

Advaxis, Inc.  
Form SB-2/A  
June 09, 2005

As filed with the Securities and Exchange Commission on June 9, 2005.

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

**AMENDMENT NO. 4 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.)

**212 Carnegie Center  
Suite 206  
Princeton, NJ 08540  
(609) 895-7150**  
(Address, including zip code, and telephone number, including area code, of registrant's principal place of business)

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**Mr. Todd Derbin, Chief Executive Officer**

**212 Carnegie Center  
Suite 206  
Princeton, NJ 08540  
(609) 895-7150**  
(Name, address, including zip code, and telephone number, including area code, of registrant's agent for service)

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*Copies to:*

**Gary A. Schonwald, Esq.**

**Reitler Brown & Rosenblatt LLC**  
**800 Third Avenue**  
**21<sup>st</sup> 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 any of the Securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, 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 of 1933, check the following box and list the Securities Act of 1933 registration statement number of the earlier effective registration statement for the same offering:

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

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**CALCULATION OF REGISTRATION FEE**

<b><u>Title of each class of securities to be registered</u></b>	<b><u>Amount to be Registered</u></b> <sup>(1)</sup>	<b><u>Proposed maximum offering price per unit</u></b> <sup>(2)</sup>	<b><u>Proposed maximum aggregate offering price</u></b> <sup>(2)</sup>	<b><u>Amount of registration fee</u></b>
common stock par value \$0.001 per share <sup>(3)</sup>	37,099,457	\$1.00	\$4,366.61	\$4,366.61
common stock par value \$0.001 per share <sup>(4)</sup>	19,630,588	\$1.00	\$2,310.52	\$2,310.52

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.

- (1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of shares that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions as well as anti-dilution provisions applicable to shares underlying the warrants.
- (2) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee.
- (3) Represents shares of the Registrant's common stock being registered for resale that have been issued to the selling stockholders named in the prospectus or a prospectus supplement.
- (4) Represents shares of the Registrant's common stock being registered for resale that have been or may be acquired upon the exercise of warrants issued to the selling stockholders named in the prospectus or a prospectus supplement.

Subject to completion  
Dated June 9, 2005

PRELIMINARY PROSPECTUS

**56,730,045 Shares**

**Advaxis, Inc.**

This prospectus relates to the resale of up to 36,690,056 shares of common stock and 19,630,588 shares of common stock underlying warrants of Advaxis, Inc. by certain selling stockholders identified in this prospectus. This prospectus also relates to the resale of 409,401 shares of common stock (representing penalty shares issuable to certain selling stockholders). All of the shares, when sold will be sold by these selling stockholders. The selling stockholders may sell their 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 funds from the exercise of warrants held by selling stockholders, if exercised and if payment is made by means other than cashless exercise.

We have applied for our common stock to be quoted on the Over The Counter Bulletin Board, which is commonly referred to as the "OTC Bulletin Board" maintained by various broker dealers. There is no "public market" for shares of our common stock.

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 common stock 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 9.**

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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 \_\_\_\_\_, 2005.

<p>The information in this prospectus is not complete and may be changed without notice. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.</p>
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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.

You should rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell shares of our common stock and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of the prospectus, regardless of the time the prospectus is delivered or the common stock is sold.

## 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, melanoma, ovarian, lung and other cancers. Our lead products in development are as follows:

<b><u>Product</u></b>	<b><u>Indication</u></b>	<b><u>Stage</u></b>
Lovaxin C	Cervical and head and neck cancers	Pre-clinical; Phase I study in cervical cancer anticipated to commence in the first half of 2005*
Lovaxin B	Breast cancer and melanoma	Pre-clinical; Phase I study anticipated to commence in 2006

Lovaxin NY	Ovarian, melanoma and lung cancer	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin W	Wilms tumor and leukemia	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin T	Cancer through control of telomerase	Pre-clinical
Lovaxin H	Prophylactic vaccine for HIV (AIDS)	Pre-clinical

\* Possible delays of up to three months may occur based on the production schedule of Cobra Biomanufacturing PLC of material, the length of time for Pharm Olam to complete toxicology studies 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, 2005 aggregate (\$1,903,996), 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: we may be perceived by desirable potential partners as too early stage; we may need to demonstrate more human safety or



efficacy data; or our technology may be perceived as high risk for patients or to the environment.

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## History of the Company

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were administratively dissolved January 1, 1997 and reinstated 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"), through 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 of such acquisition, Advaxis become our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. Our principal executive offices are located at 212 Carnegie Center, Suite 206, Princeton, NJ 08540 and our telephone number is (609) 895-7150.

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## Recent Developments

In November 2004, we acquired 100% of the stock of Advaxis. Advaxis 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."

The acquisition of Advaxis was pursuant to the Share Exchange. In connection with the Share Exchange (i) our existing stockholders entered into a Surrender and Cancellation Agreement whereby such stockholders 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 the existing stockholders of Advaxis and others 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 November 12, 2004, we completed an initial closing of a private placement offering (the "Private Placement"), whereby we sold an aggregate of \$2.925 million worth of units to accredited investors. Each unit was sold for \$25,000 (the "Unit Price") and consisted of (a) 87,108 shares of common stock and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, 87,108 shares of common stock included at a price equal to \$0.40 per share of common stock (a "Unit"). 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 Units.

On December 8, 2004, we completed a second closing of the Private Placement, whereby we sold an aggregate of \$200,000 of Units to accredited investors.

On January 4, 2005, we completed a third and final closing of the Private Placement, whereby we sold an aggregate of \$128,000 of Units to accredited investors.

The aggregate sale of the Units in the Private Placement was \$3,253,000.

Pursuant to the terms of a 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.

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On January 12, 2005, we completed a second private sale of Units whereby we sold an aggregate of \$1,100,000 of Units to a single investor. As with the Private Placement, each Unit issued and sold in this subsequent private placement was sold at \$25,000 per Unit and is comprised of (i) 87,108 shares of our common stock, and (ii) a five-year warrant to purchase 87,108 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, by and among us and certain of our stockholders and a Registration Rights Agreement, dated as of January 12, 2005, by and between us and one of our stockholders, we are obligated to issue shares of our common stock to certain stockholders on a monthly basis if this registration statement is not declared effective by a certain date. As of May 10, 2005, we were obligated to issue an aggregate of 409,401 shares (the "*Penalty Shares*") to such stockholders.

Our auditors, in their report on our financial statements as of December 31, 2002 and 2003, indicated that the Company has incurred losses from operations, has a working capital deficiency, and a shareholder's deficiency, which raise substantial doubt about the Company's ability to continue as a going concern. Subsequent to the issuance of those financial statements the Company has raised additional equity financing in the Private Placement and intends to raise additional funds. As a result of raising such funds our ability to continue as a going concern is no longer an issue for our accountants. See further discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations - Liquidity and Capital Resources".

#### **Our Website**

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.

**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 31<sup>st</sup> and as a result is providing herein its audited financial statements for the years ended December 31, 2002 and 2003 and for the ten months ended October 31, 2004.

The following condensed statement of operations data for the period from March 1, 2002 (inception) to December 31, 2002, the year ended December 31, 2003, the ten months ended October 31, 2004 and the selected balance sheet data at December 31, 2002 and 2003, and at October 31, 2004 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 December 31, 2002 and 2003 and for period ended December 31, 2002, the year ended December 31, and 2003 and the ten months ended October 31, 2004 are included elsewhere herein. The selected unaudited statement of operations data for the ten months ended October 31, 2003, and the unaudited selected statement of operations data for the three months ended January 31, 2004 and 2005, and the unaudited consolidated selected balance sheet data at January 31, 2005, 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.

	<b>Period from March 1, 2002 (inception) to December 31,</b>	<b>Year ended December 31,</b>	<b>Ten Months Ended October 31,</b>	<b>Three Months Ended January 31, (unaudited)</b>		
<b>Statement of Operations Data:</b>	<b>2002</b>	<b>2003</b>	<b>Unaudited 2003</b>	<b>2004</b>	<b>2004</b>	<b>2005</b>
Income		\$ 4,000	\$ 3,600	\$ 116,406	\$ 400	
Total operating expenses	\$ 167,902	\$ 897,076	821,725	650,310	\$ 132,241	\$ 245,126
Interest expense (income)	--	17,190	7288	4229	10,655	2,968
Other income	966	521	106	56	(30)	(2,739)
Provision for income taxes	--	--	--	--	--	--
Net loss	\$ (166,936)	\$ (909,745)	(825,907)	(538,076)	\$ (142,466)	\$ (245,355)
<b>Loss per Share Information:</b>						
Basic and diluted net loss per share	\$ (0.01)	\$ (0.05)	\$ (0.05)	\$ (0.04)	\$ (0.01)	\$ (0.01)

October 31

<b>Balance Sheet Data:</b>	<b>December 31, 2002</b>	<b>December 31, 2003</b>	<b>2004</b>	<b>January 31, (unaudited) 2005</b>
Cash and cash equivalents	\$ 204,382	\$ 47,160	\$ 32,279	\$ 3,217,430
Intangible assets	--	\$ 277,243	\$ 469,803	\$ 666,447
<b>Total assets</b>	<b>\$ 204,382</b>	<b>\$ 324,403</b>	<b>\$ 502,083</b>	<b>\$ 3,886,327</b>
Total liabilities	\$ 125,825	\$ 1,131,138	\$ 1,841,579	\$ 923,517
Stockholders' equity (deficiency)	78,557	(806,735)	\$ (1,339,496)	2,962,810

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## THE OFFERING

Common stock offered by selling stockholders	56,730,045 <sup>(1)</sup>
Common stock outstanding	36,690,056 <sup>(2)</sup>
Use of proceeds	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”	None

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(1) Represents 36,690,056 shares of common stock that were issued to selling stockholders and 19,630,588 shares of common stock underlying warrants that were issued to selling stockholders and 409,401 shares of common stock issuable to certain selling stockholders as Penalty Shares.

(2) The number of shares of common stock outstanding as of January 31, 2005 listed above excludes

- 2,182,894 shares of common stock issuable upon exercise of options;
- 20,302,582 shares of common stock issuable upon exercise of warrants with exercise prices ranging from \$0.1952 to \$0.40 per share;
- 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, 2005, we had an accumulated deficit of \$1,903,996 and stockholders' equity of \$2,962,810. 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 the sale of Units 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 issue 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 Lovaxin 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. We are not certain 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.**

The testing, marketing and manufacturing of any product will require the approval of the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical 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. 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. For more information about Cerus Corporation and its claims with respect to listeria-based technology, you should visit their web site at [www.cerus.com](http://www.cerus.com) or to view its publicly filed documents, [www.sec.gov](http://www.sec.gov). 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". 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 or 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 agreement with Cobra Manufacturing for production of our vaccines in small quantities for research and development purposes. We are negotiating with Cobra to produce large quantities of our vaccines for trials purposes, but no definitive agreement has been reached with them. 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 prove 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, 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 preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

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

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

- decreased demand for our product candidates,
  - 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 developing 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.; Corixa Corporation; 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 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 March 31, 2005, there were an aggregate of 59,374,162 shares of our common stock issued and outstanding on a fully diluted basis. In addition, 2,341,198 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. 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.

