Advaxis, Inc. Form POS AM April 13, 2006

As filed with the Securities and Exchange Commission on April 13, 2006 Registration No. 333 - 132298

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

AMENDMENT NO. 1 TO FORM SB-2

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Advaxis, Inc. (Name of small business issuer in our charter)

Colorado (State or other jurisdiction of incorporation or organization) 2836 (Primary Standard Industrial Classification Code Number) 841521955 (I.R.S. Employer Identification No.)

Technology Center of New Jersey 675 Route 1 Suite 119 North Brunswick, NJ 08902

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

Mr. Roni Appel, Chief Executive Officer Technology Center of New Jersey

> 675 Route 1 Suite 119

North Brunswick, NJ 08902

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

Copies to:

Gary A. Schonwald, Esq.
Reitler Brown & Rosenblatt LLC
800 Third Avenue

#### 21st Floor New York, New York 10022 (212) 209-3050 / (212) 371-5500 (Telecopy)

#### Approximate date of commencement of proposed sale to the public.

From time to time after this Registration Statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or reinvestment plans, please check the following box. o

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: **S** 

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: o

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: o

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: o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: o

#### **CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be Registered	Proposed maximum offering price per unit	Proposed maximum aggregate ffering price	Amount of gistration fee
common stock par value \$0.001 per share	43,341,513 <sup>(a)</sup>	\$0.43 <sup>(b)</sup>	\$ 18,636,851	\$ 1,994.14
common stock par value \$0.001 per	(c)			
share	4,200,000	\$0.43 <sup>(d)</sup>	\$ 1,806,000	\$ 193.24
common stock par value \$0.001 per	(e)			
share	300,000	\$0.52 <sup>(f)</sup>	\$ 156,000	\$ 16.69
TOTAL	47,841,513			\$ 2,204.07

<sup>(</sup>a) Estimate of shares which may be issued upon conversion of \$3,000,000 principal and payment of \$540,000 of interest on the Secured Convertible Debentures at a "Market Conversion Price" provided for in the Debenture which is calculated for the purpose of the number of shares to be registered at one-third of the "Fixed Conversion Price" of \$0.287 per share.

(b) 150% of the Fixed Conversion Price of \$0.287.

(c) Shares to be offered upon exercise of Warrant to purchase 4,200,000 shares

(d) 150% of the exercise price of \$0.287 per share.

(e) Shares to be offered upon exercise of B Warrant to purchase 300,000 shares.

(f) 150% of exercise price \$0.3444 per share.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION SATEMENT 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 SECTION8(A) MAY DETERMINE.

#### **EXPLANATORY NOTE**

Pursuant to Rule 429 promulgated under the Securities Act of 1933 as amended, the Prospectus included herein relates to two Registration Statements on Form SB-2 (Registration Nos. 333-132298 and 333-122504). This Registration Statement as amended constitutes the amended filing of the Registration Statement on Form SB-2 (Registration No. 333-12298) and Post-Effective Amendment No. 3 to the Registration Statement on Form SB-2 (Registration No. 333-122504).

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The information in this prospectus is not complete and may be changed without notice. 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.

Subject to completion Dated April 13, 2006

#### PRELIMINARY PROSPECTUS

The information in this prospectus is not complete and may be changed without notice. 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.

#### Advaxis, Inc.

#### Common Stock

This is an offering (the "Offering") by the stockholders identified in this prospectus (the "Selling Stockholders") of the following shares of Common Stock, \$0.001 par value, of Advaxis, Inc. (the "Company" or "Advaxis") issued to them:

Up to 37,099,457 of the shares outstanding as of February 28, 2006;

- ·Up to 43,341,513 shares underlying our Convertible Secured Debentures due February 1, 2009 sold in a February and March 2006 private placement
- ·Up to 24,130,588 shares underlying warrants, including 4,500,000 shares underlying warrants issued in the Debenture private placement

All of the shares, when sold will be sold by the Selling Stockholders who may sell the shares of common stock from time to time at prevailing market prices. We will not receive any proceeds from the sales by the Selling Stockholders, but we will receive the benefit of a reduction of indebtedness from the conversion of the Debentures and the receipt of funds by the cash exercise of the warrants.

