended. 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.

In connection with our Series B preferred equity financing, we originally 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, of which no shares of our common stock remain available to purchase. In connection with the amendment to the Series B purchase agreement, we subsequently issued to an affiliate of Optimus a three-year warrant to purchase up to an additional 25,560,000 shares of our common stock, at an initial exercise price of \$0.15 per share. The warrants provide that on each tranche notice date under the Series B purchase agreement, as amended, (i) that portion of the warrants, in the aggregate, 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, as amended, and require Optimus to purchase shares of Series B preferred stock if the number of registered shares underlying the warrant issued to the affiliate of Optimus is insufficient to cover the portion of the warrant that will vest and become exercisable in connection with such tranche notice. If the average closing sale price of our common stock on each tranche notice date is less than \$0.15 per share, we may not be able to require Optimus to purchase the remaining \$2.84 million of Series B preferred stock issuable under the Series B purchase agreement, as amended, without issuing additional warrant shares. We cannot assure you that we will be able to timely effect and maintain a registration statement for the remaining 25,560,000 warrant shares (or any additional warrant shares that may be necessary) so as to permit us to require Optimus to purchase the remaining \$2,840,000 of Series B preferred stock under the Series B purchase agreement, as amended.

***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 immunotherapies. 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, as amended. 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 6, 2012, our total outstanding indebtedness was approximately \$2.5 million, which included the face value of all our outstanding junior bridge notes in the amount of approximately \$0.06 million, a note outstanding to our chief executive officer in the amount of approximately \$0.3 million, debt acquired in May 2012 with a remaining aggregate principal amount of approximately \$0.9 million, debt acquired in July and August 2012 with a remaining aggregate principal balance at approximately \$0.4 million, debt acquired in September and October 2012 with a remaining aggregate principal amount of approximately \$0.5 million and debt acquired in November and December 2012 with a remaining aggregate principal balance of approximately \$0.3 million. Maturity dates for the remaining \$2.5 million range between October 2011 and on or about September 30, 2014. Certain of our indebtedness contain restrictive covenants that limit our ability to issue certain types of indebtedness, which may prevent us from obtaining additional indebtedness on commercially reasonable terms, or at all. 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 junior bridge notes issued in October 2009 may trigger the anti-dilution protection provisions in certain of our warrants, 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 *Lm-LLO* based immunotherapy 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 our immunotherapies;
- 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 drug 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 immunotherapies 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 licensable, FDA-approvable, commercially competitive products on a timely basis. Immunotherapies and vaccines that we may develop are not likely to be commercially available until five to ten or more years. The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or 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 our immunotherapies;
- 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 drug 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 agents such as ADXS-HPV. We are not certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of the Phase 3 trials of ADXS-HPV.

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 or do not demonstrate clinical benefit. 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. Immunotherapies 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 immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

Clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable 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 immunotherapy uneconomical; and

The proprietary rights of others and their competing products and technologies that may prevent the immunotherapy 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 immunotherapy 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 trials to establish the safety and efficacy of the investigational new drug 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 investigational new drug, 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 immunotherapies through clinical testing and to market.



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

In February 2006, we received permission from the appropriate governmental/regulatory agencies in Israel, Mexico and Serbia to conduct a Phase 1 clinical study of ADXS-HPV, our first *Lm*-LLO based immunotherapy targeting HPV16-E7 to determine safety and the maximum tolerated dose in patients with recurrent or refractory cervical cancer. The study was completed in the fiscal quarter ended January 31, 2008. The next step was to test ADXS-HPV in the U.S. which required the filing of an IND with the FDA. The filing included the required preclinical animal pharmacology and toxicology studies, manufacturing information, proposed clinical protocol and investigator information as well as the data generated from the Phase 1 study. Unlike the Phase 2 study patient population of late stage cervical cancer patients, the clinical protocol submitted in the IND proposed to evaluate the safety and efficacy of ADXS-HPV in healthy young patients with CIN 2/3, the pre-neoplastic stage of cervical cancer. On January 6, 2009 we received permission from the FDA to conduct the Phase 2 clinical trial and the trial was initiated in March 2010. However, even though we were allowed to initiate this trial, as with any investigational new drug under an IND, we are always at risk of a clinical hold. There can be delays in obtaining FDA or any other necessary regulatory approvals of any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that an approved 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 *Lm*-LLO based immunotherapy platform technology, and the proprietary technology of others with whom we have entered into collaboration and licensing agreements.

As of December 6, 2012 we have 39 patents that have been issued and licenses for 39 patent applications that are pending (including the 23 patent applications obtained in May 2010 and 2 patent applications obtained in November 2011). 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 Aduro Biotech, a company comprised in part of former Cerus and Anza (two former biotech companies) employees that is investigating *Listeria* vaccines. We believe that through our exclusive worldwide license with Penn we have the earliest known and dominant patent positions in the U.S. and rest of world for the use of recombinant *Listeria monocytogenes* expressing fusion proteins or tumor antigens as an immunotherapy for the treatment of infectious diseases and cancer. 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 is that 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 and Third Amendment Agreements with Penn, as amended, we have acquired exclusive worldwide licenses for an additional 25 patent applications related to our proprietary *Listeria* vaccine technology. As of December 6, 2012, we owed Penn approximately \$510,000 in patent expenses (including licensing fees). We can provide no assurance that we will be able to make all payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights which may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms.

If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug 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. 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 agreements with Recipharm Cobra Biologics Limited, which we refer to as Recipharm Cobra, and Vibalogics GmbH for production of our immunotherapies for research and development and testing purposes. Our reliance on third parties for the manufacture of our drug substance, investigational new drugs and approved 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 manufacture clinical drug supplies of our immunotherapies, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail.

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

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of ADXS-HPV, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other immunotherapies. 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 and production of drug supplies for use in clinical trials. In addition, we have not yet licensed, marketed or sold any of our immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our immunotherapies. 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, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our immunotherapies 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 drug 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 immunotherapies. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our immunotherapies. 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 immunotherapies in human clinical trials, and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against us if one of the immunotherapies 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 immunotherapies;
- 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 immunotherapies; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We have insurance coverage on our clinical 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 immunotherapies. 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 December 6, 2012, 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 investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like: Aduro Biotech, Agenus Inc., Bionovo Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech Inc., Oncothyreon Inc., et al.

We believe that our immunotherapies under development and in clinical trials will address unmet medical needs in the treatment of cancer. 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 immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

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

*The price of our common stock may be volatile.*

The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market after the sale of the shares of common stock by a selling stockholder 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, as amended;
- 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 immunotherapies, 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, as amended;

· 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. In addition, we may not be able to deliver a tranche notice to Optimus under the Series B purchase agreement.

***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 July 31, 2012, 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 December 6, 2012, our officers and directors and their affiliates, in the aggregate, beneficially own approximately 11.0% 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 drug 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 1,000,000,000 shares of our common stock. As of December 6, 2012, we had 423,827,618 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options and convertible promissory notes. As of December 6, 2012, we had outstanding options to purchase 44,807,424 shares of our common stock at a weighted average exercise price of approximately \$0.16 per share and outstanding warrants to purchase 164,896,321 shares of our common stock. To the extent the shares of common stock are issued, options and warrants are exercised or convertible promissory notes are converted, 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. As of December 6, 2012, warrants to purchase 77,519,641 shares of our common stock are exercisable at \$0.025287 per share and are subject to “full ratchet” anti-dilution protection upon certain equity issuances below \$0.025287 per share (as may be further adjusted).



***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.

### **Risks Related to the Offering**

***Our management has broad discretion over the use of the net proceeds that we may receive under our committed equity line financing facility, and we may not use the net proceeds in ways that would increase the value of our stock price.***

We have broad discretion over the use of the net proceeds that we may receive if we sell shares of common stock to Hanover, and we could spend the proceeds in ways that do may not necessarily improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

***If we sell shares of our common stock under our committed equity line financing facility, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.***

In October 19, 2012, we entered into a committed equity line financing facility, or financing arrangement, under which we may sell up to \$10.0 million of our common stock to Hanover over a 24-month period subject to a maximum of 115,000,000 shares of our common stock. In connection with such financing arrangement, we issued 3,500,000 shares of common stock to Hanover upon receipt of their commitment to purchase our common stock in the financing arrangement and we agreed to pay up to 1,800,000 additional shares of our common stock to Hanover to maintain such financing arrangement for the 24-month term, which together with the other 109,700,000 shares of our common stock being registered hereunder, represents approximately 27.1% of our outstanding shares of our common stock as of December 6, 2012 (approximately 16.3% on a fully diluted basis). The issuance of such shares of our common stock to Hanover will have an immediately dilutive impact on our existing shareholders. See also “Equity Enhancement Program – Commitment Fee Shares and Maintenance Fee Shares” below. If we elect to use the committed equity line financing facility, the sale of shares of our common stock to Hanover will have an additional dilutive impact on our existing shareholders.

Hanover may resell some or all of the shares we issue to them pursuant to the financing arrangement and such sales could cause the market price of our common stock to decline significantly with advances under the financing arrangement. To the extent of any such decline, any subsequent advances would require us to issue a greater number of shares of common stock to Hanover in exchange for each dollar of the advance. Under these circumstances, our existing shareholders would experience greater dilution and the total amount of financing that we will be able to raise pursuant to the financing arrangement could be significantly lower than \$10.0 million. Although Hanover is precluded from short sales of shares acquired pursuant to advances under the financing arrangement, the sale of our common stock under the financing arrangement could encourage short sales by third parties, which could contribute to the further decline of our stock price.

***If we are not able to satisfy the conditions to each draw down under the committed equity line financing facility, we will not be able to sell our common stock pursuant to the committed equity line financing facility.***

Our ability to sell securities pursuant to the committed equity line financing facility is subject to conditions to each draw down notice that we present to Hanover requiring Hanover to purchase a specified number of shares of our common stock, which we refer to in this prospectus as a draw down, that must be satisfied prior to the closing of any sale of our common stock pursuant to such draw down. These include, among others:

- Accuracy in all material respects of our representations and warranties (except for such representations and warranties qualified by materiality, which shall be accurate in all respects) and our compliance with covenants in all material respects (including, without limitation, our prior delivery to Hanover of any commitment fee shares or maintenance fee shares to be issued to Hanover pursuant to the Purchase Agreement). See “Equity Enhancement

Program – Representations and Warranties”, “Equity Enhancement Program – Covenants” and “Equity Enhancement Program – Fees and Expenses” below;

A resale registration statement with respect to shares of our common stock to be purchased by Hanover in such draw down must have been declared effective by the SEC and must be available for resale of such shares of our common stock by Hanover;

No material adverse effect on us shall have occurred or be continuing;

All the material filings by us required under the Securities Exchange Act of 1934, as amended, shall have been filed with the SEC; and

The number of shares of our common stock in such draw down shall not exceed:

300% of the average trading volume of our common stock during the 10 trading day period prior to such draw down date;

o Together with the shares of our common stock in all prior draw downs, \$10 million of the shares of our common stock; or

o Such number of shares of our common stock that would result in Hanover beneficially owning more than 9.99% of our common stock after giving effect to such draw down.

See “Equity Enhancement Program – Overview” below. We may not be able to satisfy these conditions and/or the other conditions to a draw down under the committed equity line financing facility. If we are unable to satisfy such conditions, we will not be able to sell any of our common stock pursuant to the committed equity line financing facility.

***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. 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 4,238,276 shares as of December 6, 2012, 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.

## 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 immunotherapies;
- 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 immunotherapies, 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 *Lm*-LLO based immunotherapy platform technology;

· 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 stockholder as all of such proceeds will be paid to the selling stockholder.

## EQUITY ENHANCEMENT PROGRAM

### Overview

On October 26, 2012, we entered into the Purchase Agreement with Hanover providing for a financing arrangement that is sometimes referred to as a committed equity line financing facility, which we refer to in this prospectus as the Equity Enhancement Program. The Equity Enhancement Program was entered into in reliance upon the provisions of Section 4(a)(2) and Rule 506 of Regulation D promulgated by the SEC under the Securities Act of 1933, as amended, or the Securities Act. The Purchase Agreement provides that Hanover has committed to purchase up to \$10 million of shares of our common stock, in one or more draw downs, over the 24-month term of the Purchase Agreement under certain specified conditions and limitations as specified in the Purchase Agreement, which include:

- Accuracy of our representations and warranties and our compliance with covenants in all material respects;

A resale registration statement with respect to shares of our common stock to be purchased by Hanover in such draw down must have been declared effective by the SEC and must be available for resale of such shares by Hanover;

- No stop order or injunction with respect to our common stock or such offering shall be in effect;

All the material filings by us required under the Securities Exchange Act of 1934, as amended, or the Exchange Act shall have been filed with the SEC;

- No suspension of trading or delisting of our common stock shall have occurred;

- Our compliance in all material respect with applicable laws with respect to such offering;

No action, suit, proceeding or other litigations shall be pending or threatened to restrain, prevent or change the transactions contemplated by the Purchase Agreement;

· The number of shares of our common stock in such draw down shall not exceed the lesser of:

o 300% of the average trading volume of our common stock during the 10 trading day period prior to such draw down date;

o Together with the shares of our common stock in all prior draw downs, \$10 million worth of shares of our common stock; and

o Such number of shares of our common stock that would result in Hanover beneficially owning more than 9.99% of our common stock after giving effect to such draw down.

· No material adverse effect on us shall have occurred or be continuing; and

· The shares of our common stock to be delivered in such draw down shall be duly authorized, validly issued and delivered electronically to Hanover's or its designee's account at DTC.

In addition, we have agreed to (a) reserve and keep available at all times such number of authorized but unissued shares of our common stock as required to be issued pursuant to the Purchase Agreement, from time to time and (b) take all action necessary to cause our common stock to continue to be registered under the Exchange Act and listed on the OTC Bulletin Board and use commercially reasonable efforts to comply with the reporting and filing obligations under applicable securities laws, rules and regulations.



### **Mechanics of each Draw Down Notice**

From time to time over the term of the Purchase Agreement, and in our sole discretion, subject to the satisfaction of the conditions described above, we may present Hanover with a draw down based on a purchase price per share calculated over 10 consecutive trading days following the start date we designate in our draw down, which we refer to in this prospectus as the Pricing Period (subject to adjustment as described in “Mechanics of Each Draw Down Notice – Purchase Price of Required Shares” below). Only one draw down may be made during any Pricing Period and at least five trading days must elapse before a subsequent Pricing Period may occur.

#### *Closing of Draw Down*

Each closing of a draw down shall occur no later than the 12<sup>th</sup> business day following the commencement of the applicable Pricing Period.

#### *Floor Price; Reduction in Required Purchase of Shares*

The purchase price of our common stock to be sold in connection with such draw down is subject to the Floor Price. If the closing sale price of our common stock on any trading day in the applicable Pricing Period falls below the Floor Price, the number of shares of our common stock required to be purchased by Hanover will be reduced by 10%.