Currently, holders of 15,597,723 shares of our common stock are subject to a standstill agreement. Pursuant to the standstill agreement, such holders agree not to effect any sale, transfer or distribution of his, her or its equity securities in us, or any securities convertible into or exchangeable or exercisable for such securities, during the period from the November 12, 2004 until the earlier of (i) the date that this registration statement has been filed with and declared effective by the Securities and Exchange Commission (“SEC”) and (ii) the first year anniversary of the Private Placement, unless (a) such sale, transfer or distribution is approved in writing by a majority of the investors in the Private Placement, and (b) the transferee of such sold, transferred or distributed securities agrees in writing to be bound by the terms of the standstill agreement to the same extent as if they had originally been a party hereto.

**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 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 presently 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.**

We have applied to have our common stock quoted on the OTC Bulletin Board. 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 shareholders could suffer losses or be unable to liquidate their holdings.

**There is no assurance of an established public trading market.**

A regular trading market for our common stock may not be established or sustained in the future. The NASD has enacted recent changes that limit quotation on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the SEC. 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 are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTC Bulletin Board may be difficult to obtain and holders of 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;
- Changes in interest rates;
- 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 have applied to have our common stock quoted on the OTC Bulletin Board. In addition we are subject to a covenant to use our best efforts to apply to be listed on the American Stock Exchange or quoted on the Nasdaq National Stock Market. We cannot assure you that we will be successful in obtaining approval for such applications.

**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 approved for trading on the Nasdaq National Market or 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 United States in addition to federal securities law. This regulation covers any primary offering we might attempt and all secondary trading by our stockholders. While we intend to take appropriate steps to register our common stock or qualify for exemptions for our common stock, in all of the states and jurisdictions of the United States, if we fail to do so 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.

**Our executive officers, directors and principal stockholders control our business and may make decisions that are not in our best interests.**

Our officers, directors and principal stockholders, and their affiliates, in the aggregate, beneficially own approximately 63.79% of the outstanding shares of our common stock on a fully diluted basis. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in 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.**

The Selling Stockholders hereunder have the right to register securities for resale that they hold pursuant to registration rights agreements. We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights; provided, that the Selling Stockholders consent to such registration rights. 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, any new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

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

We are authorized to issue 500,000,000 shares of our common stock. As of January 31, 2005, we had 36,690,056 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants and options. As of January 31, 2005, we had outstanding 2,182,894 options to purchase shares of our common stock at a weighted exercise price of \$0.40 per share and outstanding warrants to purchase 20,302,582 shares of our common stock, with exercise prices ranging from \$0.1952 to \$0.40 per share. Pursuant to our 2004 Stock Option Plan, 2,381,525 shares of common stock are reserved for issuance under the plan. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution.

**Shares eligible for future sale may adversely affect the market.**

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 (“Rule 144”) promulgated under the Securities Act of 1933, as amended (the “Securities Act of 1933”), subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

Holders of 17,734,165 shares of our common stock and 2,808,434 shares of our common stock underlying exercisable warrants are subject to a standstill agreement. Pursuant to the standstill agreement, such holders agree not to effect any sale, transfer or distribution of his, her or its equity securities in us, or any securities convertible into or exchangeable or exercisable for such securities, during the period from the November 12, 2004 until the earlier of (i) the date that this registration statement has been filed with and declared effective by the SEC and (ii) the first year anniversary of the Private Placement, unless (a) such sale, transfer or distribution is approved in writing by a majority of the investors in the Private Placement, and (b) the transferee of such sold, transferred or distributed securities agrees in writing to be bound by the terms of the standstill agreement to the same extent as if they had originally been a party hereto.

An aggregate of 56,730,045 shares of common stock are being registered with the SEC in the registration statement of which this prospectus forms a part (which amount includes the Penalty Shares). These shares would otherwise be eligible for future sale under Rule 144 after passage of the minimum one year holding period for holders who are not officers, directors or affiliates of the Company. The registration and subsequent sales of such shares of common stock will likely have an adverse effect on the market price of our common stock when it commences to trade.

**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 Articles of Incorporation provide for the authorization of 5,000,000 shares of “blank check” preferred stock. Pursuant to our Articles 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.

**We do not intend to pay dividends.**

We have never declared or paid any dividends on our securities. We currently intend to retain our earnings for funding growth and, therefore, do not expect to pay any dividends in the foreseeable future.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

- Our limited operating history and ability to continue as a going concern;
- Our ability to successfully develop and commercialize products based on our therapies and the Listeria System;
- A lengthy approval process and the uncertainty of FDA and other government regulatory requirements may have a material adverse effect on our ability to commercialize our applications;
- Clinical trials may fail to demonstrate the safety and effectiveness of our applications or therapies, which could have a material adverse effect on our ability to obtain government regulatory approval;
- The degree and nature of our competition;
- Our ability to employ and retain qualified employees; and

- The other factors referenced in this prospectus, including, without limitation, under the section entitled “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations”, and 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 to 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 sale of the shares of common stock by the selling stockholders, but we will receive funds from the exercise of warrants held by selling stockholders, if exercised for cash.

### **MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS**

Prior to March 31, 2005, there is no record of any quotes in the Pink Sheets or OTC Bulletin Board and according to our records no public sales of our securities have occurred.

At March 31, 2005, there were approximately 84 holders of our common stock.

### **DIVIDEND POLICY**

We have not declared nor paid any cash dividend on our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and we do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our Board of Directors, in their discretion, and will depend on our financial condition, operating results, capital requirements and other factors that our Board of Directors considers significant.

### **DILUTION**

We are only registering shares of common stock already outstanding and held by selling stockholders under this prospectus. As such, purchasers of shares of common stock sold under this prospectus shall not experience any immediate dilution as a result of or upon such purchase. Upon issuance of the Penalty Shares, our outstanding shares increased by 1.01%, reducing our book value per share (as of January 31, 2005) by \$0.00089, and keeping it at \$0.08 per share.

**CAPITALIZATION**

The following table sets forth as of January 31, 2005, our actual capitalization. This table should be read in conjunction with the information contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations” and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

	Actual (Unaudited)
Long-term debt	\$ 230,000
Stockholders’ equity (deficit):	
Common stock	36,690
Additional paid in capital	4,830,116
Deferred compensation	-----
Retained earnings (deficit)	(\$1,903,996)
Total stockholders equity	\$ 2,962,810
<b>Total capitalization</b>	<b>\$ 3,192,810*</b>

\* Not including short term payables.



**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 recapitalization. Accordingly, the historical financial statements of Advaxis will be our financial statements for reporting purposes. Advaxis, Inc has changed its fiscal year to October 31<sup>st</sup> and as a result is providing herein its audited financial statements for the years ended December 31, 2002 and 2003 and for the ten months ended October 31, 2004.

The following condensed statement of operations data for the period from March 1, 2002 (inception) to December 31, 2002, the year ended December 31, 2003, the ten months ended October 31, 2004 and the selected balance sheet data at December 31, 2002 and 2003, and at October 31, 2004 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 December 31, 2002 and 2003 and for periods ended December 31, 2002 and 2003 and the ten months ended October 31, 2004 are included elsewhere herein. The selected unaudited statement of operations data for the ten months ended October 31, 2003, and the unaudited selected statement of operations data for the three months ended January 31, 2004 and 2005, and the unaudited consolidated selected balance sheet data at January 31, 2005, 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.

	<b>Period from March 1, 2002 (inception) to December 31,</b>	<b>Year ended December 31,</b>	<b>Ten Months Ended October 31,</b>	<b>Three Months Ended January 31, (unaudited)</b>		
<b>Statement of Operations Data:</b>	<b>2002</b>	<b>2003</b>	<b>Unaudited 2003</b>	<b>2004</b>	<b>2004</b>	<b>2005</b>
Income		\$ 4,000	\$ 3,600	\$ 116,406	\$ 400	
Total operating expenses	\$ 167,902	\$ 897,076	821,725	650,310	\$ 132,241	\$ 245,126
Interest expense (income)	--	17,190	7,288	4,229	10,655	2,968
Other income	966	521	506	56	(430)	(2,739)
Provision for income taxes	--	--	--	--	--	--
Net loss	\$ (166,936)	\$ (909,745)	(825,907)	(538,076)	\$ (142,466)	\$ (245,355)
<b>Loss per Share Information:</b>						

Basic and diluted net loss per share           \$       (0.01) \$       (0.05) \$       (0.05) \$       (0.04) \$       (0.01) \$       (0.01)

	<b>December 31,</b>	<b>December 31,</b>	<b>October 31</b>	<b>January 31, (unaudited)</b>
<b>Balance Sheet Data:</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
Cash and cash equivalents	\$ 204,382	\$ 47,160	\$ 32,279	\$ 3,217,430
Intangible assets	--	\$ 277,243	\$ 469,803	\$ 666,447
Total assets	\$ 204,382	\$ 324,403	\$ 502,083	\$ 3,886,327
Total liabilities	\$ 125,825	\$ 1,131,138	\$ 1,841,579	\$ 923,517
Stockholders' equity (deficiency)	78,557	(806,735)	\$ (1,339,496)	2,962,810

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

*This Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations and other portions of this prospectus contain forward-looking information that involve 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 Condition and Results of Operations and Plan of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus.*

### **Overview**

We are a biotechnology company utilizing multiple mechanisms of immunity with the intent to develop cancer vaccines that are more effective and safer than existing vaccines. We believe that by using our licensed Listeria System to engineer a live attenuated Listeria monocytogenes bacteria to secrete a protein sequence containing a tumor-specific antigen, 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. The 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 the tumor. Accordingly, we believe that the Listeria System is a broadly enabling platform technology that can be applied in many cancers, infectious diseases and auto-immune disorders.

Our therapeutic approach is based upon, and we have obtained an exclusive license with respect to, 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 focused our initial development efforts on six lead compounds and anticipate commencing a Phase I clinical study of Lovaxin C, a potential cervical and neck cancer vaccine, in the first quarter of 2005. See "Business - Research and Development Program".

We were originally incorporated in the state of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were administratively dissolved January 1, 1997 and reinstated 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 in November 2004 without any business. On November 12, 2004, we acquired Advaxis through the Share Exchange, as a result of which Advaxis became our wholly-owned subsidiary and our sole operating company. For financial reporting purposes, we have treated the Share Exchange as a recapitalization. As a result of the foregoing as well as the fact that the Share Exchange is treated as a recapitalization of Advaxis rather than as a business combination, the historical financial statements of Advaxis became our historical financial statements after the Share Exchange.

On November 12, 2004, December 8, 2004 and January 4, 2005, we closed a private offering of an aggregate of 11,334,495 shares of our common stock and warrants to purchase an aggregate of 11,334,495 shares of our common stock resulting in aggregate net proceeds of approximately \$3,253,000. Such offering was solely to "accredited investors", as defined in Rule 501(a) of Regulation D under the Securities Act of 1933, through the Placement Agent. See "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations - Liquidity and Capital Resources".



On November 12, 2004 we converted \$595,000 of aggregate principal promissory notes plus accrued interest outstanding into an aggregate of 2,136,441 shares of our common stock and warrants to purchase 2,223,549 shares of our common stock.