Our Common Stock is quoted on the Over The Counter Bulletin Board, which is commonly referred to as the "OTC Bulletin Board" maintained by various broker dealers, under the symbol ADXS.

No underwriter or person has been engaged to facilitate the sale of shares of Common Stock in this offering. None of the proceeds from the sale of the shares by the Selling Stockholders will be placed in escrow, trust or any similar account. There are no underwriting commissions involved in this offering. We have agreed to pay all the costs of this offering. Selling Stockholders will pay no offering expenses.

This offering is highly speculative and these securities involve a high degree of risk. You should purchase shares only if you can afford a complete loss. See "Risk Factors" beginning on page 8.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 13, 2006.

#### WHERE YOU CAN FIND MORE INFORMATION ABOUT US

We file reports, proxy statements, information statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy this information, for a copying fee, at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information in its public reference rooms. Our SEC filings are also available to the public from commercial document retrieval services, and at the web site maintained by the SEC at http://www.sec.gov.

We have not authorized anyone to give any information or make any representation about the 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.

THIS PROSPECTUS IS NOT AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

#### CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING INFORMATION

Certain information contained in this prospectus includes forward-looking statements (as defined in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act) that reflect the Company's current views with respect to future events and financial performance. Certain factors, such as unanticipated technological difficulties, the volatile and competitive biotechnological environment for products, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the degree of success, if any, in concluding business partnerships or licenses with viable pharmaceutical or biotechnological companies, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors" in this prospectus could cause actual results to differ materially from those in the forward-looking statements. We assume no obligation to update the matters discussed in this prospectus.

Please read this prospectus carefully. It describes our business, our financial condition and results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision.

#### PROSPECTUS SUMMARY

This summary highlights some 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 our company and the common stock being sold in this offering, including "Risk Factors" and our consolidated financial statements and related notes, included elsewhere in this prospectus.

#### General

We are a development stage biotechnology company utilizing multiple mechanisms of immunity with the intent to develop cancer vaccines that are more effective and safer than existing vaccines. To that end, we have licensed rights from the University of Pennsylvania ("Penn") to use a patented system to engineer a live attenuated Listeria monocytogenes bacteria (the "Listeria System") to secrete a protein sequence containing a tumor-specific antigen. Using the Listeria System, we believe we will force the body's immune system to process and recognize the antigen as if it were foreign, creating the immune response needed to attack the cancer. Our licensed Listeria System, developed at Penn over the past 10 years, provides a scientific basis for believing that this therapeutic approach induces a significant immune response to a tumor. Accordingly, we believe that the Listeria System is a broadly enabling platform technology that can be applied to many types of cancers. In addition, we believe there may be useful applications in infectious diseases and auto-immune disorders.

The therapeutic approach that comprises the Listeria System is based upon the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn, involving the creation of genetically engineered Listeria that stimulate the innate immune system and induce an antigen-specific immune response involving humoral and cellular components. We have obtained an exclusive 20-year license from Penn to exploit the Listeria System, subject to meeting various royalty and other obligations (the "Penn License").

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

<b>Product</b>	<b>Indication</b>	<u>Stage</u>
Lovaxin C	Cervical and head and neck cancers	Pre-clinical; Phase I study in cervical cancer anticipated to commence in early 2006*
Lovaxin B	Breast cancer and melanoma	Pre-clinical; Phase I study anticipated to commence in late 2006*
Lovaxin P	Prostate cancer	Pre-clinical; Phase I study anticipated to commence in early 2007
Lovaxin W	Wilms tumor and leukemia	Pre-clinical
Lovaxin T	Cancer through control of telomerase	Pre-clincial
Lovaxin H	Prophylactic vaccine for HIV (AIDS)	Pre-clincial

<sup>\*</sup> Possible delays of up to six months may occur based on the production schedule of Cobra Biomanufacturing PLC of material, vaccine stability testing and the issuance of required regulatory approval.