#### *Purchase Price of Required Shares*

The purchase price per share for any shares of our common stock required to be purchased by Hanover will be equal to 90% of the arithmetic average of the five lowest closing sale prices of our common stock during the applicable Pricing Period (or, if less, the arithmetic average of all trading days with closing sale prices in excess of the Floor Price), subject to adjustment upon an alternative transaction as describe below. See “Mechanics of Each Draw Down – Alternative Transactions” below. Each trading day with a closing sale price less than the Floor Price is excluded from the calculation of the purchase price and automatically reduces the number of trading days in the applicable Pricing Period.

#### *Purchase Price Adjustment upon an Alternate Transaction*

In connection with any proposed draw down, if a third party purchases our common stock and/or securities convertible or exercisable or exchangeable into common stock during the period beginning at the start of the applicable Pricing Period and ending on the second trading day after the closing date of such draw down at a purchase price per share of our common stock that is less than the purchase price in such proposed draw down, the proposed draw down purchase price shall be adjusted downward to the purchase price in such alternate transaction.

### **Commitment Fee Shares and Maintenance Fee Shares**

In consideration for Hanover's execution and delivery of the Purchase Agreement, in connection with the execution and delivery of the Purchase Agreement, we have issued Hanover 3,500,000 Commitment Fee Shares.

We have also agreed to issue Hanover up to 1,800,000 Maintenance Fee Shares, during any full calendar quarter during the term of the Purchase Agreement, if no shares of our common stock have been purchased or sold because we did not deliver a draw down to Hanover. The number of Maintenance Fee Shares to be delivered to Hanover, from time to time, with respect to any calendar quarter, shall be equal to approximately \$15,000 worth of shares of our common stock at a 10% discount to market.

The offering contemplated hereunder includes the 3,500,000 Commitment Fee Shares previously issued to Hanover and the 1,800,000 Maintenance Fee Shares that may become issuable to Hanover as described above pursuant to the Purchase Agreement.

## **Selling Restrictions**

Hanover has agreed that during the term of the Purchase Agreement, that neither Hanover nor any of its affiliates will, directly or indirectly, engage in any short sales involving our securities or grant any option to purchase, or acquire any right to dispose of or otherwise dispose for value of, any shares of our common stock or any securities convertible into or exercisable or exchangeable for any shares of our common stock, or enter into any swap, hedge or other similar agreement that transfers, in whole or in part, the economic risk of ownership of any shares of our common stock. The foregoing restrictions do not prohibit Hanover from engaging in transactions relating to any of the shares of our common stock that it owns, including the Commitment Fee Shares, or that it is obligated to purchase under a pending draw down.

## **Termination**

The Purchase Agreement may be terminated at any time by the mutual written consent of the parties. Unless earlier terminated, the Purchase Agreement will terminate automatically on the earlier to occur of (i) the first day of the month next following the 24-month anniversary of the effective date of the registration statement of which this prospectus forms a part (which term may not be extended by the parties) or (ii) the date on which Hanover purchases the entire commitment amount under the Purchase Agreement. We may terminate the Purchase Agreement effective upon one trading day prior written notice to Hanover, subject to certain conditions. Hanover may terminate the Purchase Agreement effective upon one trading day prior written notice to us under certain circumstances, including the following:

- The existence of any condition, occurrence, state of facts or event having, or insofar as reasonably can be foreseen would likely have, any effect on our business, operations, properties or financial condition that is material and adverse to us;
- We enter into an agreement providing for certain types of financing transactions that are similar to the equity line with Hanover;
- Certain transactions involving a change in control of the company or the sale of all or substantially all of our assets have occurred;
- We are in breach or default in any material respect under any of the provisions of the Purchase Agreement or the Registration Rights Agreement, and, if such breach or default is capable of being cured, such breach or default is not cured within 10 trading days after notice of such breach or default is delivered to us.

While Hanover holds any shares issued under the Purchase Agreement, the effectiveness of the registration statement that includes this prospectus is suspended or the use of this prospectus is suspended or prohibited, and such suspension or prohibition continues for a period of 20 consecutive trading days or for more than an aggregate of 60 trading days in any 365-day period, subject to certain exceptions.

Trading in our common stock is suspended or our common stock ceases to be listed or quoted on a trading market, and such suspension or failure continues for a period of 20 consecutive trading days or for more than an aggregate of 60 trading days in any 365-day period.

- We have filed for and/or are subject to any bankruptcy, insolvency, reorganization or liquidation proceedings.

The Purchase Agreement provides that no termination of the Purchase Agreement will limit, alter, modify, change or otherwise affect any of the parties' rights or obligations with respect to any pending draw down, and that the parties must fully perform their respective obligations with respect to any such pending draw down under the Purchase Agreement, provided all of the conditions to the settlement thereof are timely satisfied.

### **Indemnification**

The Purchase Agreement also provides for indemnification of Hanover and its affiliates in the event that Hanover incurs losses, liabilities, obligations, claims, contingencies, damages, costs and expenses related to a breach by us of any of our representations and warranties under the Purchase Agreement or the other related transaction documents or any action instituted against Hanover or its affiliates due to the transactions contemplated by the Purchase Agreement or other transaction documents, subject to certain limitations.

### **Transferability**

Hanover's rights and obligations under the Purchase Agreement are not transferable.

## **Registration Rights Agreement**

In connection with the Purchase Agreement, we entered into the Registration Rights Agreement, pursuant to which we granted to Hanover certain registration rights related to the Commitment Fee Shares, the Maintenance Fee Shares, and the shares issuable under the Purchase Agreement. Pursuant to the Registration Rights Agreement, we have filed with the SEC a registration statement, of which this prospectus is a part, relating to the selling stockholder's resale of the Commitment Fee Shares, the Maintenance Fee Shares, and any shares of common stock purchased by Hanover under the Purchase Agreement. As previously noted above, the effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Hanover under the Purchase Agreement.

We also agreed, among other things, to indemnify Hanover from certain liabilities and fees and expenses of Hanover incident to our obligations under the Registration Rights Agreement, including certain liabilities under the Securities Act. Hanover has agreed to indemnify and hold harmless us and each of our directors, officers and persons who control us against certain liabilities that may be based upon written information furnished by Hanover to us for inclusion in a registration statement pursuant to the Registration Rights Agreement, including certain liabilities under the Securities Act of 1933.

**The foregoing description of the Purchase Agreement and the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement and Registration Rights Agreement, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.**

**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 2012		Fiscal 2011	
	High	Low	High	Low
First Quarter (November 1-January 31)	\$0.19	\$ 0.14	\$0.16	\$0.11
Second Quarter (February 1- April 30) (1)	\$0.17	\$ 0.11	\$0.22	\$0.11
Third Quarter (May 1 - July 31)	\$0.14	\$ 0.07	\$0.25	\$0.14
Fourth Quarter (August 1 - October 31)	\$0.08	\$ 0.04	\$0.17	\$0.13

From March 1, 2011 through April 1, 2011, our common stock was traded on the OTCQB Market place, a new (1)market for OTC-traded companies that are registered and current in their reporting obligations to the SEC or a U.S. banking or insurance regulator.

As of December 6, 2012, there were approximately 93 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 December 6, 2012, the last reported sale price per share for our common stock as reported by the OTC Bulletin Board was \$0.04

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 immunotherapies for cancer and infectious diseases. These immunotherapies are based on a platform technology under exclusive worldwide license from Penn that utilizes live attenuated *Listeria monocytogenes* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains use a fragment of the protein listeriolysin (LLO), fused to a tumor associated antigen (TAA) or other antigen of interest. We believe these *Lm*-LLO agents redirect the potent immune response to *Lm* which are inherent in humans, to the TAA or antigen of interest. The immune response to a live, metabolically competent pathogen is much more complex than the response to a synthetic or organic molecule and may enable a more comprehensive therapeutic outcome than current treatment modalities. We believe this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers and infectious diseases.

We have no customers. Since our inception in 2002, we have focused our development efforts on understanding our technology and establishing a drug development pipeline that incorporates this technology into therapeutic immunotherapies (currently those targeting HPV-associated diseases (CIN 2/3, cervical cancer, head and neck cancer), prostate cancer, and HER2 expressing cancers (breast, gastric, bladder, brain, pancreatic and ovarian cancers). Although no immunotherapies 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 as we continue conducting our clinical development program.

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.

If additional capital were raised through the sale of equity or convertible debt securities, including pursuant to our committed equity line financing facility, 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 \$0.025287 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 2 clinical trials of ADXS-HPV, our first *Lm*-LLO based immunotherapy targeting diseases associated with the Human Papilloma Virus, which we refer to as HPV. One trial is a 120 patient study in the U.S. in CIN 2/3, and the other trial is a 110 patient study in India in recurrent or refractory cervical cancer. We also anticipate using the funds to further our preclinical and clinical research and development efforts in developing immunotherapies in prostate cancer, HER2 expressing cancers (such as breast, gastric, bladder, brain, pancreatic and ovarian 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 2 clinical studies of ADXS-HPV in the treatment of CIN 2/3 and recurrent or refractory cervical cancer;

Continue an additional Phase 2 clinical trial of ADXS-HPV 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 1/2 clinical trial of ADXS-HPV in the treatment of head and neck cancer entirely underwritten by the CRUK;

To support our Cooperative Research and Development Agreement with the NCI to understand the mechanisms of action of *Lm*-LLO based immunotherapies, to develop new constructs, 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 focus on our collaboration with the School of Veterinary Medicine at Penn to carry out our Phase 1 clinical trial of ADXS-HER2 in canine osteosarcoma;

Continue to develop strategic and development collaborations with academic laboratories and potential commercial partners;

Continue the development work necessary to bring ADXS-PSA for the treatment of prostate cancer into clinical trials, and initiate that trial provided that funding is available;

Continue the development work necessary to bring ADXS-HER2 for the treatment of HER2 expressing cancers (such as breast, gastric, bladder, brain, pancreatic and ovarian cancer) into clinical trials, and initiate these trials when and if funding is available; and

Continue the preclinical development of other immunotherapies, 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, 2011. The cost of our Phase 2 clinical studies in therapeutic treatment of CIN 2/3 and recurrent and refractory cervical cancer is estimated to be approximately \$11.2 million over the estimated 30 month period of the trial. While approximately \$6 million has already been paid towards these costs, we must raise additional funds in order to complete the Phase 2 trials. If we can raise additional funds, we intend to commence the clinical work in prostate cancer and a HER2 expressing cancer in 2012. 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, drug development, and development of strategic and other relationships required ultimately for the licensing, manufacture and distribution of our immunotherapies. We regard to three of our immunotherapies as major research and development projects. The timing, costs and uncertainties of those projects are as follows:

ADXS-HPV - Phase 2 CIN 2/3 Trial Summary Information (U.S.: target enrollment: 120 Patients)

The ADXS-HPV CIN 2/3 study is a randomized, single blind, placebo controlled Phase 2 dose-ranging study designed to assess the safety and efficacy of ADXS-HPV in up to 3 different dose cohorts:

- Cost incurred through July 31, 2012: approximately \$4.9 million.
- Estimated future clinical costs: approximately \$2.3 million.

Anticipated Timing: commenced in March 2010 (with patient dosing having commenced in June 2010); reporting of low dose cohort in early 2012, mid dose cohort is actively enrolling; completion October 2012 or beyond. High dose cohort commenced recruiting in April 2012, completion anticipated in February-March 2013.

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;
- Lack of clinical benefit;
- Difficulty in recruiting patients;
- Delays in the program;
- Material cash flows; and

Anticipated Timing: 2012/2013 and dependent upon completion and results from each dose cohort adequate fund raising, entering a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

ADX-HPV - Phase 2 Cervical Cancer Trial Summary Information (India: target enrollment: 110 Patients)

The ADXS-HPV cervical cancer trial in India is a Phase 2 study of ADXS-HPV +/- Cisplatin in patients with recurrent or refractory cervical cancer that has failed previous treatment:

- Cost incurred through July 31, 2012: approximately \$2.3 million.
- Estimated future clinical costs: approximately \$2.5 million.

Anticipated Timing: commenced in November 2010; reporting of preliminary survival data began in January 2012, completion 2012 or beyond.

Additional Uncertainties:

- One or more serious adverse events in these advanced cancer patients enrolled in the trial; and
- Lack of clinical benefit.

ADX-HPV - Phase 2 Cervical Cancer Trial Summary Information (U.S. GOG/NCI: target enrollment: 67 Patients)

The ADXS-HPV cervical cancer trial in the US is a randomized, active therapy controlled Phase 2 study to assess the safety and efficacy of ADXS-HPV +/- cisplatin as second line therapy for the treatment of recurrent or refractory cervical cancer that has not responded to previous treatment:

- Cost incurred through July 31, 2012: Minimal.
  
- Estimated future clinical costs: \$500,000 (NCI underwriting costs of \$4.0 million to \$5.0 million).
  
- Anticipated Timing: commenced September 2011 and open to enrollment; 1st patient dosed on January 9, 2012; completion 2013 and beyond.

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on GOG/NCI controlled study; and
  
- Delays in the program;
  
- One or more serious adverse events in these advanced cancer patients enrolled in the trial; and
  
- Lack of clinical benefit.

ADX-HPV - Phase 2 Cancer of the Head and Neck Trial Summary Information (U.K. CRUK: target enrollment: 45 Patients)

The ADXS-HPV head and neck cancer trial is a Phase 1/2 dose escalation trial of ADXS-HPV in patients with head & neck cancer:

- Cost incurred through July 31, 2012: 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 sites that we expect will commence in late 2012.

Additional Uncertainties:

- Unknown timing in recruiting patients and conducting the study based on CRUK controlling the study;
- Delays in the program;
- One or more serious adverse events in these advanced patients enrolled in the trial; and
- Lack of clinical benefit.

ADX-HER2 Phase 1/2 Trial Summary Information (Canine Osteosarcoma: target enrollment: 9-18 dogs)

The ADXS-HER2 canine osteosarcoma trial is a Phase 1 study to evaluate the safety of ADXS-HER2 for the treatment of osteosarcoma in dogs:

- Cost incurred through July 31, 2012: Minimal.

- Estimated future costs: approximately \$500,000.

- Anticipated Timing: to be determined.

Additional Uncertainties:

- Unknown timing in recruiting dogs and conducting the study based on Penn controlling the study;

- Delays in the program;

- One or more serious adverse events in these dogs enrolled in the trial; and

- Lack of clinical benefit.

ADX-PSA - GMP Production and Phase 1/2 Trial Summary Information (Prostate Cancer: target enrollment: 20-35 Patients)

ADX-PSA is an *Lm-LLO* based immunotherapy that is designed to target PSA and intended for the treatment of castration resistant prostate cancer:

- Cost incurred through July 31, 2012: 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.