On January 12, 2005, we closed a private offering of 3,832,753 shares of our common stock and warrants to purchase 3,832,753 shares of our common stock resulting in aggregate net proceeds of approximately \$1,100,000. Such offering was to a single "accredited investor", as defined in Rule 501(a) of Regulation D under the Securities Act of 1933. See "Management's Discussion and Analysis of Financial Condition and Results of Operations and Plan of Operations - Liquidity and Capital Resources".

To date we have been in the development stage. During the year ended December 31, 2003, the ten months ended October 31, 2004 and the three months ended January 31, 2005, we had no customers and focused our efforts on research and development related to our product candidates, capital raising and formation, and activities relating to the Share Exchange. During these periods, our net loss was \$909,745 and \$245,355, respectively. As of December 31, 2003, October 31, 2004 and January 31, 2005, we had a working capital (deficit) of (\$997,184), (\$1,396,062) and \$2,523,913, respectively and an accumulated deficit of \$1,076,861, \$1,658,641 and 1,903,996, respectively.

### **Plan of Operations**

We intend to use the proceeds of the Private Placement closed on November 12, 2004, December 8, 2004 and January 4, 2005 and the proceeds of the offering closed on January 12, 2005 to conduct a Phase I clinical trial in cervical cancer using Lovaxin C, one of our lead product candidates in development using our Listeria System. We intend to expand our research and development team and further the development of the product candidates. We also intend to deploy a portion of the funds in expanding our manufacturing capabilities and in strategic activities. Our corporate staff will be responsible for the general and administrative activities.

During the next 12 to 24 months, we anticipate that our strategic focus will be to achieve several objectives. Our foremost objectives are as follows and are further described under "Business - Strategy":

- Initiate and complete phase I clinical study of Lovaxin C;
- Continue pre-clinical development of our products;
- Continue research to expand our technology platform.

### **Accounting Policies; Impact of Growth**

Below is a brief description of basic accounting principles which we have adopted in determining our recognition of expenses, as well as a brief description of the effects that our management believes that our anticipated growth will have on our revenues and expenses in the future 12 months.

*Revenues.* We do not anticipate that we will record any material revenues during at least the year ending December 31, 2005. When we recognize revenues, we anticipate that the revenue sources will be principally comprised of grants and licensing fees.

*Expenses.* We recorded operating expenses for the year ended December 31, 2003 and the ten months ended October 31, 2004 of \$897,076 and \$650,310, respectively.

The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, based on historical experience and on various other assumptions that we believe to

be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policy involves significant estimate and judgment. We amortize trademark and patent costs over their estimated useful lives. We may be required to adjust these lives based on advances in science and competitor actions. We review the recorded amounts of trademarks and patents at each period end to determine if their carrying amount is still recoverable based on expectations regarding potential licensing of the intangibles or sales of related products. Such an assessment, in the future, may result in a conclusion that the assets are impaired, with a corresponding charge against earnings.

Due to the limited nature of our operations, we do not identify any other accounting policies involving estimates or assumptions that are material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and where the impact of the estimates and assumptions on financial condition or operating performance is material.

In accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, revenue from license fees and grants is recognized when the following criteria are met; persuasive evidence of an arrangement exists, services have been rendered, the contract price is fixed or determinable, and collectibility is reasonably assured. In licensing arrangements, delivery does not occur for revenue recognition purposes until the license term begins. Nonrefundable upfront fees received in exchange for products delivered or services performed that do not represent the culmination of a separate earnings process will be deferred and recognized over the term of the agreement using the straightline method or another method if it better represents the timing and pattern of performance.

For revenue contracts that contain multiple elements, we will determine whether the contract includes multiple units of accounting in accordance with EITF No. 00-21, Revenue Arrangements with Multiple Deliverables. Under that guidance, revenue arrangements with multiple deliverables are divided into separate units of accounting if the delivered item has value to the customer on a standalone basis and there is objective and reliable evidence of the fair value of the undelivered item.

Research and Development. During the year ended December 31, 2003 and the ten months ended October 31, 2004, we recorded research and development expenses of \$491,508 and \$125,942, respectively. Such expenses were principally comprised of manufacturing scale up and process development, license fees, sponsored research and consulting. We recognize research and development expenses as incurred.

During the year ending December 31, 2005 and beyond, we anticipate that our research and development expenses will increase as a result of our expanded development and commercialization efforts related to clinical trials, product development, and development of strategic and other relationships that will be required ultimately for the licensing, manufacture and distribution of our product candidates. We regard four of our product candidates as major research and development projects. The timing, costs and risks of those projects are as follows:

#### **Lovaxin C - Phase I trial Summary Information**

- Cost incurred to date: approximately \$700,000
- Estimated future costs: \$1,000,000
- Anticipated completion date: second quarter of 2006
- Risks and uncertainties:
  - the FDA (or relevant foreign regulatory authority) may not approve the study
  - any adverse event in a patient in the trial
  - difficulty in recruiting patients

- delays in the program
- strong side effects in patients in the trial



- Commencement of material cash flows:

– Unknown at this stage and dependent upon a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

#### **Lovaxin B - Phase I trial Summary Information**

- Cost incurred to date: \$100,000

- Estimated future costs: \$1,800,000

- Anticipate completion dates: second quarter of 2007

- Risks and uncertainties:

- Obtaining favorable animal data
- Proving low toxicity in animals and obtaining favorable animal data
  - Manufacturing scale up to GMP level
- FDA (or foreign regulatory authority) may not approve the study
  - The occurrence of an adverse event in a patient
    - Delays in the program

- Commencement of material cash flows:

– Unknown at this stage, upon a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

#### **Lovaxin T - Phase I trial Summary Information**

- Cost incurred to date: None

- Estimated future costs: \$1,500,000

- Anticipate completion dates: third quarter of 2007

- Risks and uncertainties:

- Obtaining favorable animal data
- Proving low toxicity in animals and obtaining favorable animal data
  - Manufacturing scale up to GMP levels
- FDA (or foreign regulatory authority) may not approve the study initiation
  - Adverse event in a patient in the program
    - Delays in the program

- Commencement of material cash flows:

– Unknown at this stage and dependent upon a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

#### **Lovaxin NY - Phase I trial Summary Information**

· Cost incurred to date: \$100,000

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- Estimated future costs: Unknown at this stage.
- Anticipated completion dates: Unknown at this stage.
  - Risks and uncertainties:
    - Obtaining favorable animal data
    - Proving low toxicity in animals and obtaining favorable animal data
      - Manufacturing scale up to GMP levels
    - FDA (or foreign regulatory authority) may not approve the study
    - The occurrence of an adverse event in a patient in the program
      - Delays in the program
- Commencement of material cash flows:
  - Unknown at this stage and dependent upon a licensing deal or pursuant to a marketing collaboration subject to regulatory approval to market and sell the product.

**General and Administrative Expenses.** During the year ended December 31, 2003 and the ten months ended October 31, 2004, we recorded general and administrative expenses of \$405,568 and \$524,368, respectively. General and administrative costs primarily include the salaries for executive, finance, facilities, insurances, accounting and legal assistance, as well as other corporate and administrative functions that serve to support Advaxis' current and our future operations and provide an infrastructure to support this anticipated future growth. During the year ending December 31, 2005 and beyond, we anticipate that our general and administrative costs will increase due to the increased compliance requirements, including, without limitation, legal, accounting, and insurance expenses, arising out of complying with periodic reporting and other regulations applicable to public companies.

**Interest Expense.** During the year ended December 31, 2003 and the ten months ended October 31, 2004, we recorded interest expense of \$17,190 and \$4,229, respectively. Interest expense, relates primarily to our convertible promissory notes which have been converted into Units at the initial closing of our Private Placement on November 12, 2004. Each Unit consisting of 87,108 shares of common stock and warrants to purchase 87,108 shares of common stock.

**Recently Issued Accounting Pronouncements.** In December 2004, the Financial Accounting Standards Board issued FASB Statement No. 123 (revised 2004), share-based payment. This statement requires that compensation cost relating to share based payment transactions be recognized in financial statements. The cost will be measured based on the fair value of the equity or liability instruments issued. At present, we are unable to determine what effect, if any, the adoption of FASB Statement No. 123 (revised 2004) will have on our financial statements.

## Results of Operations

### Three Months Ended January 31, 2005 Compared to the Three Months Ended January 31, 2004

**Revenue.** Our revenue decreased by \$400 or 100% from \$400 for the three months ended January 31, 2004 to \$0 for the three months ended January 31, 2005 due to the decrease in grant money received by the Company in these periods.

**Research and Development Expenses.** Research and development expenses increased by \$132,109, or 152.13%, from \$86,842 for the three months ended January 31, 2004 to \$218,951 for the three months ended January 31, 2005. This decrease was principally attributable to the following:

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an increase in our related manufacturing expenses of \$189,947 or 10,629% from \$1,787 to \$191,734; such decrease reflects the delay in the manufacturing program during 2004 because of delays in funding;

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- an increase in expenses related to toxicology studies from \$0 to \$27,216; such increase reflects the initiation of toxicology studies by Pharm Olam in connection with our Lovaxin C product candidates, and the payment of deferred license fees to Penn;
- a decrease in outside research fees and consulting expenses of \$85,054 or 100% from \$85,054 to \$0; such decrease reflects the completion of sponsored research payment paid by the Company to Penn, and a decrease in various consulting expenses paid to consultants in connection with our grant and pre-clinical development program, as well as in other research expenses.

*General and Administrative Expenses.* General and administrative expenses decreased by \$19,224 or 42.3% from \$45,399 for the three months ended January 31, 2004 to \$26,175 for the three months ended January 31, 2005. This decrease is primarily attributable to the following:

- employee related expenses increased by \$18,720, or 43.90%, from \$42,670 for the three months ended January 31, 2004 to \$61,390 for the three months ended January 31, 2005 arising from a bonus to Mr. Derbin, the Chief Executive Officer, in stock;
- A decrease in legal fees from \$832 for the three-months ended January 31, 2004 to (\$166,346) for the three months ended January 31, 2005, as a result of a settlement with the Company's Intellectual Property law firm which resulted in a reduction by approximately \$177,000 of accounts payable previously recorded as legal fee expense
- Other General and Administrative expenses increased by \$129,234 from \$1,897 for the three-months ended January 31, 2004 to \$131,131 for the three months ended January 31, 2005 principally due to an increase in professional, legal and accounting fees, information technology and internet expenses, insurance cost and others.

*Interest Expenses.* Interest expense decreased by \$7,687, or 72.14%, from \$10,655 for the three months ended January 31, 2004 to \$2,968 for the three months ended January 31, 2005. The decrease results primarily from a reduction on interest payable on certain notes which were converted on November 12, 2004.

*Other Income.* Other Income increased by \$2,709, or 903%, from \$30 for the three months ended January 31, 2004 to \$2,739 for the three months ended January 31, 2005. The increase results primarily from an increase in interest paid to the company on cash deposits held by the Company.

No provision for income taxes was made for the three months ended January 31, 2004 or 2005 due to significant tax losses during and prior to such periods.

### **Ten Months Ended October 31, 2004 Compared to the Ten Months Ended October 31, 2003**

*Revenue.* Our revenue increased by \$112,806 or 3133.5% from \$3,600 for the ten months ended October 31, 2003 to \$116,406 for the ten months ended October 31, 2004 due to the increase in grant money received by the Company in these periods.