See "Business - Research and Development Programs".

Since our formation, we have had a history of losses, which as of January 31, 2006 aggregated \$3,878,685, and because of the long development period for new drugs, we expect to continue to incur losses for several years. Our

business plan to date has been realized by substantial outsourcing of virtually all major functions of drug development including scaling up for manufacturing, research and development, grant applications and others. The expenses of these outsourced services account for most of our accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or FDA approved. Even if one or more of our products becomes commercially viable and receives FDA approval, we are not certain that we will ever become a profitable business.

#### **Strategy**

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

- Initiate and complete Phase I clinical study of Lovaxin C;
- · Continue the pre-clinical development of our product candidates, as well as continue research to expand our technology platform; and
  - · Initiate strategic and development collaborations with biotechnology and pharmaceutical companies.

There are many potential obstacles to the implementation of our proposed strategy. Among the potential obstacles we may encounter with respect to the Phase I clinical study of Lovaxin C are: difficulty in recruiting patients for the study; a material, adverse medical result in a patient during the study; and extended time for FDA approval of the IND (or foreign regulatory authority approval) required to proceed with the test.

Among the potential obstacles which we may encounter with respect to continuing preclinical development of our product candidates such as Lovaxin B or T are ambiguous animal data not sufficient to establish a proof of concept; insufficient or adverse preclinical data on future products; and unexpected higher costs or preclinical studies.

Among the potential obstacles which we may encounter in establishing strategic collaborations are a possible perception by desirable potential partners that the stage of our development is too early, the need to demonstrate more human safety or efficiency data, or a possible perception that our technology is high risk for patients or to the environment.

#### **History of the Company**

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc., 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 of 1934 (the "Exchange Act"). Until November 2004, we were a shell company without any business. On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation ("Advaxis"), pursuant to a Share Exchange and Reorganization Agreement, dated as of August 25, 2004 (the "Share Exchange"), by and among Advaxis, the stockholders of Advaxis and us. As a result, 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. Our principal executive offices are located at Technology Center of New Jersey, 675 Route 1, Suite 119, North Brunswick, New Jersey 08902 and our telephone number is (732) 545-1590.

#### **Recent Developments**

In November 2004, we acquired 100% of the stock of Advaxis which was organized in 2002 to develop the Listeria System under patents licensed from Penn, which are described above under "General" and later in this prospectus under "Business."

Pursuant to the Share Exchange, (i) our existing stockholders entered into a Surrender and Cancellation Agreement whereby they contributed to us 199 shares of every 200 shares of common stock beneficially owned by them so that their ownership was reduced to 752,600 shares of common stock and (ii) we issued to them and others an aggregate of 16,350,323 shares of common stock, warrants to purchase 584,885 shares of common stock and options to purchase 2,381,525 shares of common stock. Upon the closing of the Share Exchange, the total number of shares of our common stock outstanding was 20,069,333 shares on a fully-diluted basis. The transaction is being accounted for as a recapitalization. The historical financial statements of Advaxis are our financial statements for reporting purposes.

On same date, we sold as the first tranche of a private placement offering (the "November 2004 Private Placement"), for \$2.925 million to accredited investors an aggregate of 10,191,636 shares of common stock and warrants to purchase 10,191,636 shares of common stock. The sale was made in units at a price of \$25,000 per unit with each consisting of 87,108 shares of common stock and warrants to purchase 87,108 shares of common stock at any time prior to the fifth anniversary following the date of issuance of the warrant, at a price equal to \$0.40 per share of common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. Also, in November 2004, we converted approximately \$618,000 aggregate principal of promissory notes and accrued interest outstanding into 2,153,310 shares and a like number of warrants.