ADXS-HER2 - GMP Production and Phase 1/2 Trial Summary Information (HER2 Expressing Cancer: target enrollment: 15-35 Patients)

ADXS-HER2 is an *Lm*-LLO based immunotherapy that is designed to target the HER2 antigen and intended for the treatment of HER2 expressing cancers (breast, gastric, bladder, brain, pancreatic and ovarian):

·Cost incurred through July 31, 2012: Minimal.

·Estimated future costs: to be determined.

·Anticipated Timing: to be determined.



Additional Uncertainties:

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

**Results of Operations**

**Three Months Ended July 31, 2012 Compared to Three Months Ended July 31, 2011**

*Revenue*

We did not record any revenue for the three months ended July 31, 2012 and 2011.

*Research and Development Expenses*

Research and development expenses decreased by approximately \$627,000 or 32% to approximately \$1,331,000 for the three months ended July 31, 2012 as compared with approximately \$1,959,000 for the same period a year ago principally attributable to decreases in clinical trial expenses and related manufacturing costs as well as lower overall supply costs. In addition, there was an overall decrease in compensation expense resulting from bonuses paid to employees in the period a year ago that were not repeated in the current period.

We anticipate continued overall decrease in R&D expenses resulting from lower clinical trial costs more than offsetting expanded development efforts primarily related to new 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 \$613,000 or 37%, to approximately \$2,252,000 for the three months ended July 31, 2012 as compared with approximately \$1,638,000 for the same period a year ago. This was primarily the result of noncash expenses related to the issuance of shares of our common stock related to the Numoda-Socius various agreements entered into in the current period resulting in certain shares being issued to Socius. These increases were offset by decreases in cash spending for legal and consulting fees in the current period when compared with the same period a year ago as well as decreases in compensation expense resulting from bonuses paid to employees in the period a year ago that were not repeated in the current period.

#### *Interest Expense*

For the three months ended July 31, 2012, interest expense decreased approximately \$725,000 to approximately \$1,045,000 for the three months ended July 31, 2012 as compared with approximately \$1,770,000 in the period a year ago. The Company recorded less interest expense in the current period primarily resulting from the exchange of convertible promissory notes in the aggregate principal amount of approximately \$4.5 million for (i) an aggregate of approximately 52.2 million shares of our common stock and (ii) warrants to purchase up to approximately 5.8 million shares of our common stock. This decrease was slightly offset by additional interest expense related to the issuance of May 2012 convertible promissory notes in the current period and the issuance of shares to JMJ under the above mentioned Settlement Agreement, resulting in noncash expense from the recognition of a beneficial conversion feature.

Additionally, the debt discounts related to the original fair values of both warrants and embedded derivatives are amortized to interest expense over the life of these convertible promissory notes.

#### *Other Expense/ Income*

Other income was approximately \$25,000 for the three months ended July 31, 2012 as compared with other expense of approximately \$4,000 in the same period a year ago as a result of favorable changes in foreign exchange rates relating to transactions with certain vendors.

#### *(Loss) on Note Retirement*

For the three months ended July 31, 2012, we recorded a charge to income of approximately \$932,000 primarily resulting from the Company entering into exchange agreements with convertible note holders in which these investors exchanged convertible promissory notes in the aggregate principal amount of approximately \$4.5 million for (i) an aggregate of approximately 52.2 million shares of our common stock and (ii) warrants to purchase up to approximately 5.8 million shares of our common stock at an exercise price of \$0.15. These charges were partially offset by noncash income resulting from the issuance of 15 million shares in payment of \$2.25 million of trade

accounts payable under a stock purchase and the July warrant exchanges.

For the three months ended July 31, 2011, the Company recorded a charge to income of approximately \$115,000 primarily due to the exchange by an investor of 2007 warrants that contained anti-dilution provisions, for a larger number of warrants with no anti-dilution provisions.

#### *Changes in Fair Values*

For the three months ended July 31, 2012, the Company recorded income from changes in the fair value of the warrant liability and embedded derivative liability of approximately \$2.4 million compared with income of approximately \$9.1 million in same period a year ago. In the current period, the Company recorded income of approximately \$2.2 million resulting from a decrease in the Black-Scholes value of each liability warrant primarily due to a decrease in our share price from \$0.13, at April 30, 2012 to \$0.07, at July 31, 2012.

For the three months ended July 31, 2011, the Company recorded income from the change in fair value of the common stock warrant liability and embedded derivative liability of approximately \$9.1 million resulting from decreases in the underlying stock price (and therefore decreases in the corresponding warrant liability and embedded derivative liability).

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 or decreased expenses being recognized in our statement of operations in future periods.

#### **Nine Months Ended July 31, 2012 Compared to Nine Months Ended July 31, 2011**

##### *Revenue*

We did not record any revenue for the nine months ended July 31, 2012 and 2011.

##### *Research and Development Expenses*

Research and development expenses were approximately \$5,760,000 for the nine months ended July 31, 2012 as compared with approximately \$6,393,000 for the same period a year ago principally attributable to decreases in clinical trial expenses and related manufacturing costs.

We anticipate continued overall decrease in R&D expenses resulting from lower clinical trial costs more than offsetting expanded development efforts primarily related to new 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 \$715,000 or 20%, to approximately \$4,297,000 for the nine months ended July 31, 2012 as compared with approximately \$3,582,000 for the same period a year ago. This was primarily the result of noncash expenses related to the issuance of shares of our common stock related to the Numado-Socius various agreements entered into in the current period resulting in certain shares being issued to Socius. These increases were offset by decreases in cash spending for legal and consulting fees in the current period when compared with the same period a year ago as well as decreases in compensation expense resulting from bonuses paid to employees in the period a year ago that were not repeated in the current period.

*Interest Expense*

For the nine months ended July 31, 2012, interest expense increased to approximately \$4,242,000 from approximately \$2,721,000 primarily due to the sale of convertible promissory notes in May, October and December 2011. In addition, the Company recorded interest expense resulting from the issuance of 4 million shares to JMJ under the above mentioned Settlement Agreement, resulting in noncash expense from the recognition of a beneficial conversion feature. Additionally, the debt discounts related to the original fair values of both warrants and embedded derivatives are amortized to interest expense over the life of these convertible promissory notes.

*Other Expense/ Income*

Interest Income was \$0 as compared with approximately \$102,000 in the same period a year ago. We record all interest earned on Optimus promissory notes to equity in accordance with ASC 505 10-45. The Optimus promissory notes are classified in the equity section of the balance sheet as a promissory note receivable.

Other income was approximately \$26,000 for the nine months ended July 31, 2012 as compared with other expense of approximately \$49,000 in the same period a year ago as a result of favorable changes in foreign exchange rates relating to transactions with certain vendors.

*Gain (Loss) on Note Retirement*

For the nine months ended July 31, 2012, we recorded a charge to income of approximately \$2,173,000 primarily resulting from the Company entering into exchange agreements with May, October and December 2011 investors in which these investors exchanged convertible promissory notes in the aggregate principal amount of approximately \$4.5 million for (i) an aggregate of approximately 52.2 million shares of our common stock and (ii) warrants to purchase up to approximately 5.8 million shares of common stock at an exercise price of \$0.15 per share. In addition, the Company recognized noncash expense resulting from the conversion of promissory notes, by investors, during the nine months ended July 31, 2012. These expenses were partially offset by noncash income resulting from the issuance of shares to Numoda Corporation, which we refer to as Numoda, under a stock purchase agreement and the July warrant exchanges.

For the nine months ended July 31, 2011, we recorded a charge to income of approximately \$109,000 primarily due to the exchange by an investor of 2007 warrants that contained anti-dilution provisions, for a larger number of warrants

with no anti-dilution provisions.. In the period a year ago, we recorded a gain of approximately \$77,000 primarily resulting from repayments of bridge notes in the same period a year ago.

### *Changes in Fair Values*

For the nine months ended July 31, 2012, the Company recorded income from changes in the fair value of the warrant liability and embedded derivative liability of approximately \$6.0 million compared with income of approximately \$7.1 million in same period a year ago. In the current period, the Company recorded income of approximately \$4.9 million resulting from a decrease in the Black-Scholes value of each liability warrant due primarily to a decrease in our share price from \$0.15, at October 31, 2010 to \$0.07, at July 31, 2012. In addition, there was a decrease in the Black Scholes value of each liability warrant due to a smaller range of share prices used in the calculation of the BSM Model volatility input.

For the nine months ended July 31, 2011, the Company recorded income from changes in the fair value of the warrant liability and embedded derivative liability of approximately \$7.1 million resulting from a change in fair values of our common stock warrant liability providing a gain of \$5.8 million and a \$1.3 million (gain) change in fair value associated with embedded derivative liabilities from the May 2011 Notes (\$1.2 million of the total \$1.3 million gain) that were established on May 12, 2011 and revalued on July 31, 2011. The change in fair value for both derivative instruments resulted from a decrease in our share price during the current quarter of \$0.21 on April 30, 2011 (\$0.18 on May 12, 2011) compared with \$0.1485.

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 or decreased expenses being recognized in our statement of operations in future periods.

*Income Tax Benefit*

In the nine months ended July 31, 2012, the income tax benefit was approximately \$347,000 due to the receipt of a NOL tax credit from the State of New Jersey tax program compared to approximately \$379,000 in NOL tax credits received from the State of New Jersey tax program in the nine months ended July 31, 2011.

**Fiscal Year 2011 Compared to Fiscal Year 2010**

*Revenue*

We recorded no revenue for the fiscal year ended October 31, 2011 as compared with \$508,481 in grant revenue for the same period a year ago resulting from multiple grants received by the Company to support research related to our LM-LLO based immunotherapies (i.e. – constructs, delivery).

*Research and Development Expenses*

Research and development expenses increased by approximately \$3,175,000 to approximately \$8,079,000 for the fiscal year ended October 31, 2011 as compared with approximately \$4,904,000 for the same period a year ago. This is mostly 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. In addition, overall compensation expense was higher in the current fiscal year resulting from additional employees, increased stock-based compensation and increases in salaries and bonus. Lastly, research and development expenses increased in the current fiscal year due to higher general and due diligence costs associated with our intangible assets (patents).

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 \$1,410,000 or 40%, to approximately \$4,940,000 for the fiscal year ended October 31, 2011 as compared with approximately \$3,530,000 for the same period a year ago. This was the result of higher legal, professional and other consulting fees in the current period as compared with the same period a year ago primarily due to the sale of convertible debt instruments. Overall compensation expense was also higher in the current fiscal year resulting from bonuses paid to employees. Additionally, office and related expenses increased in the current fiscal year resulting from the relocation of our operations to Princeton, NJ in April 2011. Lastly, we recorded non-cash expense related to the issuance of warrants to investors and our chief executive officer.

*Interest Expense*

In the fiscal year ended October 31, 2011, net interest expense increased by approximately \$884,000 to approximately \$4,699,000 compared to approximately \$3,815,000 for the same period a year ago, primarily due to the sale of convertible promissory notes in May 2011 in addition to bridge notes sold during the fiscal year ended October 31, 2011. Additionally, the debt discounts related to the original fair values of both warrants and embedded derivatives are amortized to interest expense over the life of such short-term convertible promissory notes.

*Other Expense / Income*

Interest income decreased to \$0 for the fiscal year ended October 31, 2011 as compared to approximately \$80,000 in the same period a year ago. We record all interest earned on Optimus promissory notes to equity in accordance with ASC 505 10-45. The Optimus promissory notes are classified in the equity section of the balance sheet as a promissory note receivable.

Other expense increased to approximately \$46,000 for the fiscal year ended October 31, 2011 as compared to \$0 in the same period a year ago as a result of changes in foreign exchange rates relating to transactions with certain vendors.

*Gain on Note Retirement*

For the fiscal year ended October 31, 2011, we recorded a charge to income of approximately \$462,000 primarily due to the exchange by an investor of 2007 warrants that contained anti-dilution provisions, for a larger number of warrants with no anti-dilution provisions. In the period a year ago, we recorded a gain of approximately \$124,000 resulting from the elimination of embedded conversion features associated with bridge notes that were repaid.

*Write-off of Intangible Assets*

In the fiscal year ended October 31, 2011, the Company wrote off approximately \$33,000 in capitalized patent costs related to four patent applications that had either expired or been abandoned.

### *Changes in Fair Values*

The change in fair value of the common stock warrant liability and embedded derivative liability increased income by approximately \$9.8 million for the fiscal year ended October 31, 2011 compared to approximately \$446,000 in the same period a year ago. During the current fiscal year, we recorded income as the fair value of its warrant and embedded derivative liability decreased primarily due to declines in the underlying stock price (and therefore decreases in the corresponding warrant liability and embedded derivative liability) from share prices as high as \$0.21, at April 30, 2011, to share prices as low as \$0.14 at October 31, 2011. In addition, the number of warrants increased in the current fiscal year, increasing the income recorded due to changes in fair value from decreases in the underlying stock price.

For the first nine months of the fiscal year ending October 31, 2010, the Black-Scholes-Merton (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 (resulting from a “ratchet” in September 2010). In addition, the BSM values decreased due to a decline in the price of our common stock, and as a result we recorded some income for the full fiscal 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.

### *Income Tax Benefit*

In the fiscal year ended October 31, 2011, the Company recorded an income tax benefit of approximately \$379,000 in income, due to the receipt of a NOL tax credit from the State of New Jersey tax program compared to approximately \$279,000 in NOL tax credits received from the State of New Jersey tax program in the year ended October 31, 2010.

### **Liquidity and Capital Resources**

Since our inception through July 31, 2012, the Company has reported accumulated net losses of approximately \$45.6 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities, for the nine months ended July 31, 2012, was approximately \$3.9 million, primarily as a result of the following: increased R&D spending on clinical trials and higher general and administrative spending.

Cash used in investing activities, for the nine months ended July 31, 2012, was approximately \$351,000 resulting from spending in support of our intangible assets (patents), costs paid to the University of Pennsylvania for patents and the purchase of equipment for use in research and development activities.

Cash provided by financing activities, for the nine months ended July 31, 2012, was approximately \$3.2 million, resulting from net proceeds received from the sale of convertible promissory notes (\$2.8 million) and the exercise of warrants of approximately \$400,000.

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, NOL tax 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, 2011 and July 31, 2012, we had an accumulated deficit of \$35,531,740 and \$45,611,368, respectively and shareholders' deficiency of \$12,279,713 and \$4,999,243, respectively.

During May 2011, we sold approximately \$7.1 million of convertible promissory notes for a net purchase price of approximately \$6.0 million and received cash from warrant exercises in the amount of approximately \$350,000. During October 2011, we sold approximately \$2.3 million of convertible promissory notes for a net purchase price of approximately \$2.0 million. This cash was used to reduce overdue payables and finance day to day operations. During January 2012, we sold approximately \$1.2 million of convertible promissory notes for a net purchase price of approximately \$1.0 million. This cash was used to reduce overdue payables and finance day to day operations.

During May 2012, we closed on the sale of approximately \$1.0 million of convertible promissory notes for a net purchase price of approximately \$0.7 million. This cash will be used to reduce overdue payables and finance day to day operations.