*Research and Development Expenses.* Research and development expenses decreased by \$320,382, or 71.8%, from \$446,324 for the ten months ended October 31, 2003 to \$125,942 for the ten months ended October 31, 2004. This decrease was principally attributable to the following:

- A decrease in our manufacturing expenses of \$228,452 or 103.9% from \$219,948 to \$(8,504); such decrease reflects the delay in the manufacturing program during 2004 because of delays in funding;
- A decrease in our License Fees of \$110,164 or 196.4% from \$56,082 to \$(54,082); such decrease reflects the reclassification of License Fees from an R&D expense to an investment;

- A decrease in our outside research fees from \$97,306 to \$38,382; such decrease reflects the completion in year 2004 of our expenses resulting from our sponsored research agreement with Penn;
- Development consulting expenses increased from \$72,988 to \$150,147 or 105.7%. This increase reflects primarily increased success fees due to DNA Bridges in connection with two NIH grants awarded to the Company in 2004

*General and Administrative Expenses.* General and administrative expenses increased by \$148,965 or 39.7% from \$375,403 for the ten months ended October 31, 2003 to \$524,368 for the ten months ended October 31, 2004. This decrease was principally attributable to the following:

- employee related expenses increased by \$34,790, or 22.5%, from \$154,512 for the ten months ended October 31, 2003 to \$189,302 for the ten months ended October 31, 2004 arising from a bonus to Mr. Derbin, the Chief Executive Officer, in stock;
- professional fees increased by \$14,368 from \$204,145 for the ten months ended October 31, 2003 to \$218,514 for the ten months ended October 31, 2004 principally due to (a) an increase in consulting fees from \$95,651 to \$110,332, and (b) an increase in accounting fees from \$350 to \$23,070;
- Insurance expense was increased from \$1,901 for the ten months ended October 31, 2003 to \$9,929 for the ten months ended October 31, 2004; and
- Other General and Administrative expenses increased by \$66,701 from \$14,844 to \$81,545 principally due to an increase in amortization expenses, information technology and internet expenses, postage, telephone and travel expenses.

*Interest Expenses.*

Interest expense decreased by \$4,059, or 49%, from \$8,288 for the ten months ended October 31, 2003 to \$4,229 for the ten months ended October 31, 2004. The decrease results primarily from a reduction on interest payable on certain fees owed to Penn.

*Other Income.*

Other Income increased by \$112,357, or 2,736%, from \$4,106 for the ten months ended October 31, 2003 to \$116,463 for the ten months ended October 31, 2004. The increase results primarily from an increase in grants from \$3,600 to \$116,406.

**Year ended December 31, 2003 and the period from March 1, 2002 (inception) to December 31, 2002**

*Revenue.* Our revenue increased by \$4,000 or 100% from \$0 for the period from March 1, 2002 (inception) to December 31, 2002 to \$4,000 for the year ended December 31, 2003 due to the increase in grant money received by the Company in these periods.

*Research and Development Expenses.* Research and development expenses increased by \$440,609, or 865.6%, from \$50,899 for the period from March 1, 2002 (inception) through December 31, 2002 to \$491,508 for the year ended December 31, 2003. This increase was principally attributable to the increase in outside research expenses increased by \$33,838, or 53%, from \$63,468 for the period from March 1, 2002 (inception) through December 31, 2002 to \$97,306 for the year ended December 31, 2003 due to increased research fees due to Penn relating to an increased research program, the initiation of our manufacturing scale up program with Cobra Biomanufacturing PLC in year 2003 where such plan did not yet exist in year 2002 as well as the hire of certain pre clinical and regulatory consultants in early 2003 such as Therrimune Research Corporation, Dr. Bruce Mackler and AccessBio.

*General and Administrative Expenses.* General and administrative expenses increased by \$288,565 or 246.6% from \$117,003 for the period from March 31, 2002 (inception) through December 31, 2002 to \$405,568 for the year ended December 31, 2003. This increase is primarily attributable to the increase in professional fees increased by \$316,457, or 328.85%, from \$96,231 for the period from March 1, 2002 (inception) to December 31, 2002 to \$412,688 for the year ended December 31, 2003 due to increased consulting and legal requirements and increased consulting fees paid to financial advisors in 2003

*Other Income.* Other Income decreased by \$445, or 46% from \$966 for the period from March 1, 2002 (inception) to December 31, 2002 to \$521 for the year ended December 31, 2003. The decrease results from a decrease in interest paid to the Company on cash deposits held by the Company.

*Interest Expenses.* Interest expense increased by \$17,190 or 100% from \$0 for the period from March 31, 2002 (inception) through December 31, 2002 to \$17,190 for the year ended December 31, 2003. The increase results primarily from the interest attributable to notes issued during such later period.

No provision for income taxes was made for the period from March 31, 2002 (inception) through December 31, 2002 or the year ended December 31, 2003 due to significant tax losses incurred.

**Liquidity and capital resources**

At December 31, 2003 and January 31, 2005, our cash was \$47,160 and \$3,217,430, respectively, and we had a working capital deficit of \$997,184 at December 31, 2003 and working capital of \$2,523,913 at January 31, 2005.

To date, our principal sources of liquidity has been cash provided by private offerings of our securities. These offering have been structured so as to be exempt from the prospectus delivery requirements under the Securities Act of 1933. Our principal uses of cash have been research and development and working capital. We anticipate these uses will continue to be our principal uses of cash in the future.

Although we believe that the net proceeds received by us from the Private Placement and the private offerings will be sufficient to finance our currently planned operations for approximately the next 12 to 24 months, we do not believe that these amounts will be sufficient to meet our longer-term cash requirements or our cash requirements for the commercialization of any of our existing or future product candidates. We will be required to issue equity or debt securities or to enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

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, 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 are under no duty to update any of the forward-looking statements after the date of this prospectus to conform them to actual results or to make changes in our expectations.

We expect our future sources of liquidity to be primarily 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.

On November 12, 2004, we sold to accredited investors at an initial closing of the Private Placement 117 Units at \$25,000 per unit for an aggregate purchase price of \$2,925,000. Each Unit is comprised of (i) 87,108 shares of our common stock and (ii) a five-year warrant to purchase 87,108 shares of our common stock at an exercise price of \$0.40 per share. At the initial closing, the accredited investors received an aggregate of 10,191,638 shares of common stock and warrants to purchase 10,191,638 shares of common stock. In addition, on November 12, 2004, \$595,000 aggregate principal amount of convertible promissory notes of Advaxis, including accrued interest, were converted into units on the same terms as those upon which the Units sold. The holders of these notes received an aggregate of 2,136,441 shares of common stock and warrants to purchase 2,136,441 shares of common stock upon conversion of these notes plus accrued interest thereon.

On December 8, 2004, we sold to accredited investors at a second closing of the Private Placement 8 units for an aggregate purchase price of \$200,000. At such closing, the accredited investors received an aggregate of 696,864 shares of common stock and warrants to purchase 696,864 shares of Common Stock.

On January 4, 2005, we sold to accredited investors at a third closing of the Private Placement 5.12 Units for an aggregate purchase price of \$128,000. At such closing, the accredited investors received an aggregate of 445,993 shares of common stock and warrants to purchase 445,993 shares of Common Stock.

Pursuant to the terms of a investment banking agreement, dated March 19, 2004, by and between us and Sunrise Securities, Corp. ("Sunrise" or 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 Sunrise, as our placement agent in the Private Placement. In addition, we paid Sunrise a total cash fee of \$50,530.

On January 12, 2005, we sold to one accredited investor at a closing of a subsequent private placement offering 44 units for an aggregate purchase price of \$1,100,000. As with the Private Placement, each Unit issued and sold in this subsequent private placement was sold at \$25,000 per unit and is comprised of (i) 87,108 shares of our common stock, and (ii) a five-year warrant to purchase 87,108 shares of our common stock at an exercise price of \$0.40 per share. At such closing, the accredited investor received an aggregate of 3,832,752 shares of common stock and warrants to purchase 3,832,752 shares of common stock.

We are party to a license agreement, dated June 17, 2002, as amended, between Advaxis and The Trustees of the University of Pennsylvania, pursuant to which Advaxis has agreed to pay \$525,000 over a four-year period as a royalty after the first commercial sale of our products covered by the license. Advaxis is also obligated to pay annual license maintenance fees under this agreement ranging from \$25,000 to \$125,000 per year after the first commercial sale of a product under the license, as well as pay up to \$482,000 to the licensor upon receiving financing. The amount due is contingent upon the size of the financing.

For a description of material employment agreements to which we are party, see “Certain Relationships and Related Party Transactions”.

### **Critical Accounting Policies**

The preparation of financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policy involves significant estimate and judgment. The Company amortizes trademark and patent costs over their estimated useful lives. The Company may be required to adjust these lives based on advances in science and competitor actions. The Company reviews the recorded amounts of trademarks and patents at each period end to determine if their carrying amount is still recoverable based on expectations regarding potential licensing of the intangibles or sales of related products. Such an assessment, in the future, may result in a conclusion that the assets are impaired, with a corresponding charge against earnings.

Due to the limited nature of the Company’s operations, the Company has not identified any other accounting policies involving estimates or assumptions that are material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and where the impact of the estimates and assumptions on financial condition or operating performance is material.

### **Impact of Inflation**

We believe that our results of operations are not dependent upon moderate changes in inflation rates.

## BUSINESS

### 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 Penn to use 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 the Penn License to exploit the Listeria System.

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

<b><u>Product</u></b>	<b><u>Indication</u></b>	<b><u>Stage</u></b>
Lovaxin C	Cervical and head and neck cancers	Pre-clinical; Phase I study in cervical cancer anticipated to commence in the first half of 2005*
Lovaxin B	Breast cancer and melanoma	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin NY	Ovarian, melanoma and lung cancer	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin W	Wilms tumor and leukemia	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin T	Cancer through control of telomerase	Pre-clinical
Lovaxin H	Prophylactic vaccine for HIV (AIDS)	Pre-clinical

\* Possible delays of up to three months may occur based on the production schedule of Cobra Biomanufacturing PLC of material, the length of time for Pharm Olam to complete toxicology studies 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, 2005 aggregate \$1,903,996, 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: we may be perceived by desirable potential partners as too early stage; we may need to demonstrate more human safety or efficacy data; or our technology may be perceived as a high risk for patents or to the environment.

*Initiate and Complete Phase I Clinical Study of Lovaxin C.* We have had several meetings with the FDA and the Recombinant Advisory Committee of the National Institutes of Health (the "NIH") and have designed a Phase I clinical study, which is primarily a study of the safety of Lovaxin C. We plan to commence this clinical study in the first quarter 2005 and complete this clinical study by the first quarter of 2006. We anticipate that the study will be conducted on 20 to 30 patients with advanced cervical cancer.

We have demonstrated that the therapeutic response works in concept. In preparation for the commencement of our Phase I study of Lovaxin C, we have done the following:

- optimized the Listeria strain to be used;
- identified and contracted with a manufacturing partner for material manufactured in accordance with "good manufacturing practices" or "GMP" as established by the FDA;
- identified a principal investigator for the trial;
- written a protocol; and
- commenced preparing an investigational new drug application, or IND, with an external consulting group.