On December 8, 2004, we completed a second tranche of the November 2004 Private Placement, whereby we sold for an aggregate price of \$200,000 eight units to accredited investors consisting of 696,864 shares of common stock and 696,864 warrants.

On January 4, 2005, we completed a third and final tranche of the November 2004 Private Placement, whereby we sold for an aggregate price of \$128,000 to accredited investors, 445,993 shares of common stock and a like number of warrants.

The aggregate proceeds from the November 2004 Private Placement was \$3,253,000.

Pursuant to the terms of an investment banking agreement, dated March 19, 2004, by and between us and Sunrise Securities, Corp. (the "Placement Agent"), we issued to the Placement Agent and its designees an aggregate of 2,283,445 shares of common stock and warrants to purchase up to an aggregate of 2,666,900 shares of common stock. The shares were issued as part consideration for the services of the Placement Agent, as our placement agent in the Private Placement. In addition, we paid the Placement Agent a total cash fee of \$50,530.

On January 12, 2005, we completed a second private sale whereby we sold for \$1,100,000 to a single investor 3,832,752 shares of common stock and five-year warrants to purchase 3,832,752 shares of our common stock at an exercise price of \$0.40 per share.

Pursuant to the terms of a certain Registration Rights Agreement, dated as of November 12, 2004 and as of January 12, 2005, with certain stockholders, we issued on June 9, 2005 an aggregate of 409,401 shares (the "Penalty Shares") to such stockholders.

On February 2, 2006, we sold to an investor our \$3,000,000 Debenture due February 1, 2009 convertible into shares of our common stock for \$2,760,000 after deducting a commission of \$240,000 and other placement fees of \$20,000 and issued warrants to purchase 4,500,000 shares of common stock. See "February 2006 Private Placement."

#### **Our Website**

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

#### SUMMARY CONSOLIDATED FINANCIAL DATA OF ADVAXIS

On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation through the Share Exchange. The transaction was accounted for as a recapitalization. The historical financial statements of Advaxis will be our financial statements for reporting purposes. Advaxis, Inc has changed its fiscal year to October 31st and as a result is providing herein its audited financial statements for the year ended December 31, 2003, the ten months ended October 31, 2004 and the year ended October 31, 2005.

The following condensed statement of operations data for the year ended December 31, 2003, the ten months ended October 31, 2004 and the year ended October 31, 2005 are derived from Advaxis' financial statements and the related notes, audited by Goldstein Golub Kessler LLP, Certified Public Accountants, 1185 Avenue of the Americas, Suite 500, New York, NY 10036-2602, Advaxis' independent registered public accounting firm. The financial statements and the related notes as of January 31, 2006 and October 31, 2005 and for the year ended December 31, 2003, the ten months ended October 31, 2004, year ended October 31, 2005, three months ended January 31, 2006 and three months ended January 31, 2005 are included elsewhere herein. The condensed unaudited statement of operations data for the ten months ended October 31, 2003, the year ended October 31, 2004, three months ended January 31, 2005 and three months ended January 31, 2006, are derived from Advaxis' unaudited financial statements, which have been prepared on a basis consistent with Advaxis' audited financial statements and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of Advaxis' financial position and results of operations. The results of operations for any interim period are not necessarily indicative of results to be expected for the entire year. The following data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	ear ended ecember 31,	Ten Mont Octob	 		Year Octol		3 Month Janua		
Statement of Operations Data:	2003	2003 unaudited)	2004	(u	2004 (maudited)	2005	2005 unaudited)	(u	2006 naudited)
Revenue	\$ 4,000 \$	3,600	\$ 116,406	\$	116,806	\$ 552,868 \$		\$	329,928
Total operating expenses Interest expense	\$ 897,076 \$	821,725	\$ 650,310	\$	715,754	\$ 2,395,328 \$	245,126	\$	798,990
(income)	\$ 17,190 \$	7,288	\$ 4,229	\$	13,132	\$ (36,671) \$	2,968	\$	1,008
Other income	\$ 521 \$	•	\$ 57		72	\$ \$		\$	11,931
Provision for income taxes									
Net loss Loss per Share	\$ (909,745) \$	(825,907)	\$ (538,076)	\$	(655,892)	\$ (1,805,789) \$	(245,355)	\$	(458,139)
Information:									
Basic and diluted									
net loss per share	\$ (0.06) \$	(0.05)	\$ (0.04)	\$	(0.04)	\$ (0.05) \$	(0.01)	\$	(0.01)