Effective May 14, 2012, we entered into exchange agreements with certain holders of an aggregate of approximately \$4.5 million of the existing notes originally issued either on May 12, 2011, October 31, 2011 or January 9, 2012, pursuant to which such holders received (i) an aggregate of approximately 52.2 million shares of our common stock, and (ii) warrants to purchase an aggregate of approximately 5.8 million shares of our common stock in exchange for (i) surrendering or converting the existing notes and surrendering warrants to purchase an aggregate of approximately 31.3 million shares of our common stock originally issued in the prior offerings, and (ii) amending the note purchase agreements between the Company and the holders of the existing notes, dated as of May 9, 2011, October 28, 2011 or

December 29, 2011.

On August 2, 2012, in a private placement pursuant to a note purchase agreement, we issued Dr. James Patton, a member of our board of directors, a convertible promissory note in the principal amount of \$66,667 for a purchase price of \$50,000. The Patton Note was issued with an original issue discount of 25%. Dr. Patton paid \$0.75 for each \$1.00 of principal amount of the Patton Note purchased. The Patton Note is convertible into shares of our common stock at a per share conversion price equal to \$0.025287. Additionally, Dr. Patton received a warrant to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the Patton Note at an exercise price of \$0.025287 per share. The Patton Note matures on August 2, 2013. We may redeem the Patton Note under certain circumstances. The Patton Warrant is exercisable at any time on or before August 2, 2017. The Patton Warrant may be exercised on a cashless basis under certain circumstances. The Patton Note and the Patton Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Patton be entitled to convert any portion of the Patton Note or Patton Warrant to the extent that after such conversion or exercise, as applicable, Dr. Patton (together with his affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

On August 27, 2012, we entered into a settlement agreement with JMJ Financial pursuant to which we issued to JMJ Financial 4,076,923 shares of our common stock for the mutual release of any claims held by our company or JMJ Financial relating to our failure to file the registration statement related to the May 2012 issuance of 4,000,000 shares of our common stock to JMJ Financial and have the registration statement declared effective by certain prescribed deadlines.

On August 27, 2012, in a private placement pursuant to a note purchase agreement, we issued JMJ Financial a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000. The August 2012 Note is initially convertible at a per share conversion price equal to \$0.15. In addition, if the August 2012 Note is converted after November 30, 2012 and the market price of our common stock is less than \$0.16 per share on the date of conversion, then the conversion price shall equal 95% of the arithmetic average of the three lowest closing trading prices for the common stock during the 15 trading day period ending on the latest complete trading day prior to the applicable conversion date. The August 2012 Note matures on August 29, 2013. To the extent JMJ Financial does not elect to convert the August 2012 Note as described above, the principal amount and interest of such note shall be payable in cash at maturity. The August 2012 Note may be converted by JMJ Financial, at its option, in whole or in part. The August 2012 Note includes a limitation on conversion, which provides that at no time will JMJ Financial be entitled to convert any portion of the August 2012 Note to the extent that after such conversion JMJ Financial (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. Pursuant to the terms of the August 2012 Note, we agreed to register up to 3,250,000 shares of our common stock which may be issuable upon conversion of the August 2012 Note with the SEC. These shares were registered on August 31, 2012.

On September 11, 2012, in a private placement pursuant to a note purchase agreement, we issued Asher a convertible promissory note in the aggregate principal amount of \$103,500 for a purchase price of \$100,000. The September Asher Note bears interest at a rate of 8% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the September Asher Note. The September Asher Note is convertible into shares of our common stock at a conversion price equal to 61% of the arithmetic average of the five lowest closing

trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The September Asher Note matures on June 13, 2013, nine months from its issuance date. The September Asher Note may be converted by Asher, at its option, in whole or in part. The September Asher Note includes a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the September Asher Note to the extent that after such conversion Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

On September 19, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500 for a purchase price of \$132,500. On October 19, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500 for a purchase price of \$132,500.

On September 25, 2012, in a private placement pursuant to a note purchase agreement, we issued our affiliate Dr. Yvonne Paterson a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000. The Paterson Note bears interest at a rate of 12% per annum, compounding annually. The Paterson Note is convertible into shares of our common stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Paterson Note matures one month from its issuance date. Additionally, Dr. Paterson will receive a warrant to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the Patterson Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The Paterson Warrant may be exercised on a cashless basis under certain circumstances. The Paterson Note and the Paterson Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Paterson be entitled to convert any portion of the Paterson Note or Paterson Warrant, to the extent that after such conversion or exercise, as applicable, Dr. Paterson (together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. On December 7, 2012, Dr. Paterson agreed to extend the maturity date of the Paterson Note to December 31, 2012.

On September 27, 2012, in a private placement pursuant to a note purchase agreement, we issued our employee Christine French a convertible promissory note in the aggregate principal amount of \$25,000 for a purchase price of \$25,000. The French Note bears interest at a rate of 12% per annum, compounding annually. The French Note is convertible into shares of our common stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The French Note matures one month from its issuance date. Additionally, Ms. French will receive a warrant to purchase such number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the French Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The French Warrant may be exercised on a cashless basis under certain circumstances. The French Note and the French Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Ms. French be entitled to convert any portion of the French Note or French Warrant to the extent that after such conversion or exercise, as applicable, Ms. French (together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date. On December 7, 2012, Ms. French agreed to extend the maturity date of the French Note to December 31, 2012.

In October 2012, pursuant to the terms of various Assignment Agreements, Magna Group acquired \$400,075.88 in aggregate principal amount of our outstanding convertible notes from certain third parties and entered into agreements to acquire an additional \$340,522.90 in aggregate principal amount of our outstanding convertible notes from other third parties. Pursuant to the terms of such Assignment Agreements, we delivered two convertible notes to Magna in an aggregate principal amount of \$740,598.74, in anticipation of the closing of all of the transactions contemplated by such Assignment Agreements. On October 25, 2012, the convertible note in the aggregate principal amount of \$617,722.92 previously delivered to Magna was exchanged for a new convertible note in the aggregate principal amount of \$400,075.77, convertible into share of common stock to reflect such portion of the convertible notes actually issued as of October 25, 2012 pursuant to the Assignment Agreements, and the remaining convertible note in the aggregate principal amount of \$122,875.82 previously delivered to Magna was returned to us and cancelled. Prior to the date of this filing, the First Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On November 12, 2012, in a private placement pursuant to a note purchase agreement, we issued Asher a convertible promissory note in the aggregate principal amount of \$153,500 for a purchase price of \$153,500. The November Asher Note bears interest at a rate of 8% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the November Asher Note. The November Asher Note is convertible into shares of our common stock at a conversion price equal to 65% of the arithmetic average of the four lowest closing trading prices for the common stock during the 20 trading day period ending on the latest complete trading day prior to the applicable conversion date. The November Asher Note matures on August 14, 2013, nine months from its issuance date. The November Asher Note may be converted by Asher, at its option, in whole or in part. The November Asher Note includes a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the November Asher Note to the extent that after such conversion Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the common stock as of such date.

On November 14, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$58,823.53, convertible into shares of common stock, which we refer to as the Second Magna Exchange Note. The Second Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Second Magna Exchange Note. Prior to the date of this filing, the Second Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On November 23, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$111,111.11, convertible into shares of common stock, which we refer to as the Third Magna Exchange Note. The Third Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Third Magna Exchange Note. Prior to the date of this filing, the Third Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.



On December 6, 2012, pursuant to the terms of various Assignment Agreements, we delivered a convertible note to Magna in an aggregate principal amount of \$170,588.22, convertible into shares of common stock, which we refer to as the Fourth Magna Exchange Note. The Fourth Magna Exchange Note bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Fourth Magna Exchange Note. Prior to the date of this filing, the Fourth Magna Exchange Note has been converted in full into shares of our common stock in accordance with its terms and no longer remains outstanding.

On December 6, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which we refer to as the Hanover December 2012 Note. The Hanover December 2012 Note bears interest at a rate of 12% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of such Hanover December 2012 Note. The Hanover December 2012 Note is convertible into shares of our common stock at a conversion price of \$0.03 per share. On December 5, Hanover exchanged the Initial Hanover PIPE Notes for notes in the form of the Hanover December 2012 Note that also are convertible into shares of our common stock at a conversion price of \$0.03 per share, which we refer to as the Exchanged Hanover PIPE Notes. The Hanover December 2012 Note and the Exchanged Hanover PIPE Notes are subject to limitations on conversion if after giving effect to such conversion Hanover would beneficially own more than 4.99% of our common stock.

Based on our available cash of approximately \$1,000 on December 6, 2012, 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, 2011 includes 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 immunotherapies, with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures. Further, we will not have sufficient resources to develop fully any new immunotherapies 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. However, no assurances can be given that we will be able to achieve these goals or that we will be able to continue as a going concern.

We are pursuing additional investments, grants, partnerships as well as collaborations and exploring other financing options, with the objective of minimizing dilution and disruption.

Pursuant to the Series B purchase agreement, as amended, 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, of which \$2.84 million of Series B preferred stock remains available for purchase. Under the terms of the Series B purchase agreement, as amended, 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 July 31, 2012, we had issued and sold 466 shares of Series B preferred stock to Optimus pursuant to the terms of the Series B purchase agreement, as amended. We received net proceeds of approximately \$4.19 million from this transaction. The aggregate purchase price for the Series B preferred stock was \$4.66 million. As of July 31, 2012, under the terms of the Series B purchase agreement, as amended, Optimus remained obligated, from time to time until July 19, 2013, to purchase up to an additional 284 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, as amended, are satisfied.

On December 30, 2010, immediately following the closing of the sale of 72 shares of Series B preferred stock to Optimus pursuant to the terms of 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. We redeemed the shares of Series B Preferred Stock, at a price per share equal to 136% of the Liquidation Value (defined as the original price per share plus all accrued dividends thereon) since the redemption was prior to the first anniversary of the issuance date, as stated in the Series B purchase agreement.

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. As permitted by the terms of such warrant, the aggregate exercise price of \$6,291,000 received by us as of July 31, 2012 is payable pursuant to four year full recourse promissory notes each bearing interest at the rate of 2% per year.

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, as amended, 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. 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. In August 2011, we issued 768,633 shares of common stock to the last remaining senior bridge note holder in full satisfaction of his senior bridge note. As of October 31, 2011, no senior bridge notes remained outstanding.

For the fiscal year ending October 31, 2011, we issued to certain accredited investors (i) junior bridge notes in the aggregate principal face amount of approximately \$1,887,000 (including note exchanges which resulted in additional interest of approximately \$25,000) for an aggregate net purchase price of approximately \$1,670,000 and (ii) warrants to purchase 7,305,790 shares of our common stock (including additional warrants issued as a result of note exchanges), which we refer to as junior bridge warrants, at original exercise prices ranging from \$0.15 to \$0.17 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 18% and are convertible into shares of our common stock. Approximately an aggregate of \$184,000 of principal amount of these junior bridge notes matured on or before December 6, 2012 and remain overdue.

For the fiscal year ending October 31, 2011, we repaid a total of approximately \$530,000 in principal value of junior bridge notes and converted approximately 1.3 million in principal value of junior bridge notes into approximately 8,652,737 shares of our common stock. At January 31, 2011, approximately \$756,000 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 (however, no senior bridge notes are outstanding as of October 31, 2011).

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 December 6, 2012, the exercise price has been reduced from \$0.15 per share to \$0.025287 per share with respect to an aggregate of approximately 13 million warrants such that approximately 64 million additional shares of our common stock are issuable upon exercise of such warrants at \$0.025287 per share. As of December 6, 2012, warrants to purchase 77,519,641 shares of our common stock are exercisable at \$0.025287 per share and are subject to "full ratchet" anti-dilution protection upon certain equity issuances below \$0.025287 per share (as may be further adjusted).

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. 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).

In connection with a loan made by Mr. Moore to the company in the amount of \$230,000, we agreed to amend and restate the terms of the Moore Notes on March 17, 2011 to increase the principal amount by \$230,000. Under the terms of the amended and restated Moore Notes: (i) the maturity date is the earlier of (x) the date of consummation of an equity financing by us in an amount of \$6.0 million or more and (y) the occurrence of any event of default as defined in the Moore Notes, (ii) Mr. Moore may elect, at his option, to receive accumulated interest thereon on or after April 15, 2011 (which amounted to approximately \$91,000), (iii) we will make monthly installment payments of \$100,000 on the outstanding principal amount beginning on June 15, 2011, and (iv) we may retain, at the option of Mr. Moore, \$200,000 of the repayment amount for investment in our next equity financing.

Mr. Moore acquired a convertible promissory note in the offering completed in October 2011 in exchange for the cancellation of \$400,000 of outstanding indebtedness owed by us to Mr. Moore under the Moore Notes, and Mr. Moore acquired a convertible promissory note in the offering completed in May 2012, which we refer to as the May 2012 offering, for a purchase price of \$90,000.

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.

For the nine months ending July 31, 2012, we paid Mr. Moore \$35,000 in principal. As of July 31, 2012, we were not in default under the terms of the Moore Agreement. As of July 31, 2012, we owed Mr. Moore approximately \$238,000 in principal and approximately \$158,000 in accrued interest under the Moore Notes.

We received approximately \$379,000 from selling our 2009 NOL on February 4, 2011. We have received notification from the State of New Jersey that we are eligible to sell approximately \$408,000 in NOLs related to our 2010 fiscal year.

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

As of July 31, 2012, we had no off-balance sheet arrangements.

### **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 our short-term convertible promissory notes issued from June 2009 through October 2011. At July 31, 2012, we estimated the fair value of the outstanding instruments using the Black-Scholes-Merton valuation model (BSM 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. For those warrants with anti-dilution provisions, we utilized multiple BSM values in order to estimate fair value. 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 December 6, 2012, we had outstanding warrants to purchase 164,896,321 shares of our common stock (adjusted for anti-dilution provisions to date) certain of which have an exercise price of \$0.15 per share. These warrants include 25,560,000 warrants owned by Optimus as part of the Series B purchase agreement. As of December 6, 2012, warrants to purchase 77,519,641 shares of our common stock are currently exercisable at \$0.025287 per share and are subject to “full ratchet” anti-dilution protection upon certain equity issuances below \$0.025287 per share (as may be further adjusted).

*Embedded Conversion Feature*

Substantially all of our convertible promissory notes contain embedded conversion features. At July 31, 2012, we estimated the fair value of these embedded conversion features using the BSM Model, which takes into account a variety of factors, including historical stock price volatility, risk-free interest rates, remaining term of the notes and closing price of our common stock. These embedded conversion features are recorded as liabilities on the balance sheet. 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 that the assumptions used to estimate the fair values of the warrants are reasonable.