Following the completion of the Phase I study and assuming that the results of this study are favorable, we intend to prepare Phase II clinical studies to demonstrate sufficient induction of immunity and therapeutic efficacy, as well as to optimize the dosage and dosing regimen for the final vaccine formulation. Thereafter, and assuming that the results of this study are favorable, we intend to conduct Phase III clinical studies to demonstrate safety, efficacy and the potency of the investigational vaccine. Such studies are expected to occur in the next five to ten years. Throughout this process, we will be meeting with the FDA prior to and at the conclusion of each phase to reach a consensus before initiating any studies, in order to minimize regulatory risks during this clinical development process.

At the conclusion of the Phase III studies, we intend to prepare and file a BLA with the FDA. Prior to submission of the BLA, we intend to seek Fast Track designation from the FDA, which shortens the internal FDA review process for the BLA to six months. As we accrue clinical data demonstrating the safety, efficacy and potency of the product in Phase I and II clinical studies we will also explore other regulatory approval options with the FDA that could expedite the licensure of the final vaccine.

*Continue Pre-Clinical Development of Our Products, as well as Continued Research to Expand Our Technology Platform.* We intend to continue to devote a substantial portion of our resources to the continued pre-clinical development of our product candidates as well as the continued research to expand our technology platform. Specifically, we intend to focus upon research relating to combining our Listeria System with new and additional tumor antigens which, if successful may lead to additional cancer vaccines and other therapeutic products. These activities will 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 with universities, such as its relationship with Penn and UCLA. See “Business - Partnerships and Agreements - Penn”.

## **Background**

### **Cancer**

Despite tremendous advances in science, cancer remains a major health problem, and for many it continues to be the most feared of diseases. Although age-adjusted mortality rates for all cancer fell during the 1990's, particularly for the major cancer sites (lung, colorectal, breast, and prostate), mortality rates are still increasing in certain sites such as liver and non-Hodgkin's lymphoma. The American Cancer Society estimates that more than eight million Americans were treated for cancer in 1999. According to the HCUP, in 2000, treatment of the top five cancers resulted in \$10.8 billion in hospital costs.

Cancer is the second largest cause of death in the United States, exceeded only by heart disease. Approximately 1,268,000 new cases of cancer were expected to be diagnosed in 2001, and 553,400 Americans were expected to die from the disease. Since 1990, nearly 15 million new cases have been diagnosed. The NIH estimates the overall cost for cancer in the year 2000 at \$180.3 billion: \$60 billion for direct medical costs, \$15 billion for indirect morbidity costs (loss of productivity due to illness) and, \$105.2 billion for indirect mortality costs (cost of lost productivity due to premature death). (Source: cancer facts & figures 2001, American Cancer Society).

### **Immune System and Normal Antigen Processing**

Living creatures, including humans, are continually confronted with potentially infectious agents. The immune system has developed multiple mechanisms that allows the body to recognize these agents as foreign, and to target a variety of immunological responses, including innate, antibody, and cellular immunity, that mobilize the body's natural defenses against these foreign agents that will eliminate them. In this regard, there are a host of cells involved in the recognition of and response to antigens, substances, typically proteins, that are recognized by the body's immune

system and generate an immune response. Antigens are frequently found on the outside of invading cells like bacteria, but can also be found on the body's own cells when they are either infected by a virus or transformed into a cancer cell.

The combination of the antibody (also called humoral) system and the cell mediated system results in the immune response. Different disorders need a different mix of responses to eliminate the problem, e.g., a streptococcal infection is typically attacked primarily by the humoral system, and a cancer cell is typically attacked by the cell mediated system.

The first step in recognizing a foreign antigen is antigen processing. When cells involved in the recognition and response encounter an antigen that they do not recognize, they ingest the antigen. The antigen is then cut into small pieces and the pieces are combined with proteins called “MHCs” and pushed out to the cell surface. On the cell surface, the antigen is then able to interact with certain classes of cells created by the immune system that produce the specialized cells needed to help in the production of antibodies and the induction of cytotoxic lymphocytes, primarily with antibodies. This system is called the exogenous pathway, since it is the prototypical response to an exogenous antigen like a bacteria.

There exists another pathway, called the endogenous pathway. In this system, when one of the body’s cells begins to create unusual proteins, the protein is processed and expelled to the surface cell and is the cytoplasm into fragments. These are directed into the endoplasmic reticulum, where they bind major Histocompatibility Complex proteins, and then traffic to the cell surface. This signal then calls immune cells to come to the site of the infection and kill the cell. The endogenous pathway is used by the body to eliminate cells that are creating unusual proteins (e.g., cancer cells or cells infected with a virus).

In clinical cancer, the body does not recognize the cancer cells as foreign. Our technology forces the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by combining elements of the endogenous and exogenous pathways utilizing a number of biologic characteristics of the Listeria bacteria.

### **Mechanism of Action**

Listeria is a bacteria well known to medical science because it can cause an infection in humans. When Listeria enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called lysosomes, whose destructive enzymes kill most of the bacteria. A certain percentage of these bacteria, however, are able to break out of the lysosomes and enter into the cytoplasm of the cell, where they are relatively safe from the immune system. The bacteria multiply in the cell, and the Listeria is able to force the cell to move the bacteria to its cell surface so it can push into neighboring cells and spread. In this way, Listeria can cause various clinical conditions, including sepsis, meningitis and placental infections in pregnant women.

Listeria produces a substance known as listeriolysin (“LLO”), a protein that cuts a hole in the membrane of the lysosome and allows the bacteria to escape into the relatively safe cytoplasm. Once in the cytoplasm, however, LLO is also capable of cutting a hole in the cell membrane. This would destroy the cell, and spill the bacteria back out into the space between the cells, where it would be exposed to more immune cell attacks and destruction. To prevent this, LLO has a sequence of approximately 30 amino acids attached to it known as the PEST<sup>1</sup> sequence. This PEST sequence is used by normal cells to force the rapid turnover of proteins that need only have a short life in the cytoplasm. Listeria has evolved the ability to utilize this PEST sequence itself as a routing tag that tells the cells to grab the LLO in the cytoplasm and pull it into the endoplasmic reticulum, where it is processed just like a protein antigen in the endogenous pathway. The benefit for the Listeria is that the LLO is neutralized and the bacteria can continue to prosper inside the cell; the benefit provided by our technology is that we now have a path into the antigen processing system that causes an immune response of the tumor-specific antigen.

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<sup>1</sup> PEST is a part of the LLO protein that is believed to facilitate rapid degradation of LLO in the cytoplasm. It appears to facilitate movement of the protein into the endoplasmic reticulum of the cell. In Advaxis’ application, the PEST sequence enhances the cell-mediated response to an attached antigen, presumably by preferential movement of the antigen sequence into the intracellular protein processing system of antigen



processing cells such as macrophages and dendritic cells.

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## Research and Development Program

### Overview

We use genetically engineered *Listeria monocytogenes* as a therapeutic agent. We start with an attenuated *Listeria*, and then add to this bacteria a plasmid that encodes a protein sequence that includes a portion of the LLO molecule (including the PEST sequence) and the tumor antigen of interest. This protein is secreted by the *Listeria* inside the antigen processing cells, which then results in the immune response as discussed above.

We can use different tumor antigens (or other antigens) in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, Lovaxin C, uses a human papillomavirus derived antigen that is present in cervical cancers. Lovaxin B uses her2/neu, an antigen found in many breast cancer and melanoma cells, to induce an immune response that should be useful in treating these conditions. The table below shows a list of potential products and their current status:

<u>Product</u>	<u>Indication</u>	<u>Stage</u>
Lovaxin C	Cervical and neck cancers	Pre-clinical; Phase I study in cervical cancer anticipated to commence in the first half of 2005*
Lovaxin B	Breast cancer and melanoma	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin NY	Ovarian melanoma and lung cancer	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin W	Wilms tumor and leukemia	Pre-clinical; Phase I study anticipated to commence in 2006
Lovaxin T	Cancer through control of telomerase	Pre-clinical
Lovaxin H	Prophylactic vaccine for HIV (AIDS)	Pre-clinical

\* Possible delays of up to three months based on the production schedule of Cobra Biomanufacturing PLC of materials, the length of time for Pharm Olam to complete toxicology studies, and the issuance of required regulatory approvals.

### Partnerships and Agreements

#### Penn

We have entered into a 20-year exclusive worldwide license, with the right to grant sublicenses, with Penn with respect to the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology in the area of innate immunity, or the immune response attributable to immune cells, including dendritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically. The license provides us with the exclusive rights to the patent portfolio developed at Penn in connection with Dr. Paterson and requires us to raise capital, pay various milestone and licensing payments and commercialize the technology. In exchange for the license, Penn received shares of our common stock

currently representing approximately 10.68% of our common stock on a fully-diluted basis. In addition, Penn is entitled to receive a non-refundable license initial fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones, as follows: Under a licensing agreement, Penn is entitled to receive royalties in the following amounts: 1.5% on NET SALES in countries with pending or issued patents; and 1.0% on NET SALES in countries without pending or issued patents. Notwithstanding these royalty rates, we have agreed to pay \$525,000 over a four-year period as a minimum royalty after the first commercial sale of a product under the license. We are also obligated to pay up to \$660,000 to Penn upon receiving financing or on certain dates on or before December 15, 2007, whichever is earlier. After the 6th anniversary of the licensing agreement, we shall pay Penn annual license maintenance fees of \$125,000 per year. In addition, 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 shall be entitled to certain milestone payments, as follows: \$2,500,000 shall be due for first commercial sale of the first product in the cancer field (of which \$1,000,000 shall be paid within forty-five (45) days of the date of the first commercial sale, \$1,000,000 shall be paid on the first anniversary of the first commercial sale; and \$500,000 shall be paid on the second anniversary of the date of the first commercial sale). In addition, \$1,000,000 shall be due and payable within forty-five (45) days following the date of the first commercial sale of a product in any of the following fields (a) Infectious Disease, (b) Allergy, (c) Autoimmune Disease, and (d) any other therapeutic indications for which licensed products are developed. Therefore, the maximum total potential amount of milestone payments is \$6,500,000.

As a result of the abovementioned payments, we may pay Penn significant amounts. If over the next 10 years we have net sales in the aggregate amount of \$100 million from our cancer products, our total payments to Penn shall be \$5,535,000. If over the next 10 years our net sales total an aggregate amount of \$10 million from our cancer products, our total payments to Penn shall be \$4,560,000.

However, Penn is not involved in management of our company or in exploitation of the patent portfolio. Based on the agreements with Penn, we will be responsible for filing new patents and maintaining the existing patents.

**Dr. Yvonne Paterson**

Dr. Paterson is a Professor in the Department of Microbiology at Penn and the inventor of our licensed technology. She has been an invited speaker at national and international health field conferences and leading academic institutions. She has served on many federal advisory boards, such as the NIH expert panel to review primate centers, the Office of AIDS Research Planning Fiscal Workshop, and the Allergy and Immunology NIH Study Section. She has been Section Editor of the Journal of Immunology since 1994. She has written over 115 publications in immunology (including a recently published book) with emphasis during the last several years on the areas of HIV, AIDS and cancer research. Her instruction and mentorship has trained over 30 post-doctoral and doctoral students in the fields of Biochemistry and Immunology, many of whom are research leaders in academia and industry.