<b>Balance Sheet Data:</b>	December 31,	October 31,	October 31,	January 31
	2003	2004	2005	2006

Cash and cash equivalents	\$ 47,160 \$	32,279 \$	2,075,206 \$	1,805,640
Intangible assets	\$ 277,243 \$	469,803 \$	751,088 \$	765,245
Total assets	\$ 324,403 \$	502,083 \$	2,904,039 \$	2,646,651
Total liabilities	\$ 1,131,138 \$	1,841,579 \$	1,152,465 \$	1,188,155
Stockholders' equity (deficiency)	\$ (806,735) \$	(1,339,496) \$	1,751,575 \$	1,458,496

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#### THE OFFERING

Common stock offered by Selling Stockholders Common stock outstanding as of January 31, 2006

Use of proceeds

73,564,540<sup>(1)</sup>

\$.26

38,167,028 shares (2)

We will not receive any proceeds from the sale of the common stock, but we will receive funds from the exercise of warrants by selling

stockholders, if exercised for cash.

"OTC Bulletin Board Quote" as of March 2, 2006.

- (1) Represents 37,099,457 shares issued to Selling Stockholders, 24,130,588 shares which may be acquired upon exercise of warrants issued to Selling Stockholders, and 12,334,495 shares which may be acquired upon conversion of principal and interest on our Debentures issued to a Selling Stockholder in February 2006 at a fixed conversion price of \$0.287 per share. Such price is to be revised downward if the "market price" as defined is lower at time of conversion in which event the number of shares issued upon conversion will increase. Up to an additional 31,007,018 shares may be offered for resale by the Selling Stockholders pursuant to this Prospectus in the event the shares were acquired by the Selling Stockholders as a result of conversions or dividend payments at a price less than \$0.287 per share.
- (2) The number of shares of common stock outstanding as of January 31, 2006 listed above excludes, in addition to the shares offered.
- · 20,509,220 shares issuable upon exercise of the warrants with exercise prices ranging from \$0.1952 to \$0.40 per share;
  - · 5,959,078 additional shares of common stock issuable upon exercise of options;
    - · Commitments to issue stock, options or warrants.

#### ADDITIONAL INFORMATION

In this prospectus, the terms "we", "us", and "our" refer to Advaxis, Inc., a Colorado corporation, and its consolidated subsidiary, Advaxis, as appropriate in the context, and, unless the context otherwise requires, "common stock" refers to the common stock, par value \$0.001 per share, of Advaxis, Inc.

#### RISK FACTORS

An investment in the common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. 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 Specific to Us

#### We are a development stage company.

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

We have sustained losses from operations in each fiscal year since our inception and losses are expected to continue, due to the substantial investment in research and development, for the next several years. At January 31, 2006, we had an accumulated deficit of (\$3,922,869) and stockholders' equity of \$1,458,496. We expect to spend substantial additional sums on the continued research and development of proprietary products and technologies with no certainty that losses will not increase or that we will ever become profitable as a result of these expenditures.