## New Accounting Pronouncements

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 immunotherapies for cancer and infectious diseases. These immunotherapies are based on a platform technology under exclusive license from Penn that utilizes live attenuated *Listeria monocytogenes* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains use a fragment of the protein listeriolysin (LLO), fused to a tumor associated antigen (TAA) or other antigen of interest. We believe these *Lm*-LLO agents redirect the potent immune response to *Lm* which are inherent in humans, to the TAA or antigen of interest. The immune response to a live, metabolically competent pathogen is much more complex than the response to a synthetic or organic molecule and may enable a more comprehensive therapeutic outcome than current treatment modalities. We believe this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers and infectious diseases.

The discoveries that underlie this innovative technology are based upon the work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn. *Lm*-LLO based immunotherapies stimulate the immune system to induce antigen-specific anti-tumor immune responses involving both innate and adaptive arms of the immune system. In addition, this technology facilitates the immune response by altering the microenvironment of tumors to make them more susceptible to immune attack.

We have focused our initial development efforts on therapeutic immunotherapies targeting HPV-associated diseases: cervical intraepithelial neoplasia, recurrent or refractory cervical cancer, and head and neck cancer. In addition we have developed immunotherapies for prostate cancer, and HER2 expressing cancers (such as breast, gastric, bladder, brain, pancreatic and ovarian cancer). Our lead drug candidates in clinical development are as follows:

Immunotherapy	Indication	Stage of Clinical Development
ADX5-HPV	Cervical Cancer	<b>Phase 1</b> Company sponsored & completed in 2007 with 15 patients.

	Cervical Intraepithelial Neoplasia	<b>Phase 2</b> Company sponsored study, initiated in March 2010 in the US. The Company completed enrollment of the low-dose cohort in September 2011 (41 patients) and in June 2012 (40 patients) in the mid-dose cohort.
	Cervical Cancer	<b>Phase 2</b> Company sponsored study initiated in November 2010 in India in 110 patients with recurrent or refractory cervical cancer. The Company completed enrollment (110 patients) in May 2012.
	Cervical Cancer	<b>Phase 2</b> The Gynecologic Oncology Group (GOG) of the National Cancer Institute is conducting a study in 67 patients with recurrent or refractory cervical cancer which is currently open to enrollment. As of October 3, 2012, 6 out of 67 patients have been enrolled in the safety run-in phase.
	Head & Neck Cancer	<b>Phase 1</b> The Cancer Research UK (CRUK) is funding a study of 27 patients with head & neck cancer at 3 UK sites. As of October 3, 2012, 6 patients have been enrolled.
ADX-PSA	Prostate Cancer	<b>Phase 1</b> Company sponsored (timing to be determined).
ADX-HER2	HER2 Expressing Cancer	<b>Phase 1</b> Company sponsored (timing to be determined).
ADX-HER2	Canine Osteosarcoma	<b>Phase 1</b> Company sponsored study, initiated in July 2011 in the US. As of October 3, 2012, 2 dogs have been dosed.

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, 2011 and July 31, 2012, we had an accumulated deficit of \$35,531,740 and \$45,611,368, respectively and shareholders' deficiency of \$12,279,713 and \$4,999,243, respectively.

To date, we have outsourced many functions of drug development including manufacturing and clinical trials management. Accordingly, the expenses of these outsourced services account for a significant amount of our accumulated loss. We cannot predict when, if ever, any of our immunotherapies 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 immunotherapies, with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures.

## Strategy

During the next 24 months, data from two Phase 2 trials evaluating the safety and efficacy of ADXS-HPV, our first *Lm*-LLO based immunotherapy, will mature on the safety and effectiveness of ADXS-HPV in recurrent and refractory cervical cancer and its dysplastic precursor, CIN 2/3. In the U.S., we have initiated a randomized, placebo controlled single blind, dose ranging Phase 2 study of ADXS-HPV with three dose cohorts in patients with CIN 2/3. In India, we have an ongoing randomized Phase 2 study in 110 patients with recurrent or refractory cervical cancer who have failed previous therapies.

In January 2012, we initiated a NCI-supported study in recurrent or refractory cervical cancer. In the next three months, we will initiate a trial in 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 on 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 2 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 ADXS-HER2 for the treatment of osteosarcoma in dogs, a leading cancer killer of large dogs.

We have also initiated GMP production of two new *Lm*-LLO based immunotherapies for use in clinical trials which will be initiated in 2012 once the regulatory requirements for the respective INDs have been completed and approved. Planning has begun for Phase 1 trials for ADXS-PSA for the treatment of prostate cancer, and ADXS-HER2 for the treatment of HER2 expressing 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 fully develop any new immunotherapies or technologies unless we are able to raise substantial additional financing on acceptable terms or secure funds from new partners.

Given our expertise in bioengineering live attenuated *Listeria* to create immunotherapies for many different diseases, our longer term strategy will be to license the commercial development of ADXS-HPV for the indications of CIN 2/3, cervical cancer and head and neck cancer. On a global basis, these indications are extremely large and will require one

or more significant partners. We do not intend to engage in commercial development beyond Phase 2 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 preclinical development and optimization of our platform 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 National Institutes of Health estimated the 2010 overall annual costs of cancer:

Total cost: \$263.8 billion

Direct medical costs (total of all health expenditures): \$102.8 billion

Indirect morbidity costs (cost of lost productivity due to illness): \$20.9 billion

Indirect mortality costs (cost of lost productivity due to premature death): \$140.1 billion

The American Cancer Society states that cancer is the second most common cause of death and that 571,950 people in the US will die from cancer in 2011.

#### *HPV / CIN*

According to the American Cancer Society, in the United States, more than 6 million people (men and women) get an HPV infection every year. In fact, at least one-half of the people who have ever had sex will have HPV at some time in their life. In 2009, the CDC reported that about 45% of women aged 20 to 24 had HPV. The American Cancer Society's estimates for newly diagnosed cervical cancer in the U.S. in 2010 was 12,200 and about 500,000 patients per year are diagnosed with high grade CIN (2-3), the predecessor condition to cervical cancer (source: Jones HW, Cancer 1995;76:1914-18; Jones BA and Davey, Arch Pathol Lab Med 2000; 124:672-81).

#### *Prostate Cancer*

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in six will get prostate cancer during his lifetime, and one man in 36 will die of this disease.

#### *HER2 Expressing Cancers*

HER2 (human epidermal growth factor receptor 2) is a gene which is over expressed in a percentage of certain types of cancers such as breast, gastric, bladder, pancreatic, brain, and ovarian. The American Cancer Society estimates that in 2011 in the US there will be 230,480 diagnoses of invasive breast cancer, 21,520 new cases of stomach cancer, 69,250 new cases of bladder cancer, 44,030 new cases of pancreatic cancer, 22,340 new cases of brain/spinal cord cancer, and 21,900 new cases of ovarian cancer.

#### *Canine Osteosarcoma*

According the University of Pennsylvania School of Veterinary Medicine, canine osteosarcoma (bone cancer) is most commonly seen in large breed dogs. It is an aggressive cancer with a poor prognosis. Despite chemotherapy and limb amputation, dogs will most likely succumb to the illness within one year.

*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 responses. It is characterized by the release of various soluble mediators of immune response such as cytokines, chemokines and other molecules.

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

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

*Endogenous pathway of Adaptive Immunity (Class I pathway):*

The endogenous pathway provides immune protection against antigens created within the cytoplasm of the APC (as opposed to exogenous molecules contained within the digestive phagosome). These intracellular antigens are typically broken down 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 live attenuated bioengineered *Listeria* that secretes an antigen-adjuvant fusion protein that stimulates the body's own immune system to target cancer and infectious diseases. Our technology allows the body to recognize tumor-associated antigens or antigens of interest as foreign, thus creating the immune response needed to attack the cancer or infectious disease. It does this by utilizing a number of biological characteristics of the *Listeria* bacteria and the Advaxis proprietary antigen-adjuvant fusion protein technology to stimulate multiple therapeutic immune mechanisms simultaneously in an integrated and coordinated manner.

#### *Mechanism of Action*

Wild type *Listeria* is a common environmental microbe that is found in the soil, on leafy vegetables, and in meat and dairy products. People are constantly exposed to it and most people are unaware of that fact that they have ingested *Listeria*. However, wild type *Listeria* causes nearly 1,600 reported illnesses each year in the US, typically as a result of contaminated food and results in more than 1,400 hospitalizations and 250 deaths. *Listerial* infections frequently present as severe, persistent flu-like symptoms and if detected early, can be easily treated with many common antibiotics. Severe infections are rare and if not detected early are usually not diagnosed until *Listeria* can be cultured from the cerebrospinal fluid, at which time it is very difficult to treat. Advaxis has bioengineered strains of *Listeria monocytogenes* for use as vectors for immunotherapy. These vectors are highly attenuated, making them much less pathogenic than wild type *Listeria*. Advaxis *Lm*-LLO based immunotherapies are between 10,000 and 100,000 times less pathogenic than wild type *Listeria* .

Live *Listeria* is a strong stimulator of both the innate and adaptive arms of the immune system. The innate immune response can primarily be attributed to pattern recognition receptors on immune cells recognizing patterns on the bacterium, leading to a rapid, non-specific activation of the immune system. This response itself provides a basic level of immune protection, but at the same time serves to prime the adaptive arm of the immune system to respond in an antigen specific manner.

Antigen presenting cells (APCs) are phagocytic sentinel cells that circulate through the body taking up and breaking down foreign and dying cells. The breakdown of the antigens that APCs take up result in peptide fragments that are presented on the surface of the APC to activate CD4+ and CD8+ T cells to target specific cells that express these antigens. APCs actively and rapidly phagocytose *Listeria*, so in effect Advaxis *Lm*-LLO based immunotherapies are specifically targeted to the cells that will lead to a strong adaptive immune response. As *Listeria* is taken up by the APCs, it enters a cellular compartment called the phagolysosome, where enzymes kill and degrade the majority of the bacteria. A small percentage (5-10%), escape from this compartment and enter the cytoplasm of the cell, where they



produce the LLO-antigen fusion protein that they have been bioengineered to express.

The specific details of the intracellular life cycle of *Listeria* are important for the understanding of the Advaxis platform technology. In order to escape from the phagolysosome of the APC, *Listeria* produces a protein called listeriolysin O (LLO), which forms pores in the membrane of the phagolysosome allowing *Listeria* to escape into the cytosol. Once in the cytoplasm the bacterium ceases to secrete LLO, which protects the cell wall and the host cell. It is at this stage however that the fusion LLO-antigen protein is produced and secreted by *Listeria*. This version of LLO does not form pores and harm the cell as it is truncated and engineered to be targeted to the cellular degradative machinery, leading to peptides that can be presented to T cells on the surface of the APC. Due to the attenuation of the *Listeria* strains used in Advaxis immunotherapies, the *Listeria* do not replicate and spread from cell to cell at this point, limiting the potential for listeriosis from our immunotherapies.

*Listeria* and/or *Lm*-LLO fusion proteins stimulate many complimentary immune mechanisms of action:

1. Strong innate immune effects.
  - a. *Lm* -LLO vaccines are cleared in SCID and IFN-g knockout mice.
2. Strong adaptive immune effects.
  - a. High titers of activated CD4+T cells, CD8+T cells, APCs, and TILs.
3. A brief exposure to the antigen results in normal memory generation.
  - a. Antibiotics immediately after dosing do not impair long term responses.
4. Alters the tumor microenvironment.
  - a. Reduces both Tregs and MDSCs in tumors but not in other tissues or systemically.
5. Induces cytokine and chemokine secretion from non-infected cells adjacent to infected cells.
  6. Synthesis of new immune cells and maturation of existing cells.
    - a. Marrow, tissue, and blood borne effects.
7. Chemotaxis and extravasation of activated immune cells.
  - a. Chemokine mediated effects and effects directly on vascular endothelium increase TIL.

8. Upregulation of tumor chemokines and chemokines receptors.
  - a. CXCL8, CXCL9, CXCL10, CXCR3 on T cells in TDLN.
9. Epitope and antigen spreading.
  - a. Vaccines directed against one antigen result in immune activation against other antigens.
10. Predominantly a cellular immune response.
  - a. Little antibody formation so *Listeria* is not neutralized by humoral immunity. This is a useful property for cellular immune vaccines because it allows for follow-up dosing.

Figure 1: Live attenuated bioengineered *LM* (*Lm*-LLO) being phagocytosed by an APC leading to the stimulation of CD4+ and CD8+ T cells.

## Research and Development Program

### *Overview*

We use live attenuated bioengineered *Listeria monocytogenes* as a therapeutic agent. We start with a live, 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 associated antigen or antigen of interest. This fusion 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 fuse different antigens of interest (specific to tumors or for infectious disease), to LLO making this a versatile platform technology. Our first *Lm*-LLO based immunotherapy, ADXS-HPV, uses an antigen that is present in HPV. HPV induced disease include CIN, cervical cancer, anal cancer, vulvar cancer, penile cancer, head and neck cancer, and others. ADXS-PSA is directed against PSA, an important antigen in prostate cancer. ADXS-cHER2 that uses Advaxis proprietary chimeric HER2 antigen is directed to HER2, an antigen found in HER2 expressing cancers such as breast, gastric, bladder, pancreatic, CNS, and ovarian cancer. By varying the antigen, we create different therapeutic agents that induce an immune response that should be useful in treating multiple disease states.

## Collaborations, 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 3 clinical trial and the regulatory approval for the first Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

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

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

Pursuant to Amendment No. 1 to the Penn license agreement, which we entered into on March 26, 2007 with Penn the list of list of intellectual property licensed to us was amended to include Penn docket R3702, The Construction of L. Monocytogenes Strains that Express and Secrete HER-2neu Fragments and the Efficacy of such Strains in Inducing a CTL Response and Controlling Tumor Growth in Vivo. Amendment No. 1 also required us to pay to Penn an option exercise fee of \$10,000 and to pay for all historically accrued patent and licensing expenses incurred by Penn before the effective date of Amendment No. 1, totaling approximately \$33,800 as of March 22, 2007. The Penn license agreement, as amended, terminates upon the expiration of the last to expire or become abandoned of the patent rights licensed thereunder; provided, that Penn may earlier terminate the Penn license agreement upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to us.

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 patent applications acquired under the second amendment. As of December 6, 2012, approximately \$138,000 of these historical costs remained outstanding.

On December 12, 2011, we entered into a third amendment to the Penn license agreement pursuant to which we acquired an exclusive worldwide license agreement for additional patent applications from the laboratory of Dr. Yvonne Paterson. One application pertains to the antigen ISG15 from Penn for use in our *Lm*-LLO based immunotherapies for the treatment of cancer and other diseases. This intellectual property resulted from work performed in the laboratory of Dr. Yvonne Paterson that demonstrated ISG15 was an effective immunological target for the treatment of a number of different cancers in animal models, including ovarian, colon, breast and other cancers. SG-15 expression is elevated in "triple negative" breast cancer, a disease in which HER2, estrogen and progesterone receptors are lacking, and thus has no defined therapeutic immune target at the moment. An *Lm*-LLO vaccine that targets ISG-15 may prove to be an effective agent in an area where there is a significant unmet medical need.

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.

*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.