Dr. Paterson is currently the principal investigator on grants from the federal government and charitable foundations totaling approximately \$1.8 million dollars per year. Her research interests are broad, but her laboratory has been focused for the past ten years on developing novel approaches for prophylactic vaccines against infectious disease and immunotherapeutic approaches to cancer. The approach of the laboratory is based on a long-standing interest in the properties of proteins that render them immunogenic and how such immunogenicity may be modulated within the body.

*Consulting Agreement.* We entered into a renewed consulting agreement with Dr. Paterson in January 2005 which expires on January 31, 2006 with automatic renewals for up to six additional periods of six months each pursuant to which we have had access to Dr. Paterson's consulting services for one full day per week. 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 agreement, Dr. Paterson has received options to purchase 169,048 shares of our common stock subject to vesting. Dr. Paterson is to receive \$3,000 per month throughout the term of the Agreement; provided, that upon the closing of an additional \$3 million in equity capital, Dr. Paterson shall receive \$5,000 per month; provided, further, that upon the closing of an additional \$6 million in equity capital, Dr. Paterson shall receive \$7,000 per month; and provided, further, that upon the closing of an additional \$9 million in equity capital, Dr. Paterson shall receive \$9,000 per month. In addition, subject to the adoption of a new stock option plan by our stockholders, Dr. Paterson shall receive options to purchase 400,000 shares of common stock at an exercise price of \$0.28 per share with 40,000 fully vested when granted and the remaining 360,000 options vesting equally over 48 months; provided that Dr. Paterson remains a consultant over the four year period. As of March 31, 2005, Dr. Paterson is being paid \$3,000 per month, and holds options to purchase a total of 169,048 shares of Common Stock. We intend to grant as options to purchase an additional 400,000 shares of common stock upon adoption of a new stock option plan by the Company.

*Sponsored Research Agreement.* We entered into a sponsored research agreement which terminates on June 30, 2005 with Penn and Dr. Paterson and have paid approximately \$199,000 to sponsor her continued research in this area. We believe that Dr. Paterson's continuing research will serve as a source of ongoing findings and data that both supports and strengthen the existing patents. Her work will expand the claims of the patent portfolio (potentially including adding claims for new tumor specific antigens, the utilization of new vectors to deliver antigens, and applying the technology to new disease conditions) and create the infrastructure for the future filing of new patents.

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

*Scientific Advisory Board.* Dr. Paterson is also the chairman of our Scientific Advisory Board and one of our stockholders.

#### **Dr. David Filer**

We have entered a consulting agreement with Dr. David Filer, a biotech consultant. The Agreement commenced on January 7, 2005 and has a six month term, which may be extended upon the agreement of both parties. Dr. Filer shall provide to us for three days per month during the term of the agreement assistance on its development efforts, reviewing our scientific technical and business data and materials and introducing us to industry analysts, institutional investors collaborators and strategic partners. In consideration for the consulting services we will pay Dr. Filer \$2,000 per month. In addition, subject to the adoption of a new stock option plan by our stockholders, Dr. Filer will receive 40,000 options to purchase shares of common stock, vesting monthly over 12 months provided that the agreement is not terminated.

#### **AccessBio, Inc (Joy Cavagnaro, Ph.D.)**

We entered into an agreement with Joy Cavagnaro, Ph.D., to advise us on an on-going basis in the preparation of our science based regulatory strategy and submissions with an emphasis on the design and safety of pre-clinical safety evaluation programs to support initiation of clinical trials and integration of pre-clinical and clinical research programs to support uninterrupted clinical development, interpretation of FDA guidelines and development of global registration strategies. A former expert toxicologist with the FDA, Dr. Cavagnaro has a distinguished reputation within the industry and the agency. Pursuant to the terms an agreement between Dr. Cavagnaro and us, in exchange for its services, AccessBio is entitled to receive cash and accrued compensation totalling \$3,000 per month, as well as options to purchase our common stock. The agreement was to terminate on September 15, 2004 but had been extended until March 15, 2005 when it was terminated.

#### **DNA Bridges, Inc. (“DNA”)**

We have entered into an agreement with DNA Bridges, Inc. to develop and manage our grant writing strategy and application program. Advaxis will pay DNA according to a fee structure based on achievement of grants awarded to us at the rate of 7% of the grant amount. To date, pursuant to the award of three grants to us, DNA has earned success fees of \$42,000, \$14,713 and \$17,924. In addition, DNA has received 16,200 options to purchase shares of our common stock. Either party may terminate this agreement upon 30 days' prior notice.

Eileen Gorman, Ph.D., a principal and owner of DNA, has extensive experience in accessing public financing opportunities, the national SBIR and related NIH/NCI programs with approximately 30 years of industry experience.

Under the DNA Agreement, DNA is compensated on a percentage basis for research grants made to us through its efforts. We are currently in arbitration with DNA concerning the timing of payments for the services rendered. See “Legal Matters.”

#### **UCLA**

We have entered into a nonexclusive license and bailment agreement with the Regents of the University of California (“UCLA”) to commercially develop products using the XFL7 strain of *Listeria monocytogenes* in humans and animals. The agreement is effective for a period of 15 years and renewable by mutual consent of the parties. Advaxis is to pay UCLA an initial licensee fee and annual maintenance fees for use of the *Listeria*. We may not sell products using the XFL7 strain *Listeria* other than agreed upon products or sublicense the rights granted under the license agreement

without the prior written consent of UCLA.

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### **David Carpi**

We have entered into a consulting agreement with David Carpi, whereby Mr. Carpi will assist us in the preparation and refinement of our marketing summary and presentation materials and introduce us to pharmaceutical and biotechnology companies which may be interested in strategic partnerships. Mr. Carpi will receive compensation payable in cash and options for our common stock upon completion of a transaction with a strategic partner introduced by Mr. Carpi. The agreement was terminated on December 31, 2004 and we chose not to renew it. No fees were paid and no fees are owed to Mr. Carpi.

We have also entered into a government funding fee agreement with Mr. Carpi, whereby Mr. Carpi will assist us in obtaining government funding for clinical studies for certain of our products. Mr. Carpi will receive options for our common stock if he is successful in obtaining government funding for us. The agreement expires on April 5, 2005 and thereafter continues on a month-to-month basis unless terminated in writing by either party.

### **Cobra Biomanufacturing PLC**

In July 2003, we entered into an agreement with Cobra Biomanufacturing PLC for the purpose of manufacturing our vaccines. Cobra has extensive experience in manufacturing gene therapy products for investigational studies. Cobra is a full service manufacturing organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotech industry. These services include the GMP manufacturing of DNA, recombinant protein, viruses, mammalian cells products and cell banking. Cobra's manufacturing plan for us calls for several manufacturing stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase I trial. The agreement is to expire upon the delivery and completion of stability testing of the GMP material for the Phase I trial, now estimated to occur by December 31, 2005. We are currently in negotiations with Cobra to enter into agreement to manufacture our vaccines for future programs. Cobra has agreed to convert \$300,000 of its existing fees for manufacturing into future royalties from the sales of Lovaxin C at the rate of 1.5% of net sales, with payments not to exceed \$1,950,000.

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

In January 2005, we entered a consulting agreement with Pharm-Olam International Ltd. ("POI"), a Texas limited partnership specializing in the management of pre clinical and toxicology programs. Pursuant to the agreement, POI shall execute and manage our toxicology studies, with certain third parties. The term of the agreement is 12 months. In consideration for providing the consulting services, POI will receive \$272,163.

In April 2005, we entered into a consulting agreement with POI, based on which POI shall execute and manage our Phase 1 clinical trial in Lovaxin C. In consideration for providing the consulting services, POI will receive \$430,000 (50% of which is contingent on the closing of our next financing) plus certain expenses of \$181,060.

### **LVEP Management, LLC**

We entered into a consulting agreement with LVEP Management, LLC ("LVEP") which is owned by Scott Flamm, one of our directors and a principal shareholder. LVEP employs Mr. Flamm and Mr. Roni Appel, our Chief Financial Officer, and a director and a principal shareholder of the Company. Pursuant to the consulting agreement, dated as of January 19, 2005, and amended on April 15, 2005, LVEP is to provide various financial and strategic consulting services to us. The initial term of the consulting agreement is until December 31, 2005 and thereafter the term of the consulting agreement shall be automatically extended for one year periods unless we notify LVEP at least 60 days prior to the end of term of our intent not to extend. In consideration for providing the consulting services, LVEP received an initial payment of \$4,500, receive \$7,000 per month during January, February and March 2005 and \$13,875 per month thereafter for the term of the consulting agreement plus reimbursement of approved expenses in

connection with providing the consulting services and will receive a payment at the end of 2005 equal to 60% of the bonus earned by the Chief Executive Officer of the Company. Additionally, LVEP shall receive options to purchase common stock equal to 3% of the outstanding shares of the Company as of March 31, 2005.



## **Strategic Growth International, Inc.**

We entered into an agreement with Strategic Growth International, Inc. (“SGI”) whereby SGI will serve as an investor relations consultant. The term of this agreement is for a period of 18 months commencing on the date of the effectiveness of this registration statement. In consideration for performing its services, SGI is to be paid \$7,000 per month, provided, that upon the effective date of this prospectus, SGI is to receive \$8,000 per month and \$7,000 of common stock with piggyback rights. In addition, SGI is to be issued a warrant to purchase 240,000 shares of common stock, exercisable for 5 years, with cashless exercise and piggyback rights. Furthermore, SGI is to be paid a finder’s fee for any financing by us from an approved institution introduced to us by SGI.

## **Patents and Licenses**

Dr. Paterson and Penn have invested significant resources and time in developing a broad base of intellectual property around the cancer vaccine platform technology to which we have a 20-year exclusive worldwide license and a right to grant sublicenses to pursuant to our license agreement with Penn. Penn currently has eight issued and 12 pending patents in the United States and other countries including Japan, Canada, Israel, Australia, and the European Union, through the Patent Cooperation Treaty (PCT) system pursuant to which we have an exclusive license to exploit the patents. We believe that these patents will allow us to take a strong lead in the field of Listeria-based therapy.

The Penn patent portfolio is currently comprised of the following:

### **United States**

#### **Patents**

U.S. Patent No. 6,051,237, issued April 18, 2000. Patent Application No. 08/336,372, filed November 8, 1994 for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector.” Filed November 8, 1994. Expires April 18, 2017.

U.S. Patent No. 6,565,852, issued May 20, 2003, Paterson, et al., CIP Patent Application No. 09/535,212, filed March 27, 2000 for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector.” Filed March 27, 2000. Expires May 20, 2020.

U.S. Patent No. 6,099,848, issued August 8, 2000. Frankel et al., Patent Application No. 08/972,902 “Immunogenic Compositions Comprising DAL/DAT Double-Mutant, Auxotrophic, Attenuated Strains of Listeria and Their Methods of Use.” Filed November 18, 1997. Expires November 18, 2017.

U.S. Patent No. 6,504,020, issued January 7, 2003 of Divisional Application No. 09/520,207 “Isolated Nucleic Acids Comprising Listeria DAL And DAT Genes”. Filed March 7, 2000., Frankel et al. Expires March 7, 2020.