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

Although we believe that the net proceeds received from private placements (i) in November 2004 of the Units of shares of our common stock and of our warrants, and (ii) in February 2006 of our \$3,000,000 Debenture will be sufficient to finance our currently planned operations for the near-term (approximately 12 to 24 months), such amounts will not be sufficient to meet our longer-term cash requirements or cash requirements for the commercialization of certain products currently in development. We will be required to find additional equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise substantial additional capital during the five to ten year period of product development and the United States Food and Drug Administration ("FDA") testing through Phase III testing. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. If we fail to raise sufficient additional financing we will not be able to develop our product candidates, we will be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates and outsource or eliminate several business functions. Even if we are successful in raising such additional financing, we may not be able to successfully complete planned clinical trials, development, and marketing of all, or of any, of our product candidates. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products, and cease to operate. We may not be able to conduct clinical trial in Lovaxin C. See "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations".

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

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

competition from companies that have substantially greater assets and financial resources than we have;

need for acceptance of products;

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

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

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

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

#### Our research and development expenses are subject to uncertainty.

Factors affecting our research and development (or R&D) expenses include, but are not limited to:

- •The number of and the outcome of clinical studies we are planning to conduct. For example, our R&D expenses may increase based on the number of late-stage clinical studies which we may be required to conduct;
- •The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us. Some promising candidates may not yield sufficiently positive pre-clinical results to meet our stringent development criteria;

- ·In-licensing activities, including the timing and amount of related development funding or milestone payments. For example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process research and development which we may record as an R&D expense;
- ·As part of our strategy, we invest in R&D. R&D as a percent of future potential revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more limited spending on R&D efforts; and

Future levels of revenue.

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

We must outsource our clinical trials and are in the process of negotiating with third parties to conduct such trials. There is no assurance that we will successfully conclude agreements for the conduct of our clinical trials. Delay in concluding such agreements would delay the commencement of the Phase 1 Trial of Lovaxin C.

Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize Lovaxin C.

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

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

#### The successful development of biopharmaceuticals is highly uncertain.

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

·Pre-clinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

- ·Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or BLA preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data, or unexpected safety or manufacturing issues.
- · Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical; and
- •The proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

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

#### We must comply with significant government regulations.

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

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

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

We received in February 2006 permission from the appropriate governmental agencies in Israel, Mexico and Belgrade to conduct in those countries Phase I clinical testing of Lovaxin C, our Listeria based cancer vaccine which targets cervical cancer in women. However, the testing, marketing and manufacturing of any product for sale or distribution in the United States will require the approval of the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval or further approval, if any, from Israel, Mexico or Belgrade and whether any such approval will ultimately be granted. Pre-clinical and clinical trials may reveal that one or more products is ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated.

Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from governmental authorities outside of the United States which perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist. See "Business - Governmental Regulation".

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

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the Listeria System, and the proprietary technology of others with which we have entered into licensing agreements. We have licensed eight patents and 12 patent applications from Penn. Further, we rely on a combination of trade secrets and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking right.

We believe that our technology and the technology licensed from Penn do not infringe the rights of others; however, we cannot assure you that the technology licensed from Penn will not, in the future be found to infringe upon the rights of others. We have become aware of a public company, Cerus Corporation, which has issued a press release claiming to have a proprietary Listeria-based approach to a cancer vaccine. We believe that through our exclusive license with Penn of U.S. Patent Nos. 5,830,702, 6,051,237 and 6,565,852, we have the earliest known and dominant patent position for the use of recombinant Listeria monocytogenes expressing proteins or tumor antigens as a vaccine for the treatment of infectious diseases and tumors. Based on searches of publicly available databases, we do not believe that Cerus or The University of California Berkeley (which is where Cerus' consulting scientist works) or any other third party owns any published Listeria patents or has any issued patent claims that might materially negatively affect our freedom to operate our business (as currently contemplated to be operated) in the field of Listeria monocytogenes. We had received written notice from the European Patent Office that Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent) which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. We are defending against Cerus' allegations in the Opposition that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live Listeria, is deficient because of (i) insufficient disclosure in the specifications of the granted claims, (ii) the inclusion of additional subject matter in the granted claims, and (iii) a lack of inventive steps of the granted claims of the EP 835 Patent. We believe that Cerus'allegations in the opposition have no basis and we plan to vigorously defend the claims.