*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 November 2011, we granted Dr. Patterson options to purchase 600,000 shares of our common stock at an exercise price of \$0.148 per share. In total she holds 704,365 shares of our common stock and options to purchase 1,169,048 shares of our common stock, of which options 569,048 are fully vested. We are currently negotiating a follow-on consulting agreement with Penn and Dr. Paterson.

#### *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 ADXS-HPV, our Lm-LLO based immunotherapy targeted to HPV, for the treatment of head and neck cancer. This Phase 1/2 clinical trial will investigate the safety and efficacy of ADXS-HPV in 45 head and neck cancer patients who have previously failed treatment with surgery, radiotherapy and chemotherapy – alone or in combination. We will provide the study drug, with all other associated costs to be funded by CRUK. The study is to be conducted at 3 sites in the UK (Aintree Hospital at the University of Liverpool, The Royal Marsden Hospital in London, and Cardiff Hospital at the University of Wales).

#### *National Cancer Institute Gynecologic Oncology Group*

On December 15, 2009, we announced that GOG will conduct a multicenter, Phase 2 clinical trial of ADXS-HPV, our Lm-LLO based immunotherapy targeted to HPV, in 67 patients with recurrent or refractory cervical cancer who have failed prior cytotoxic therapy. This Phase 2 trial is underwritten by GOG and will be conducted by GOG investigators. This patient population is similar to the patient population that in the cervical cancer study being conducted in India as well as the patients in the Phase I trial of ADXS-HPV. Under this Clinical Trial Services Agreement, dated December 13, 2009, we are responsible for covering the costs of translational research and have agreed to pay a total of \$8,003 per patient, with the majority of the costs of this study underwritten by NCI. This agreement shall continue in force until we receive completed case histories for all participants in the clinical trial and questions about data submitted have been resolved, unless terminated earlier upon the occurrence of certain events, including, but not limited to, the FDA imposing a permanent hold on the drug which is subject to the clinical trial, a material breach by us of the agreement that is not cured within a reasonable time period after notice of the breach is provided to us, or sixty days prior written notice by either party for any reason.

#### *National Cancer Institute Vaccine Section*

On November 1, 2010 we entered into a Cooperative 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. We have paid a total of \$150,000 pursuant to this three year CRADA. The first patient was dosed on January 9, 2012.

*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. From inception through December 6, 2012, we have paid approximately \$110,000 pursuant to this collaboration.

*School of Veterinary Medicine at Penn*

We have entered into a clinical trial agreement with the School of Veterinary Medicine at Penn to investigate the use of ADXS-HER2 for the treatment of osteosarcoma in dogs.

*Recipharm Cobra Biologics Limited (formerly Cobra Biomanufacturing PLC)*

In July 2003, we entered into an agreement with Cobra Biomanufacturing PLC, which has recently been purchased by Recipharm AB, for the purpose of manufacturing our cervical cancer vaccine ADXS-HPV. Recipharm Cobra has extensive experience in manufacturing gene therapy products for investigational studies. Recipharm Cobra is a manufacturing organization that manufactures and supplies biologic therapeutics for the pharmaceutical and biotech industry. These services include the Good Manufacturing Practices, or GMP, manufacturing of DNA, recombinant protein, viruses, mammalian cell products and cell banking. Recipharm Cobra's manufacturing plan for us involves several manufacturing stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase 1 trial. The agreement to manufacture expired in December 2005 upon the delivery and completion of stability testing of the GMP material for the Phase 1 trial. Recipharm Cobra has agreed to surrender the right to \$300,000 of its outstanding fees for manufacturing in exchange for future royalties from the sales of ADXS-HPV at the rate of 1.5% of net sales, with royalty payments not to exceed \$2.0 million.

On October 20, 2007, we entered into a production agreement with Recipharm Cobra to manufacture our Phase 2 clinical materials using a new methodology now required by the U.K., and likely to be required by other regulatory bodies in the future. Currently we have two agreements with Recipharm Cobra; one to conduct ongoing stability testing of the ADXS-HPV vaccine which they have manufactured, and another to provide analytic services and certification necessary to import ADXS-HPV for use in the U.K. head and neck study mentioned above. From inception through December 6, 2012, we have paid Recipharm Cobra approximately \$1.6 million under all agreements.

#### *Vibalogics GmbH*

In April of 2008, we entered into a series of agreements with Vibalogics GmbH in Cuxhaven Germany to provide fill and finish services for our final clinical materials that were made for the scheduled clinical trials described above. These agreements cover the fill and finish operations as well as specific tests that have to be performed in order to release the clinical materials for human use. We have recently entered into agreements with Vibalogics to produce two new vaccines, ADXS-PSA and ADXS-HER2 for human use and clinical development. As of December 6, 2012, approximately \$415,000 in invoices from Vibalogics GmbH remain outstanding.

#### *Numoda Corporation*

On June 19, 2009, we entered into a Master Agreement and on July 8, 2009 we entered into a Project Agreement with Numoda, a leading clinical trial and logistics management company, to oversee Phase 2 clinical activity with ADXS-HPV for the multicenter Phase 2 U.S. trial of ADXS-HPV in CIN and to act as our U.S. CRO for the multicenter Phase 2 study of ADXS-HPV in recurrent and refractory cervical cancer being conducted in India. The scope of this agreement covers over three years and is estimated to cost approximately \$12.2 million for both trials. In May 2010, we issued 3,500,000 shares of common stock to Numoda Capital at a price per share of \$0.17 in



satisfaction of \$350,000 of services rendered to us by the Numoda Corporation. As of December 6, 2012, we have paid Numoda approximately \$7.4 million for clinical trial activities. The Master Agreement with Numoda terminates on June 12, 2012, or earlier upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Master Agreement that is not cured within 30 days after notice of the breach is provided to us. The Project Agreement with Numoda shall continue until the project which is the subject of such agreement is completed, unless earlier terminated in accordance with the Master Agreement with Numoda.

On June 13, 2012, we entered into a stock purchase agreement with Numoda, pursuant to which we issued to Numoda 15 million shares of our common stock, which we refer to as the AR Cancellation Shares, at a purchase price per share of \$0.15, in exchange for the immediate cancellation of \$2,250,000 of accounts receivables owed by us to Numoda pursuant to the Master Agreement, dated June 19, 2009, between Numoda and us. Numoda has agreed not to sell the AR Cancellation Shares until July 3, 2012, twenty calendar days from the closing of the transaction on June 13, 2012, which period we refer to as the Lock-Up Period. During the Lock-Up Period, we have the option, in our sole discretion, to redeem up to 100% of the AR Cancellation Shares at a purchase price per share of \$0.15. In connection with such issuance, we have also agreed to register the resale by Numoda of the AR Cancellation Shares with the SEC within thirty business days from the closing of the transaction on June 13, 2012. We fulfilled this obligation by filing a registration statement on Form S-1 (File No. 333-183690) with the SEC on August 31, 2012, which was declared effective by the SEC on September 13, 2012.

#### *Pharm-Olam International Ltd.*

In April 2005, we entered into a consulting agreement with Pharm-Olam International Ltd., which we refer to as POI, whereby POI is to execute and manage our Phase 1 clinical trial in ADXS-HPV for a fee of \$430,000 plus reimbursement of certain expenses. As of December 6, 2012 we have an outstanding balance due to POI of \$223,620.

#### *Wistar Institute*

We are collaborating with the Wistar Institute to explore the potential of FAP as a target for immune attack and as the basis for the development of an Advaxis immunotherapy. Therapeutically targeting FAP (fibroblast activation protein) might significantly reduce tumor growth, as it has in some mouse studies. There is no financial obligation in our collaboration with the Wistar Institute.

#### *Montefiore Medical Center*

We are collaborating with the Albert Einstein College of Medicine and Montefiore Medical Center to develop the ADXS-PSA immunotherapy for the treatment of prostate cancer. The goal of the collaboration is to investigate how ADXS-PSA can be combined with conventional chemo-radiation therapy to treat solid tumors.

## Patents and Licenses

Dr. Paterson and Penn have invested significant resources and time in developing a broad base of intellectual property around the cancer vaccine platform technology for which on July 1, 2002 we entered into a 20-year exclusive worldwide license and a right to grant sublicenses pursuant to our license agreement with Penn. As of December 6, 2012, Penn has 39 issued and 39 pending patents in the U.S. and other large countries including Japan, and the European Union, through the Patent Cooperation Treaty system pursuant to which we have an exclusive license to exploit the patents. On May 10, 2010, we entered into a second amendment to the 20-year exclusive worldwide license agreement with Penn, which we refer to as the Second Amendment Agreement. Pursuant to the Second Amendment Agreement, we acquired exclusive licenses for additional patent applications related to our proprietary *Listeria* vaccine technology that were not included in the initial agreement. As of December 6, 2012, we owe Penn approximately \$138,000 in patent expenses pursuant to the Second Amendment Agreement.

On December 12, 2011, we entered into a third amendment to the Penn license agreement pursuant to which we acquired an exclusive worldwide license agreement for additional patent applications from the laboratory of Dr. Yvonne Paterson. One application pertains to the antigen ISG15 from Penn for use in our *Lm*-LLO based immunotherapies for the treatment of cancer and other diseases. This intellectual property resulted from work performed in the laboratory of Dr. Yvonne Paterson that demonstrated ISG15 was an effective immunological target for the treatment of a number of different cancers in animal models, including ovarian, colon, breast and other cancers. SG-15 expression is elevated in “triple negative” breast cancer, a disease in which HER2, estrogen and progesterone receptors are lacking, and thus has no defined therapeutic immune target at the moment. An *Lm*-LLO vaccine that targets ISG-15 may prove to be an effective agent in an area where there is a significant unmet medical need.

Another patent application which we licensed on November 15, 2011 is a collaborative provisional application between the laboratories of Dr. Paterson and Dr. Don Harn at the University of Georgia. In this work, *Lm*-LLO immunotherapies were found in a number of animal models to have the unusual ability to induce therapeutic Th-1 immune responses, which are the type of response that is desirable when treating cancer, in animals that were previously unable to mount a Th-1 response. This finding may have great utility because parasitic diseases that are endemic to the third world, and other kinds of disease, prevent patients from mounting Th-1 type responses. The ability to induce a Th-1 therapeutic response in these patients would make them susceptible to treatment with immunotherapy where they might not otherwise respond. Moreover, since chemotherapy and radiotherapy have immune components, the use of an effective *Lm*-LLO agent as part of a combination regimen might improve the therapeutic efficiency of other agents as well.

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

We are aware of Aduro Biotech, a company comprised in part of former Cerus and Anza employees that is investigating *Listeria* vaccines based upon Anza's technology and is conducting clinical trials using *Listeria*-based investigational new drugs. We believe that through our exclusive license with Penn, we have the earliest known and dominant patent position in the U.S. for the use of recombinant *Listeria monocytogenes* expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. We successfully defended our intellectual property by contesting a challenge made by Anza to our patent position in Europe on a claim not available in the U.S. The European Patent Office (EPO) Board of Appeals in Munich, Germany has ruled in favor of The Trustees of Penn and its exclusive licensee Advaxis and reversed a patent ruling that revoked a technology patent that had resulted from an opposition filed by Anza. The ruling of the EPO Board of Appeals is final and cannot be appealed. The granted claims, the subject matter of which was discovered by Dr. Yvonne Paterson, scientific founder of Advaxis, are directed to the method of preparation and composition of matter of recombinant bacteria expressing tumor antigens for treatment of patients with cancer. Subsequently, we challenged a patent by Aduro. The patent was upheld by the USPTO, and the decision resulted in a precise and limiting definition of the approved claims. The Aduro patent that we challenged does not cover our technology, or limit our business plans.

Based on searches of publicly available databases, we do not believe that Anza, Aduro or any other third party owns any published *Listeria* patents or has any issued patent claims that might materially and adversely affect our ability to operate our business as currently contemplated in the field of recombinant *Listeria monocytogenes*. Additionally, our proprietary position that is the issued patents and licenses for pending applications restricts anyone from using plasmid based *Listeria* constructs, or those that are bioengineered to deliver antigens fused to LLO, ActA, or fragments of LLO or ActA.

On May 26, 2009, the United States Patent and Trademark Office, which we refer to as the PTO, approved our patent application "*Compositions and Methods for Enhancing the Immunogenicity of Antigens*". This patent application covers the use of *Listeria monocytogenes* protein ActA and fragments of this protein for use in the creation of antigen fusion proteins. This intellectual property protects a unique strain of *Listeria monocytogenes* for use as a vaccine vector.

On February 10, 2009 the PTO issued patent 7,488,487 “*Methods of Inducing Immune response Through the Administration of Auxotrophic Attenuated *dat/dal* Double Mutant *Listeria* Strains*”, assigned to Penn and licensed to us. This intellectual property protects a unique strain of *Listeria* for use as a vaccine vector. This new strain of *Listeria* is an improvement over the strain currently in clinical testing as it is more attenuated, more immunogenic, and does not contain an antibiotic resistance gene. We believe that this strain may be result in more effective immunotherapies.

Between February and December of 2009 the U.S., Japanese, and European patent offices have approved patents for a newly developed strain of *Listeria* that uses a novel method of attenuation. This strain is attenuated by deleting genes that are responsible for making a protein that is essential for the bacterial cell wall, and by engineering back the ability to make this protein at a reduced level. In developing this strain, the objective was to improve upon the useful properties of *Listeria* while reducing potential disease causing properties of the bacterium, and, in preliminary testing this strain of *Listeria* appears to be more immunogenic and less virulent than prior vaccine strains.

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

Material patents currently underlying the license agreement with Penn are shown in the table below.

Title	Expiration	Product Candidate	Jurisdiction
Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector	18-Apr-2017	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US, Germany, Switzerland, France, Ireland, UK, Belgium, Japan, Canada
Live, Recombinant <i>Listeria</i> Monocytogenes and Production of Cytotoxic T-Cell Response	03-Nov-2015	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US
Methods and Compositions for Immunotherapy of Cancer	08-Nov-2014	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US
Fusion of Non-Hemolytic, Truncated Form of Listeriolysin O to Antigens to Enhance Immunogenicity	2-Aug-2020	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US, Germany, France, Great Britain Israel, European Union
	2-Aug-2020		

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Compositions and Methods for Enhancing Immunogenicity of Antigens		All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US, Germany, France European Union, Israel
Compositions and Methods for Enhancing Immunogenicity of Antigens	15-Nov-2023	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US
Methods and Compositions for Immunotherapy of Cancer	08-Nov-2014	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US
Compositions and Methods for Enhancing Immunogenicity of Antigens	29-Mar-2020	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	US

Title	Expiration	Product Candidate	Jurisdiction
Immunogenic Compositions Comprising DAL/DAT Double-Mutant, Auxotrophic, Attenuated Strains of Listeria and their Methods of Use	18-Nov-2017	ADXS-PSA and ADXS-HER	US, Canada, European Union, Great Britain, Germany
Isolated Nucleic Acids Comprising Listeria DAL and DAT Genes	18-Nov-2017	ADXS-PSA and ADXS-HER	US
Isolated Nucleic Acids Comprising Listeria DAL and DAT Genes	18-Nov-2017	ADXS-PSA and ADXS-HER	US
Immunogenic Compositions Comprising DAL/DAT Double Mutant, Auxotrophic Attenuated Strains of Listeria and their Methods of Use	31-Jan-2020	ADXS-PSA and ADXS-HER	US
Methods and Compositions for Immunotherapy of Cancer	13-Jul-2016	ADXS-HER2	US
Listeria-based and LLO-based Vaccines	24-Sep-2024	ADXS-HER2	US

## Governmental Regulation

### *The Drug Development Process*

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

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

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

protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

Criteria for subject or patient inclusion/exclusion;

Dosing requirements and timing;

Tests to be performed; and

Evaluations and data assessment.