U.S. Patent No. 6,635,749, issued October 21, 2003; Divisional U.S. Patent Application No. 10/136,253 for “Isolated Nucleic Acids Comprising Listeria DAL and DAT Genes.” Filed May 1, 2002, Frankel, et al. Filed May 1, 2022. Expires November 18, 2017.

U.S. Patent No. 5,830,702, issued November 3, 1998. Patent Application No. 08/366,477, filed December 30, 1994 for “Live, Recombinant Listeria SSP Vaccines and Productions of Cytotoxic T Cell Response” Portnoy, et al. Filed December 30, 1997. Expires November 3, 2015.

US Patent No. 6,767,542 issued July 27, 2004, Paterson, et al. Patent Application No. 09/735,450 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed December 13, 2000. Expires March 29, 2020.

## **Patent Applications**

U.S. Patent Application No. 10/441,851, “Methods And Compositions For Immunotherapy of Cancer,” Filed May 20, 2003, Paterson et al.

U.S. Patent Application No. 10/239,703 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed September 24, 2002, Paterson, et al.

Patent Application No. 09/537,642 for “Fusion of Non-Hemolytic, Truncated Form of Listeriolysin o to Antigens to Enhance Immunogenicity.” Filed March 29, 2000. Paterson, et al.

U.S. Patent Application No. 10/660,194, “Immunogenic Compositions Comprising DAL/DAT Double Mutant, Auxotrophic Attenuated Strains Of Listeria And Their Methods Of Use,” Filed September 11, 2003, Frankel et al.

## **International**

### **Patents**

Australian Patent No. 730296, Patent Application No. 14108/99 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Filed May 18, 2000. Frankel, et al. Expires November 13, 2018.

## **Patent Applications**

Canadian Patent Application No. 2,204,666, for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector”. Filed November 3, 1995, Paterson et al.

Canadian Patent Application No. 2,309,790 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Filed May 18, 2000, Frankel, et al.

Canadian Patent Application No. 2,404,164 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001. Paterson, et al.

European Patent Application No. 95939926.2, for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector”. Filed November 3, 1995, Paterson, et al.

European Patent Application No. 01928324.1 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001. Paterson, et al.

European Patent Application No. 98957980.0 for “Bacterial Vaccines Comprising Auxotrophic, Attenuated Strains of Listeria Expressing Heterologous Antigens.” Filed May 18, 2000, Frankel, et al.

Israel Patent Application No. 151942 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001, Paterson, et al.

Japanese Patent Application No. 515534/96, filed November 3, 1995 for “Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector”, Paterson, et al.

Japanese Patent Application No. 2001-570290 for “Compositions and Methods for Enhancing Immunogenicity of Antigens.” Filed March 26, 2001, Paterson, et al.



In 2001, an issue arose regarding the inventorship of U.S. Patent 6,565,852 and U.S. Patent Application No. 09/537,642. These patent rights are included in the patent rights licensed by Advaxis from Penn. It is contemplated by GSK, Penn and us that the issue will be resolved through: (1) a correction of inventorship to add certain GSK inventors, (2) where necessary and appropriate, an assignment of GSK's possible rights under these patent rights to Penn, and (3) a sublicense from us to GSK of certain subject matter, which is not central to our business plan. To date, this arrangement has not been finalized and we cannot assure that this issue will ultimately be resolved in the manner described above.

Pursuant to our license with Penn, we have a three year option to license from Penn any new future invention conceived by either Dr. Yvonne Paterson or by Dr. Fred Frankel in the vaccine area. We intend to expand our intellectual property base by exercising this option and gaining access to such future inventions. Further, our consulting agreement with Dr. Paterson provides, among other things, that, to the extent that Dr. Paterson's consulting work results in new inventions, such inventions will be assigned to Penn, and we will have access to those inventions under license agreements to be negotiated.

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

We 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 in the field of Listeria monocytogenes. For more information about Cerus Corporation and its claims with respect to listeria-based technology, you should visit their web site at [www.cerus.com](http://www.cerus.com) or to view its publicly filed documents, [www.sec.gov](http://www.sec.gov).

## **Trademarks**

We have two trademark applications pending in the United States relating to the trademark of "Advaxis" and ten trademark applications pending relating to the trademark of "Lovaxin" in the United States and internationally. We work closely with our trademark counsel to build a brandname for ourself and potential products. Aventis, Inc. has filed trademark opposition proceedings in the United States Patent and Trademark Office against our trademark applications Serial Nos. 78/252527 and 78/252586 related to the trademark of "Advaxis". The opposition proceedings are in the early stages and it is impossible to assess the merits at this point. We will vigorously defend our trademark applications.

## **Governmental Regulation**

### **The Drug Development Process**

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

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

*Protocols.* Before commencing human clinical studies, the sponsor of a new drug must submit an investigational new drug application, or IND, to the FDA. The application contains what is known in the industry as a *protocol*. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

- who must be recruited as qualified participants;
  - how often to administer the drug;
- what tests to perform on the participants; and
- what dosage of the drug to give to the participants.

*Institutional Review Board.* 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, but its records are audited by the FDA. Its members are not appointed by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board's role is to protect the rights of the participants in the clinical studies. It approves the protocols to be used, the advertisements which the company or contract research organization conducting the study proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

*Clinical Trials.* Human clinical studies or testing of a potential product are generally done in three stages known as Phase I through Phase III testing. The names of the phases are derived from the regulations of the FDA. Generally, there are multiple studies conducted in each phase.

*Phase I.* Phase I studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase I studies determine a drug's basic safety and how the drug is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year.

*Phase II.* Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to review the substance in Phase III studies.

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

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





*Phase IV.* The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

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 Food and Drug Administration 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 FDA and the sponsor to improve the efficiency of preclinical and clinical development, and to reach agreement on the design of the major clinical efficacy studies that will be needed to support approval. Under the Fast Track program, a sponsor also has the option to submit and receive review of parts of the NDA or BLA on a rolling schedule approved by FDA, which expedites the review process.

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

The Orphan Drug Act provides incentives to develop and market drugs ("Orphan Drugs") for rare disease conditions in the United States. A drug that receives Orphan Drug designation and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. A drug which is considered by the FDA to be different than such FDA-approved Orphan Drug is not barred from sale in the United States during such exclusive marketing period even if it receives approval for the same claim. We can provide no assurance that the Orphan Drug Act's provisions will be the same at the time of the approval, if any, of our products.

### **Other Regulations**

Various Federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movements, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, are used in connection with our research or applicable to our activities. They include, among others, the United States

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.

## **Manufacturing**

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

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

## **Competition**

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

We expect that our products under development and in clinical trials will address major markets within the cancer sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the 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".

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 in the field of Listeria monocytogenes. For more information about Cerus Corporation and its claims with respect to listeria-based technology, you should visit their web site at [www.cerus.com](http://www.cerus.com) or to view its publicly filed documents, [www.sec.gov](http://www.sec.gov).

### **Scientific Advisory Board**

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

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

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

*Pramod Srivastava, Ph.D.* Dr. Srivastava is Professor of Immunology at the University of Connecticut School of Medicine, where he is also Director of the Center for Immunotherapy of Cancer and Infectious Diseases. He holds the Physicians Health Services Chair in Cancer Immunology at the University. Professor Srivastava is the Scientific Founder of Antigenics, Inc. He serves on the Scientific Advisory Council of the Cancer Research Institute, New York, and was a member of the Experimental Immunology Study Section of the National Institutes of Health of the U.S. Government (1994 to 1999). He serves presently on the Board of Directors of two privately held companies: Ikonisys (New Haven, Connecticut) and CambriaTech (Lugano, Switzerland). In 1997, he was inducted into the Roll of Honor of the International Union Against Cancer and was listed in Who's Who in Science and Engineering. He is among the 20 founding members of the Academy of Cancer Immunology, New York. Dr. Srivastava obtained his bachelor's degree in biology and chemistry and a master's degree in botany (paleontology) from the University of Allahabad, India. He then studied yeast genetics at Osaka University, Japan. He completed his Ph.D. in biochemistry at the Center for Cellular and Molecular Biology, Hyderabad, India, where he began his work on tumor immunity, including identification of the first proteins that can mediate tumor rejection. He trained at Yale University and Sloan-Kettering Institute for Cancer Research. Dr. Srivastava has held faculty positions at the Mount Sinai School of Medicine and Fordham University in New York City.



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

## **Employees**

As of March 31, 2005, we have three employees, all of whom are on a full-time basis.

Additional senior employees have been identified and are anticipated to join Advaxis in the near future.

We anticipate increasing the number of employees in the research and development department significantly during the next two years, as well as increasing the number of employees in the general and administrative and business development department.

## **Facilities**

Our corporate offices are currently located at the corporate center at 212 Carnegie Center, Suite 206, Princeton, New Jersey 08540. We have entered into a lease effective April 1, 2005, which will continue on a monthly basis, at the Princeton Corporate Plaza, a biotech industrial park, located at 7 Deer Park Drive, Monmouth Junction, NJ 08852 for research and development offices and executive offices. We believe that our facility will be sufficient for our purposes for the foreseeable future. Our monthly payment on this facility will be approximately \$2,500 per month. In the event that our facility should, for any reason, become unavailable, we believe that alternative facilities are available at competitive rates.

## **Litigation**

There are no material legal proceedings threatened against us. In the ordinary course of our business we may become subject to litigation regarding our products or our compliance with applicable laws, rules, and regulations. Aventis, Inc. has filed trademark opposition proceedings in the United States Patent and Trademark Office against our trademark applications Serial Nos. 78/252527 and 78/252586 related to the trademark of "Advaxis". The opposition proceedings are in the early stages and it is impossible to assess the merits at this point. We intend to vigorously defend our trademark applications

## MANAGEMENT

### Executive Officers, Directors, and Key Employees

The following are our executive officers and directors and their respective ages and positions as of January 1, 2005:

<u>Name</u>	<u>Age</u>	<u>Position</u>
J. Todd Derbin(3)	52	President, Chief Executive Officer, and Director
Dr. James Patton(1)	47	Chairman of the Board of Directors
Roni A. Appel(3)	38	Chief Financial Officer, Secretary and Director
Dr. Thomas McKearn(2)	55	Director
Dr. Steven Roth	62	Director
Scott Flamm(1) (2)	50	Director

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Nominating and Corporate Governance Committee.

*J. Todd Derbin.* Mr. Derbin has served as our President, Chief Executive Officer and a director since November 2004. Prior thereto he served as the President, Chief Executive Officer and a director of Advaxis since November 2002. From 1996 until June, 2001, Mr. Derbin was the founder and Chairman of the Board of Directors, President, and Chief Executive Officer of Micrus Corporation, a market leader in the design and development of highly differentiated and proprietary interventional neuroradiology devices and delivery systems. From 1992 until 1996, he served as Director of Corporate Business Development, Commercial Director - Cardiovascular and Director of Strategic Planning, Mergers & Share Exchanges with Biocompatibles International, plc, a UK biotechnology/biomedical Company. Prior to this, Mr. Derbin served as Chief Executive Officer of Syncare Corporation, developers of synthetic wound care products and drug delivery systems. His 20 year tenure in life sciences includes senior management, strategic and operational positions with CollaTec, Inc., a subsidiary of Marion Merrell Dow, and American Medical Products Corporation's domestic and international divisions. He began his career at Procter & Gamble and American Hospital Supply Corporation (Baxter) where he held marketing positions. Mr. Derbin is an alumnus of Wilkes College and the Wharton School of the University of Pennsylvania.