The opposition is in the early stages and, as yet, we are unable to evaluate the merits, if any, to the opposition proceeding. If the European Patent Office rules that the allegations are correct in whole or in part, and such ruling is upheld on appeal, our patent position in Europe may be eroded to the degree that the claims of the patent are narrowed or not allowed. The likely result of this decision will be increased competition for us in the European market for recombinant live Listeria based vaccines. Regardless of the outcome of the opposition proceeding, we believe that our freedom to operate in Europe, or any other territory, for recombinant live Listeria based vaccine products will not be diminished.

For more information about Cerus Corporation and its claims with respect to listeria-based technology, you should visit their web site at <a href="www.cerus.com">www.cerus.com</a> or to view its publicly filed documents, <a href="www.sec.gov">www.sec.gov</a>. Others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology or the licensed technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of our intellectual property, enter into royalty agreements or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on acceptable terms, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking right. See "Business—Patents and Licenses".

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

The manufacture and sale of any products developed by us will involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained licenses with regard to the use of Penn's patents as described herein and certain of such processes, products and information of others, we can provide no assurance that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights which may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in product development and introduction or preclude the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future. Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. Furthermore, we call to your attention that in 2001 an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642 of Penn. These patent rights are included in the patent rights licensed by us from Penn. It is contemplated by GlaxoSmithKline Biologicals PLC ("GSK"), Penn and us that the issue will be resolved through: (1) a correction of inventorship to add certain GSK inventors, (2) where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and (3) a sublicense from us to GSK. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above. See "Business - Patents and Licenses". To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. See "Business - Corporate Partnerships and Agreements".

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

We do not intend to create facilities to manufacture our products and therefore are dependent upon third parties to do so. We currently have an exclusive Long Term Vaccine Supply Agreement with Cobra Manufacturing for the manufacture and supply of large quantities of our vaccines for trial and commercial purposes, but subject to possible future price fluctuation and termination by either party upon notice. Our reliance on third parties for the manufacture of our products creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to replace the development of our product candidates, including the clinical testing program, and therefore it could not go forward and our entire business plan could fail.

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

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

Management of our relationships with our collaborators will require:

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

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

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

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

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

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

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

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

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

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

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

At the date of this prospectus, we have three employees. We intend to expand our operations and staff materially. Our new employees will include a number of key managerial, technical, financial, research and development and operations personnel who will not have been fully integrated into our operations. We expect the expansion of our business to place a significant strain on our limited managerial, operational and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train and manage our work force

in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials of Lovaxin C and other products, and unable to adequately address the management needs of the Company. See "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations", "Business - Strategy", and "Business--Employees."

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

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

#### Risks Related to the Biotechnology / Biopharmaceutical Industry

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

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

We are aware of certain products under development or manufactured by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for product development. Various companies are developing biopharmaceutical products that potentially directly compete with our product candidates even though their approach to such treatment is different. Several companies, such as Cerus Corporation, in particular, Dandreon Corporation and CancerVax Corporation, are attempting to develop cancer vaccines which would be directly competitive with our product candidates. In addition, numerous other companies, many of which have greater financial resources than we do, are actively engaged in the research and development of cancer vaccines, and are in Stage II and Stage III Testing of such products. Such companies include: Antigenics, Inc.; Avi BioPharma, Inc.; Biomira, Inc.; GlaxoSmithKline Biologicals PLC; Dendreon Corporation; Epimmune, Inc.; Genzyme Corp.; Progenics Pharmaceuticals, Inc.; Vical Incorporated; CancerVax Corporation; Genitope Corporation; and Xcyte Therapies, Inc.

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

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

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

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

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

### If additional authorized shares of our common stock available for issuance or shares eligible for future sale were introduced into the market, it could hurt our stock price.