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

*Clinical Trials.* Human clinical studies or testing of an investigational new drug prior to FDA approval are generally done in three stages known as Phase 1, Phase 2, and Phase 3 testing. The names of the phases are derived from the CFR 21 that regulates the FDA. Generally, there are multiple studies conducted in each phase.

*Phase 1.* Phase 1 studies involve testing a investigational new drug on a limited number of patients. Phase 1 studies determine a drug's basic safety, maximum tolerated dose, and how the drug is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year. Typically, cancer therapies are initially tested on late stage cancer patients.

*Phase 2.* Phase 2 trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 testing typically lasts an average of one to three years. In Phase 2, the drug is tested to determine its safety and effectiveness for treating a specific disease or condition. Phase 2 testing also involves determining acceptable dosage levels of the drug. If Phase 2 studies show that an investigational new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to evaluate the investigational new drug in Phase 3 studies.

*Phase 3.* Phase 3 studies involve testing even larger numbers of patients, typically several hundred to several thousand patients. The purpose is to confirm effectiveness and long-term safety on a large scale. These studies generally last two to six years. Given the larger number of patients required to conduct Phase 3 studies, they are generally conducted at multiple sites and often times multiple countries.

*Biologic License Application.* The results of the clinical trials using biologics are submitted to the FDA as part of Biologic License Application, which we refer to as BLA. Following the completion of Phase 3 studies, if the Sponsor of a potential product in the U.S. believes it has sufficient information to support the safety and effectiveness of the investigational new drug, the Sponsor submits a BLA to the FDA requesting that the investigational new drug be approved for sale. The application is a comprehensive, multi-volume filing that includes the results of all preclinical and clinical studies, information about the drug's composition, and the Sponsor's plans for manufacturing, packaging, labeling and testing the investigational new drug. The FDA's review of an application is designated either as a standard review with a target review time of 10 months or a priority review with a target of 6 months. Depending upon the completeness of the application and the number and complexity of requests and responses between the FDA and the Sponsor, the review time can take months to many years, with the mean review lasting 13.1 months. Once approved, drugs and other products may be marketed in the U.S., subject to any conditions imposed by the FDA.

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



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

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

#### *Other Regulations*

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

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

## **Manufacturing**

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

We have entered into agreements with Recipharm Cobra and Vibalogics GmbH for the manufacture of a portion of our vaccines. Both companies have extensive experience in manufacturing gene therapy products for investigational studies. Both companies are full service manufacturing organizations that manufacture and supply biologic based therapeutics for the pharmaceutical and biotech industry. These services include the GMP manufacturing of stability testing and cell banking. Recipharm's manufacturing plan for us calls for several manufacturing stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase 1 and Phase 2 trials.

Beginning in April 2008, we entered into a number of Agreements with Vibalogics to manufacture GMP material for two new vaccines ADXS-PSA, an Lm-LLO based immunotherapy for the treatment of prostate cancer, and ADXS-HER2, an Lm-LLO based immunotherapy for the treatment of HER2 expressing cancers (such as breast, gastric, bladder, brain, pancreatic and ovarian cancer). The Agreement with Recipharm Cobra covers GMP manufacturing in several stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase 1 and Phase 2 trials, filling, finishing, and the development of a stable, room temperature storage, dried formulation of our vaccines.

## **Competition**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including: Aduro Biotech, Agenus Inc., Bionovo Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech

Inc., Oncothyreon Inc., et al., each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We expect that our immunotherapies under development and in clinical trials will address major markets within the cancer therapeutic area. 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 immunotherapies or of competitors' products may be an important competitive factor. Accordingly, the speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

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

The presence of these agents in the market does not eliminate the market for a therapeutic vaccine directed against invasive cervical cancer and CIN 2/3 for a number of reasons:

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

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

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

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

Taken together, experts believe that there will be a cervical cancer and CIN 2/3 market for the foreseeable future.

## **Employees**

As of December 6, 2012, we had 11 employees, all of which were full time employees. We believe our relations with employees are good.

We do not anticipate any significant increase in the number of employees in the clinical area and the research and development area to support clinical requirements, and in the general and administrative and business development areas over the next two years.

## **Description of Property**

Our corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. On April 1, 2011, we entered into a Sublease Agreement for such office, which is a 9143 square foot leased facility in Princeton, NJ approximately 12 miles south of our prior location. The agreement is for a period of approximately twenty months at the rate of approximately \$15,600 per month plus utilities. Utility costs are estimated to be \$7,200 per month and are capped at approximately \$10,700 per month. The agreement required an initial payment of approximately \$54,000 prior to entering the new facility, which we have paid. As an inducement to enter into the agreement, the company received an abatement through July 31, 2011. The agreement has a termination date of November 29, 2012 and we are in discussions with building owner for lease terms beyond this date.

## **Legal Proceedings**

As of the date hereof, there are no material pending legal proceedings to which we are a party or of which any of our property is the subject. In the ordinary course of our business we may become subject to litigation regarding our immunotherapies or our compliance with applicable laws, rules, and regulations.

**MANAGEMENT****Executive Officers, Directors and Key Employees**

The following are our executive officers and directors and their respective ages and positions as of December 6, 2012:

Name	Age	Position
Thomas A. Moore	60	Chief Executive Officer and Chairman of our Board of Directors
Dr. James P. Patton	54	Director
Roni A. Appel	45	Director
Dr. Thomas L. McKearn	61	Director
Richard L. Berman	69	Director
John Rothman, Ph.D.	63	Executive Vice President of Clinical and Scientific Operations
Mark J. Rosenblum	59	Chief Financial Officer, Senior Vice President and Secretary

**Thomas A. Moore.** Mr. Moore joined our Board as an independent director in September 2006. Effective December 15, 2006, Mr. Moore was appointed our Chairman and Chief Executive Officer. He is currently also a director of Opt-e-scrip, Inc., which markets a clinical system to compare multiple drugs in the same patient. He also serves on the board of directors of Mayan Pigments, Inc., which has developed and patented Mayan pigment technology. Previously, from June 2002 to June 2004 Mr. Moore was President and Chief Executive Officer of Biopure Corporation, a developer of oxygen therapeutics that are intravenously administered to deliver oxygen to the body's tissues. From 1996 to November 2000 he was President and Chief Executive Officer of Nelson Communications. Prior to 1996, Mr. Moore had a 23-year career with the Procter & Gamble Company in multiple managerial positions, including President of Health Care Products where he was responsible for prescription and over-the-counter medications worldwide, and Group Vice President of the Procter & Gamble Company. Mr. Moore is a graduate of Princeton University. Mr. Moore's extensive business, managerial, executive and leadership experience in the healthcare industry make him particularly qualified to serve on our Board.

**Dr. James P. Patton.** Dr. Patton has served as a member of our board of directors since February 2002, as Chairman of our board of directors from November 2004 until December 31, 2005 and as our Chief Executive Officer from February 2002 to November 2002. Since February 1999, Dr. Patton has been the Vice President of Millennium Oncology Management, Inc., which provides management services for radiation oncology care to four sites. Dr. Patton has been a trustee of Dundee Wealth US, a mutual fund family since October 2006. In addition, he has been President of Comprehensive Oncology Care, LLC since 1999, a company which owned and operated a cancer treatment facility in Exton, Pennsylvania until its sale in 2008. From February 1999 to September 2003, Dr. Patton also served as a consultant to LibertyView Equity Partners SBIC, LP, a venture capital fund based in Jersey City, New Jersey. From July 2000 to December 2002, Dr. Patton served as a director of Pinpoint Data Corp. From February 2000 to November 2000, Dr. Patton served as a director of Healthware Solutions. From June 2000 to June 2003, Dr. Patton

served as a director of LifeStar Response. He earned his B.S. from the University of Michigan, his Medical Doctorate from Medical College of Pennsylvania, and his M.B.A. from Penn's Wharton School. Dr. Patton was also a Robert Wood Johnson Foundation Clinical Scholar. He has published papers regarding scientific research in human genetics, diagnostic test performance and medical economic analysis. Dr. Patton's experience as a trustee and consultant to funds that invest in life science companies provide him with the perspective from which we benefit. Additionally, Dr. Patton's medical experience and service as a principal and director of other life science companies makes Dr. Patton particularly qualified to serve as our director.

**Roni A. Appel.** Mr. Appel has served as a member of our board of directors since November 2004. He was our President and Chief Executive Officer from January 1, 2006 and Secretary and Chief Financial Officer from November 2004, until he resigned as our Chief Financial Officer on September 7, 2006 and as our President, Chief Executive Officer and Secretary on December 15, 2006. From 1999 to 2004, he was a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1998 he was an attorney and completed his MBA at Columbia University. Mr. Appel's longstanding service with us and his entrepreneurial investment career in early stage biotech businesses qualify him to serve as our director.

**Dr. Thomas L. McKearn.** Dr. McKearn has served as a member of our board of directors since July 2002. He brings more than 25 years of experience in the translation of biotechnology science into oncology products. First as one of the founders of Cytogen Corporation, then as an Executive Director of Strategic Science and Medicine at Bristol-Myers Squibb and now as the VP Strategic Clinical Affairs at Agennix, Inc. (formerly GPC-Biotech), he has worked at bringing the most innovative laboratory findings into the clinic and through the FDA regulatory process for the benefit of cancer patients who need better ways to cope with their afflictions. Prior to entering the biotechnology industry in 1981, Dr. McKearn received his medical, graduate and post-graduate training at the University of Chicago and served on the faculty of the Medical School at the University of Pennsylvania. Dr. McKearn's experience in managing life science companies, his knowledge of medicine and his commercialization of biotech products particularly qualify him to serve as our director.

**Richard L. Berman.** Mr. Berman has served as a member of our board of directors since September 1, 2005. Mr. Berman's business career spans over 35 years of venture capital, senior management and merger and acquisitions experience. In the past five years, Mr. Berman has served as a director and/or officer of over a dozen public and private companies. From 2006 to 2011, Mr. Berman was Chairman of National Investment Managers, a company with \$12 billion in pension administration assets. In June 2011, he became chairman of the International Corporation for Project Finance LLC, a leading private infrastructure finance company involved in over \$10 billion of projects. Mr. Berman is currently a director of four public companies: Broadcaster, Inc., Easylink Services International, Inc., Advaxis, Inc., and Neostem, Inc. From 1998 to 2000, he was employed by Internet Commerce Corporation (now Easylink Services) as Chairman and CEO. Prior to 1998, Mr. Berman worked at Goldman Sachs and was Senior Vice President of Bankers Trust Company. Mr. Berman is a past Director of the Stern School of Business of NYU where he obtained his BS and MBA. He also has U.S. and foreign law degrees from Boston College and The Hague Academy of International Law, respectively. Mr. Berman's extensive knowledge of our industry, his role in the governance of publically held companies and his directorships in other life science companies qualify him to serve as our director.

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

**Mark J. Rosenblum.** Effective as of January 5, 2010, Mr. Rosenblum joined our company as our Chief Financial Officer, Senior Vice President and Secretary. Mr. Rosenblum was the Chief Financial Officer of HemobioTech, Inc., a public company primarily engaged in the commercialization of human blood substitute technology licensed from Texas Tech University, from April 1, 2005 until December 31, 2009. From August 1985 through June 2003, Mr. Rosenblum was employed by Wellman, Inc., a public chemical manufacturing company. Between 1996 and 2003, Mr. Rosenblum was the Chief Accounting Officer, Vice President and Controller at Wellman, Inc. Mr. Rosenblum holds both a Masters in Accountancy and a B.S. degree from the University of South Carolina. Mr. Rosenblum is a certified public accountant.

## **Board of Directors**

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



## Director Independence

In accordance with the disclosure requirements of the SEC, and since the OTC Bulletin Board does not have its own rules for director independence, we have adopted the NASDAQ listing standards for independence effective April 2010. Although we are not presently listed on any national securities exchange, each of our directors, other than Mr. Thomas A. Moore and Mr. Roni Appel, is independent in accordance with the definition set forth in the NASDAQ rules. Each current member of the Audit Committee and Compensation Committee is an independent director under the NASDAQ standards. The Board considered the information included in transactions with related parties as outlined below along with other information the Board considered relevant, when considering the independence of each director.

## Committees of the Board of Directors

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

### *Audit Committee*

The audit committee of our board of directors is currently composed of two directors, both of whom satisfy the independence standards for audit committee members under the NASDAQ rules (although our securities are not listed on the NASDAQ stock market but are quoted on the OTC Bulletin Board). For fiscal 2011, the audit committee was composed of Mr. Berman and Dr. Patton, with Mr. Berman serving as the audit committee's financial expert as defined under Item 407 of Regulation S-K of the Securities Act of 1933, as amended, which we refer to as the Securities Act. Our board of directors has determined that the audit committee financial expert is independent as defined in (i) Rule 10A-3(b)(i)(ii) under the Exchange Act and (ii) under Section 121 B(2)(a) of the NYSE Amex Equities Company Guide (although our securities are not listed on the NYSE Amex Equities but are quoted on the OTC Bulletin Board).

The audit committee is responsible for the following:

- reviewing the results of the audit engagement with the independent registered public accounting firm;

identifying irregularities in the management of our business in consultation with our independent accountants, and suggesting an appropriate course of action;

- reviewing the adequacy, scope, and results of the internal accounting controls and procedures;

reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm;

- reviewing the auditors' fees; and

- recommending the engagement of auditors to the full board of directors.

#### *Compensation Committee*

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

#### *Nominating and Corporate Governance Committee*

The nominating and corporate governance committee of our board of directors currently consists of Mr. Berman and Mr. Moore. The nominating and corporate governance committee did not meet in fiscal 2011. The functions of the nominating and corporate governance committee include the following:

identifying and recommending to the board of directors individuals qualified to serve as members of our board of directors and on the committees of the board;

- advising the board with respect to matters of board composition, procedures and committees;

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

overseeing the annual evaluation of the board and our management.

The nominating and corporate governance committee will consider director candidates recommended by eligible stockholders. Stockholders may recommend director nominees for consideration by the nominating and corporate governance committee by writing to the Nominating and Corporate Governance, Attention: Chairman, Advaxis, Inc., 305 College Road East, Princeton, New Jersey 08540. Any recommendations for director made to the nominating and corporate governance committee should include the nominee's name and qualifications for membership on our board of directors, and should include the following information for each person being recommended or nominated for election as a director:

The name, age, business address and residence address of the person;

The principal occupation or employment of the person;

The number of shares of our common stock which the person owns beneficially or of record; and

Any other information relating to the person that must be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors under Section 14 of the Exchange Act and its rules and regulations.

In addition, the stockholder's notice must include the following information about such stockholder:

The stockholder's name and record address;

The number of shares of our common stock that the stockholder owns beneficially or of record;

A description of all arrangements or understandings between the stockholder and each proposed nominee and any other person or persons, including their names, pursuant to which the nomination is to be made;

A representation that the stockholder intends to appear in person or by proxy at the annual meeting to nominate the person or persons named in such stockholder's notice; and

Any other information about the stockholder that must be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors under Section 14 of the Exchange Act and its rules and regulations.

The notice must include a written consent by each proposed nominee to being named as a nominee and to serve as a director if elected. No person will be eligible for election as a director of ours unless recommended by the nominating and corporate governance committee and nominated by our board of directors or nominated in accordance with the procedures set forth above. Candidates proposed by stockholders for nomination are evaluated using the same criteria as candidates initially proposed by the nominating and corporate governance committee.

We must receive the written nomination for an annual meeting not less than 90 days and not more than 120 days prior to the first anniversary of the previous year's annual meeting of stockholders, or, if no annual meeting was held the previous year or the date of the annual meeting is advanced more than 30 days before or delayed more than 60 days after the anniversary date, we must receive the written nomination not more than 120 days prior to the annual meeting and not less than the later of 90 days prior to the annual meeting or ten days following the day on which public announcement of the date of the annual meeting is first made. For a special meeting, we must receive the written nomination not less than the later of 90 days prior to the special meeting or ten days following the day on which public announcement of the date of the special meeting is first made.

The nominating and corporate governance committee expects, as minimum qualifications, that nominees to our board of directors (including incumbent directors) will enhance our board of director's management, finance and/or scientific expertise, will not have a conflict of interest and will have a high ethical standard. A director nominee's knowledge and/or experience in areas such as, but not limited to, the medical, biotechnology, or life sciences industry, equity and debt capital markets and financial accounting are likely to be considered both in relation to the individual's qualification to serve on our board of directors and the needs of our board of directors as a whole. Other characteristics, including but not limited to, the director nominee's material relationships with us, time availability, service on other boards of directors and their committees, or any other characteristics which may prove relevant at any given time as determined by the nominating and corporate governance committee shall be reviewed for purposes of determining a director nominee's qualification.

Candidates for director nominees are evaluated by the nominating and corporate governance committee in the context of the current composition of our board of directors, our operating requirements and the long-term interests of our stockholders. The nominating and corporate governance committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The nominating and corporate governance committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of our board of directors. In the case of incumbent directors whose terms of office are set to expire, the nominating and corporate governance committee

reviews such directors' overall service to us during their term, including the number of meetings attended, level of participation, quality of performance, and any other relationships and transactions that might impair such directors' independence. The nominating and corporate governance committee meets to discuss and consider such candidates' qualifications and then selects a nominee for recommendation to our board of directors by majority vote. To date, the nominating and corporate governance committee has not paid a fee to any third party to assist in the process of identifying or evaluating director candidates.

### **Compensation Committee Interlocks and Insider Participation**

The current members of the compensation committee are Mr. Berman and Dr. McKearn. Currently, none of such persons is an officer or employee of us or any of our subsidiaries. During fiscal 2011, none of our executive officers served as a director or member of a compensation committee (or other committee serving an equivalent function) of any other entity, whose executive officers served as a director or member of our compensation committee. No interlocking relationship, as defined by the Securities Exchange Act of 1934, as amended, exists between our board of directors or our Compensation Committee and the board of directors or compensation committee of any other company.

**EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table sets forth the information as to compensation paid to or earned by our Chief Executive Officer and our two other most highly compensated executive officers during the fiscal years ended October 31, 2011 and 2010. These individuals are referred to in this prospectus as our named executive officers. As none of our named executive officers received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal years ended October 31, 2011 and 2010, we have omitted those columns from the table.

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s) (1)	Option Award(s) (1)	All Other Compensation	Total
Thomas A. Moore, CEO and Chairman	2011	\$350,000	\$-	\$-	\$-	(7) \$21,294	(2) \$371,294
	2010	350,000	-	135,000 (6)	224,800	142,174	(2) 851,974
Dr. John Rothman, Executive VP of Science & Operations	2011	275,000	83,000	30,000 (3)	- (8)	34,665	(4) 422,665
	2010	250,000	50,000	30,000 (3)	252,900	29,451	(4) 612,351
Mark J. Rosenblum Chief Financial Officer	2011	250,000	72,000	-	- (9)	19,211	(5) 341,211
	2010	225,000	-	-	134,880	8,494	(5) 368,374

The amounts shown in this column represent the fair value on grant date in accordance with ASC 718 using the (1) assumptions described under Stock Compensation in Note 2 to our financial statements included elsewhere in this prospectus.

(2) Based on our cost of Mr. Moore's coverage for health care and interest received for the Moore Notes.

(3) Represents \$30,000 of base salary paid in shares of our common stock in lieu of cash, based on the average monthly stock price.

(4) Based on our cost of his coverage for health care and the 401K company match he received.

(5) Based on our cost of his coverage for health care.

(6) For 2010, represents 750,000 shares of our common stock granted to Mr. Moore based on the financial raise milestone in his employment agreement valued at the market close price on June 29, 2010.

(7) In the fiscal year ended October 31, 2011, we did not grant any stock options to purchase shares of our common stock to Mr. Moore. However, in the fiscal year ended October 31, 2012, we granted stock options to purchase 4,000,000 shares of our common stock to Mr. Moore in connection with services he performed in fiscal 2011. The material terms of this grant is described below under the heading “Discussion of Summary Compensation Table.”

(8) In the fiscal year ended October 31, 2011, we did not grant any stock options to purchase shares of our common stock to Dr. Rothman. However, in the fiscal year ended October 31, 2012, we granted stock options to purchase 3,000,000 shares of our common stock to Dr. Rothman in connection with services he performed in fiscal 2011. The material terms of this grant is described below under the heading “Discussion of Summary Compensation Table.”

(9) In the fiscal year ended October 31, 2011, we did not grant any stock options to purchase shares of our common stock to Mr. Rosenblum. However, in the fiscal year ended October 31, 2012, we granted stock options to purchase 2,100,000 shares of our common stock to Mr. Rosenblum in connection with services he performed in fiscal 2011. The material terms of this grant is described below under the heading “Discussion of Summary Compensation Table.”

### **Discussion of Summary Compensation Table**

We are party to an employment agreement with each of our named executive officers who is presently employed by us, other than Mr. Rosenblum and Mr. Rothman. Each employment agreement sets forth the terms of that officer’s employment, including among other things, salary, bonus, non-equity incentive plan and other compensation, and its material terms are described below. In fiscal 2010, we granted stock options to our named executive officers to purchase shares of our common stock and issued stock to our Chief Executive Officer. In fiscal 2011, we did not grant any stock options to purchase shares of our common stock to our named executive officers. However, in fiscal 2012, we granted stock options to purchase shares of our common stock to our named executive officers in connection with services they performed in fiscal 2011. The material terms of these grants are also described below.

*Moore Employment Agreement and Option Agreements.* We are party to an employment agreement with Mr. Moore, dated as of August 21, 2007 (memorializing an oral agreement dated December 15, 2006), that provides that he will serve as our Chairman of the Board and Chief Executive Officer for an initial term of two years. For so long as Mr. Moore is employed by us, Mr. Moore is also entitled to nominate one additional person to serve on our board of directors. Following the initial term of employment, the agreement was renewed for a one year term, and is automatically renewable for additional successive one year terms, subject to our right and Mr. Moore's right not to renew the agreement upon at least 90 days' written notice prior to the expiration of any one year term.

Under the terms of the agreement, Mr. Moore was entitled to receive a base salary of \$250,000 per year, subject to increase to \$350,000 per year upon our successful raise of at least \$4.0 million (which condition was satisfied on November 1, 2007) and subject to annual review for increases by our board of directors in its sole discretion. The agreement also provides that Mr. Moore is entitled to receive family health insurance at no cost to him. Mr. Moore's employment agreement does not provide for the payment of a bonus.

In connection with our hiring of Mr. Moore, we agreed to grant Mr. Moore up to 1,500,000 shares of our common stock, of which 750,000 shares were issued on November 1, 2007 upon our successful raise of \$4.0 million and 750,000 shares were issued on June 29, 2010 upon our successful raise of an additional \$6.0 million (which condition was satisfied in January 2010). In addition, on December 15, 2006, we granted Mr. Moore options to purchase 2,400,000 shares of our common stock. Each option is exercisable at \$0.143 per share (which was equal to the closing sale price of our common stock on December 15, 2006) and expires on December 15, 2016. The options vested in 24 equal monthly installments. On July 21, 2009, we granted Mr. Moore options to purchase 2,500,000 shares of our common stock. Each option is exercisable at \$0.10 per share (which was equal to the closing sale price of our common stock on July 21, 2009) and expires on July 21, 2019. One-third of these options vested on the grant date, one-third of these options vested on the first anniversary of the grant and the remaining one-third will vest on the second anniversary of the grant. On October 14, 2010, we granted Mr. Moore options to purchase 2,000,000 shares of our common stock. Each option is exercisable at \$0.15 per share. These options vest over a three year period beginning one year from the grant date. On November 8, 2011, we granted Mr. Moore options to purchase 4,000,000 shares of our common stock. Each option is exercisable at \$0.148 per share. These options vest over a three year period beginning one year from the grant date.

We have also agreed to grant Mr. Moore options to purchase an additional 1,500,000 shares of our common stock if the price of common stock (adjusted for any splits) is equal to or greater than \$0.40 for 40 consecutive business days. Pursuant to the terms of his employment agreement, all options will be awarded and vested upon a merger of the company which is a change of control or a sale of the company while Mr. Moore is employed. In addition, if Mr. Moore's employment is terminated by us, Mr. Moore is entitled to receive severance payments equal to one year's salary at the then current compensation level.

Mr. Moore has agreed to refrain from engaging in certain activities that are competitive with us and our business during his employment and for a period of 12 months thereafter under certain circumstances. In addition, Mr. Moore is subject to a non-solicitation provision for 12 months after termination of his employment.



*Rothman Employment Agreement and Option Agreements.* We previously entered into an employment agreement with Dr. Rothman, Ph.D., dated as of March 7, 2005, that provided that he would serve as our Vice President of Clinical Development for an initial term of one year. Dr. Rothman's current salary is \$305,000, consisting of \$275,000 in cash and \$30,000 in stock, payable in our common stock, based on the average closing stock price for such six month period. While the employment agreement has expired and has not been formally renewed in accordance with the agreement, Dr. Rothman remains employed by us and is currently our Executive V.P. of Clinical and Scientific Operations.

In addition, on March 1, 2005, we granted Dr. Rothman options to purchase 360,000 shares of our common stock. Each option is exercisable at \$0.287 per share (which was equal to the closing sale price of our common stock on March 1, 2005) and expires on March 1, 2015. All of these options have vested. On March 29, 2006, we granted Dr. Rothman options to purchase 150,000 shares of our common stock. Each option is exercisable at \$0.26 per share (which was equal to the closing sale price of our common stock on March 29, 2006) and expires on March 29, 2016. One-fourth of these options vested on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. On February 15, 2007, we granted Dr. Rothman options to purchase 300,000 shares of our common stock. Each option is exercisable at \$0.165 per share (which was equal to the closing sale price of our common stock on February 15, 2007) and expires on February 15, 2017. One-fourth of these options vested on the first anniversary of the grant date, and the remaining vest in 12 equal quarterly installments. Pursuant to the terms of the 2005 plan, at least 75% of Dr. Rothman's options will be vested upon a merger of the company which is a change of control or a sale of the company while Dr. Rothman is employed, unless the administrator of the plan otherwise allows for all options to become vested. On July 21, 2009, we granted Mr. Rothman options to purchase 1,750,000 shares of our common stock. Each option is exercisable at \$0.10 per share (which was equal to the closing sale price of our common stock on July 21, 2009) and expires on July 21, 2019. One-third of these options vested on the grant date, one-third of these options vested on the first anniversary of the grant and the remaining one-third will vest on the second anniversary of the grant. On October 14, 2010, we granted Dr. Rothman options to purchase 2,250,000 shares of our common stock. Each option is exercisable at \$0.15 per share. These options vest over a three year period beginning one year from the grant date. On November 8, 2011, we granted Dr. Rothman options to purchase 3,000,000 shares of our common stock. Each option is exercisable at \$0.148 per share. These options vest over a three year period beginning one year from the grant date.

Dr. Rothman has agreed to refrain from engaging in certain activities that are competitive with us and our business during his employment and for a period of 18 months thereafter under certain circumstances. In addition, Dr. Rothman is subject to a non-solicitation provision for 18 months after termination of his employment.

*Rosenblum Compensation.* Mr. Rosenblum serves as our Chief Financial Officer, Senior Vice President and Secretary. His current salary is \$240,000 per annum, with a discretionary bonus of up to 30% of his base compensation awarded annually in March beginning in 2011. While an employment agreement has not been formally entered into, Mr. Rosenblum remains employed by us.

In addition, on January 5, 2010, Mr. Rosenblum was granted options to purchase 1,000,000 shares of the our common stock with an exercise price equal to \$0.128. One third of these options vested on the date of grant, one third vested on January 5, 2011, and one third vests on the second anniversary of the date of grant. On October 14, 2010, we granted Mr. Rosenblum options to purchase 1,200,000 shares of our common stock. Each option is exercisable at \$0.15 per share. These options vest over a three year period beginning one year from the grant date. On November 8, 2011, we granted Mr. Rosenblum options to purchase 2,100,000 shares of our common stock. Each option is exercisable at \$0.148 per share. These options vest over a three year period beginning one year from the grant date.

### Outstanding Equity Awards at Fiscal Year-End

The following table provides information about the number of outstanding equity awards held by our named executive officers at October 31, 2011.

Name	Option Awards			Equity Incentive Plan Awards:			Stock Awards		Equity Incentive Plan Number of Unexercised or Other Not Vested
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)		
	2,500,000	(1) —	—	0.100	7/21/19	—	\$—	—	

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Thomas A. Moore	2,400,000	—	—	0.143	12/15/16	—	—	—
	666,667	1,333,333	(2)	0.15	10/14/20	—	—	—
Dr. John Rothman	1,750,000	(3)	—	0.100	7/21/19	—	—	—
	360,000	—	—	0.287	3/1/15	—	—	—