We are authorized to issue 500,000,000 shares of common stock. As of January 31, 2006, there were an aggregate of 38,167,028 shares of our common stock issued and outstanding. In addition, 5,959,078 shares of our common stock may be issued upon the exercise of currently outstanding stock options and 20,509,220 shares of common stock may be issued upon the exercise of current outstanding warrants. There are also at least 16,834,495 shares of our common stock issuable upon conversion of the principal and payment of interest on our 6% Secured Convertible Debentures due February 1, 2009 (a minimum of 12,334,495 shares at the Fixed Conversion Price of \$0.287 per share and 4,500,000 shares issuable upon exercise of Warrants issued to Cornell Capital LP ("Cornell"). Conversion and payment effected at a lower conversion price is permitted if the Market Conversion Price as defined (see "February 2006 Private Placement") is less than the Fixed Conversion Price, and will result in the issuance of a greater number of shares upon conversion and payment. Of the shares which may be issued upon conversion, payment and exercise, a total of 47,841,513 shares are registered based on an assumed conversion price of \$.0956 per share pursuant to the Registration Statement of which this prospectus is a part under the Securities Act of 1933, as amended, for reoffering after conversion, payment or exercise. Conversion at a lower price will result in additional shares being issued.

The following table sets forth the number of shares of our common stock issued and available for resale pursuant to the prospectus by Cornell if conversion was at the Fixed Conversion Price of \$0.287 or at assumed Market Conversion Prices of \$0.25, \$0.20, \$0.15, and \$0.10 respectively

Conversion Price	Number of Shares Issuable on Conversion of Debentures	Percentage of Issued and Outstanding (1)
\$0.287	10,452,961	21.5%
\$0.25	12,000,000	23.9%
\$0.20	15,000,000	28.2%
\$0.15	20,000,000	34.4%
\$0.10	30,000,000	44.2%

(1) Assumes 38,167,028 shares outstanding immediately prior to conversion.

However, Cornell has agreed that conversions, payments and exercises will not result in its holdings and those of its affiliates of shares of our common stock amounting at the time of each conversion payment or exercise into more than 4.9% of our outstanding shares of common stock.

We have also registered for reoffering: 36,690,056 outstanding shares of common stock and 19,630,588 shares which may be acquired upon exercise of certain other options and warrants. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of the common stock in the public market by these holders or perceptions that such sales may take place may lower the common stock's market price.

The Company must account for certain derivative instruments issued on its common stock as liabilities.

The Company has outstanding debentures convertible into a variable number of common shares. In accordance with the provisions of EITF OO-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the existence of a variable share settled instrument will require the Company to account for outstanding warrants as well as warrants issued in the future as liabilities at fair value, with changes in fair value recorded in operations each period.

#### Our common stock is considered to be "penny stock".

Our common stock may be deemed to be "penny stock" as that term is defined in Rule 3a51-1, promulgated under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). Penny stocks are stocks:

with a price of less than \$5.00 per share;

that are not traded on a "recognized" national exchange;

whose prices are not quoted on the NASDAQ automated quotation system; or

•of issuers with net tangible assets less than \$2,000,000 (if the issuer has been in continuous operation for at least three years) or \$5,000,000 (if in continuous operation for less than three years), or with average revenue of less than \$6,000,000 for the last three years.

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

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

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

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

# We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the SEC and by the Nasdaq Stock Market, will result in increased costs to us as we evaluate the implications of these laws and regulations and respond to their requirements. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy

limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers. We are continuously evaluating and monitoring developments with respect to these laws and regulations and cannot predict or estimate the amount or timing of additional costs we may incur to respond to their requirements.

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

Our common stock is quoted on the OTC Bulletin Board under the symbol ADXS. The quotation of our common stock on the OTC Bulleting 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 shareholders could suffer losses or be unable to liquidate their holdings.