*Dr. James Patton.* Dr. Patton has served as Chairman of our Board and Directors since November 2004. Prior thereto, Dr. Patton served as Chairman of Advaxis' Board of Directors since February 2002 and as Advaxis' Chief Executive Officer from February 2002 to November 2002. Additionally, since February 1999, Dr. Patton has served as the President of Comprehensive Oncology Care, LLC, which owns and operates a cancer treatment facility in Exton, Pennsylvania and as Vice President of Millennium Oncology Management, Inc., which provides technical services for oncology care to four sites. From February 1999 to September 2003, Dr. Patton served as a consultant to LibertyView Equity Partners SBIC, LP, a venture capital fund based in Jersey City, New Jersey ("LibertyView"). 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 Healthcare 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 the University of Pennsylvania's Wharton School. Dr. Patton was also a Robert Wood Johnson Foundation Clinical Scholar. He has published papers regarding scientific research in human genetics, diagnostic test performance and medical economic analysis.



*Roni A. Appel.* Mr. Appel has served as a member of our Board of Directors and as our Secretary and Chief Financial Officer since November 2004. Prior thereto he has served as Advaxis' Secretary and Chief Financial Officer since it was formed. Since January 1999, Mr. Appel has been a partner and managing director in LV Equity Partners (fka LibertyView Equity Partners). From 1998 until 1999, he was a founder and the director of business development at Americana Financial Services, Inc. From 1994 to 1998, he was an attorney and completed his MBA at Columbia University.

*Dr. Thomas McKearn.* Dr. McKearn has served as a member of our Board of Directors since November 2004. Prior thereto he served as an Advaxis director since July 2002. He brings to Advaxis a 20 plus year experience in the translation of biotechnology science into innovative products that address unmet medical needs in oncology. 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. Medical Affairs at GPC-Biotech, McKearn has always worked at bringing the most innovative scientific findings into the clinic and through the FDA regulatory process for the ultimate benefit of patients who need better ways to cope with their afflictions. Prior to entering the then-nascent biotechnology industry in 1981, McKearn did his medical, graduate and post-graduate training at the University of Chicago and served on the faculty of the Medical School at the University of Pennsylvania.

*Dr. Steven Roth.* Dr. Roth has served as a member of our Board of Directors since November, 2004. Prior thereto he had served as an Advaxis director since November 2002. He is a co-founder of Neose Technologies, a publicly traded biotechnology Company, since 1990, and has served as its chief executive and board chairman since 1994. Between 1980 and 1992 he was a professor of biology at University of Pennsylvania and was appointed department chairman in 1982, serving in that role until 1987. At the University of Pennsylvania, Dr. Roth helped form its Plant Science Institute. Between 1992 and 1994 he was the chief scientific officer and VP, R&D, of Neose Technologies. From 1970 through 1980, Dr. Roth was assistant and associate professor of biology at The Johns Hopkins University. His scholarly interests centered on the roles of complex carbohydrates in embryonic morphogenesis and in malignancy, topics on which he authored or co-authored nearly 100 articles and one book. He has received several research awards and prizes, and is an inventor on 18 patents and six patent applications. Dr. Roth received an A.B. degree from Johns Hopkins in 1964, a Ph.D. from Case Western Reserve University in 1968, and did postdoctoral work in carbohydrate chemistry at Hopkins from 1968-1970. Currently, Dr. Roth is a member of the board of directors of the Philadelphia Greenhouse Corporation, a member of the board of overseers of the School of Arts and Sciences of the University of Pennsylvania, a member of the board of visitors of the School of Arts and Sciences of Case Western Reserve University, a member of the scientific advisory boards of Quaker BioVentures and Birchmere Ventures, a member of the editorial board of The Quarterly Review of Biology, a director of Neose Technologies and a director of Chiral Quest.

*Scott Flamm.* Mr. Flamm has served as a member of our Board of Directors since November, 2004. Mr. Flamm is one of Advaxis' founders and has served as an Advaxis director since its inception. Since June 1998, Mr. Flamm has been the president and general partner of LV Equity Partners (fka Liberty View Equity Partners). Among his prior positions are Senior Managing Director of Trilon Dominion Partners, a \$100 million venture fund, and Executive Vice President of Charterhouse Environment Capital Group, a subsidiary of the private equity investment firm Charterhouse Group International. From 1988 until January 1993, he was Executive Vice President, Chief Operating Officer and a Director of Catalyst Energy, a \$2 billion independent power producer. He received his masters in public health from Yale University.

*Vafa Shahabit, Ph.D.* Dr. Shahabit has been Head of Director of Science effective March 1, 2005, terminable on 30 days notice. Her duties are to work on and/or manage research and development projects as specified by the Company. The compensation is \$100,000 per annum.

*Dr. John Rothman, Ph.D.* Dr. Rothman has been hired as Vice President of Clinical Development effective March 7, 2005 for a term of one year ending February 28, 2006. His compensation is \$170,000 per annum, to increase to \$180,000 upon the closing of a \$15 million equity financing. Upon meeting incentives to be set by the Company, he will receive a bonus of up to \$45,000.

*Richard Berman (Director Nominee).* Mr. Berman has agreed to join the Board by mid May. For the past five years, Mr. Berman has been Chairman and CEO of Internet Commerce Corporation, an internet supply chain company. He is also Chairman of a financial services company and Candidate Resources, Inc., a company which delivers human resources services over the web. He is a Director of seven public companies, Dyadic International, Inc., International Microcomputer Software, Inc., Internet Commerce Corporation, MediaBay, Inc., NexMed, Inc., GVI Security Solutions, Inc., and Financial Services Co., which he serves as chairman. Previously, Mr. Berman worked at Goldman Sachs; was Senior Vice President of Bankers Trust Company, where he started the M&A and Leverage Buyout Departments. He is a past Director of the Stern School of Business of NYU where he earned a B.S. and an M.B.A. He also has law degrees from Boston College and The Hague Academy of International Law. Mr. Berman will receive a director's fee of \$2,000 per month and options for the purchase of 400,000 shares of Common Stock vesting over four years on a quarterly basis.

#### **Board of Directors and Officers**

Messrs. McKearn and Roth have each received an option package of 82,763 options to purchase shares of our common stock.

Each director is elected for a period of one year at our annual meeting of stockholders and serves until the next such meeting and until his or her successor is duly elected and qualified. Officers are elected by, and serve at the discretion of, our board of directors. Our directors do not presently receive any compensation for their services as directors. The board of directors may also appoint additional directors up to the maximum number permitted under our by-laws. A director so chosen or appointed will hold office until the next annual meeting of stockholders.

Each of our executive officers serves at the discretion of its board of directors and holds office until his or her successor is elected or until his or her earlier resignation or removal in accordance with our articles of incorporation and by-laws.

#### **Meetings and Committees of the Board of Directors**

During the year ended December 31, 2003, our board of directors held four meetings and took action by written consent on four occasions. During the year ended December 31, 2004, our board of directors held three meetings and took action by written consent on 7 occasions.

#### **Audit Committee**

Effective in November 2004, we established the audit committee of the board of directors which consists of Messrs. Flamm and Patton.

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 suggest 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**

Effective on November 2004, we established a compensation committee of the board of directors which initially consists of Messrs. Flamm and McKearn. The compensation committee determines the salaries and incentive compensation of our officers and provides recommendations for the salaries and incentive compensation of our other employees and consultants.

The compensation of our executive officers is determined by the compensation committee of our board of directors, subject to applicable employment agreements. Our compensation programs will enable us to attract, motivate, reward and retain the management talent required to achieve corporate objectives and thereby increase stockholder value. It is our policy to provide incentives to our senior management to achieve both short-term and long-term objectives and to reward exceptional performance and contributions to the development of our business. To attain these objectives, our executive compensation program includes a competitive base salary, cash incentive bonuses and stock-based compensation.

Stock options have been granted to our senior executive officer by the board of directors or the compensation committee under the 2004 Stock Option Plan. We believe that stock options provide an incentive that focuses the executive's attention on managing us from the perspective of an owner with an equity stake in the business. Options are awarded with an exercise price equal to the market value of common stock on the date of grant, have a maximum term of ten years and generally become exercisable, in whole or in part, starting one year from the date of grant. Among our executive officers, the number of shares subject to options granted to each individual generally depends upon the level of that officer's responsibility. The largest grants are awarded to the most senior officers who, in our view, have the greatest potential impact on our profitability and growth. Previous grants of stock options are reviewed but are not considered the most important factor in determining the size of any executive's stock option award in a particular year.

From time to time, the compensation committee may utilize the services of independent consultants to perform analyses and to make recommendations to the committee relative to executive compensation matters. No compensation consultant has so far been retained.

### **Relationship of Compensation to Performance and Compensation of our executive officers**

The compensation committee will annually establish, subject to the approval of the board of directors and any applicable employment agreements, the salaries that will be paid to our executive officers during the coming year. In setting salaries, the compensation committee takes into account several factors, including competitive compensation data, the extent to which an individual may participate in the stock plans maintained by us, and qualitative factors bearing on an individual's experience, responsibilities, management and leadership abilities and job performance.



### **Nominating and Corporate Governance Committee**

Effective on November 2004, we established a nominating and corporate governance committee of our board of directors which initially consists of Messers. Derbin and Appel. The functions of the nominating and corporate governance include the following:

- identifying and recommending to the board of directors individuals qualified to serve as directors of the Company 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; and
  - overseeing the annual evaluation of the board and our management.

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

### **Code of Ethics**

We have adopted a code of ethics that applies to our officers, employees and directors, including our principal executive officers, principal financial officers and principal accounting officers. The code of ethics sets forth written standards that are designated to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and understandable disclosure in reports and documents that a we file with, or submit to, the SEC and in other public communications made by us;
  - Compliance with applicable governmental laws, rules and regulations;
- The prompt internal reporting of violations of the code to an appropriate person or persons identified in our code of ethics; and
  - Accountability for adherence to our code of ethics.

A copy of our code of ethics has been filed with the SEC as an exhibit to our Form 8K dated November 12, 2004.

### **Compensation of Officers and Directors**

The aggregate compensation paid to our directors and executive officers, including stock based compensation, for the year ended December 31, 2003 and December 31, 2004 was approximately \$183,692 and \$238,795, respectively. This amount includes \$0 set aside or accrued to provide pension, severance, retirement, or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders and other benefits commonly reimbursed or paid by similarly situated companies. None of our directors has so far received any compensation for his or her services as a director other than stock options and reimbursement of expenses.

### **Compensation Committee Interlocks And Insider Participation**

There were no interlocking relationships between us and other entities that might affect the determination of the compensation of its directors and executive officers.

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**Executive Compensation**

The following table sets forth the compensation earned during the years ended December 31, 2003 and 2004 by our former and current chief executive officer:

**Summary Compensation Table For Last Fiscal Year**

Name And Principal Position	Year	Annual Compensation		Long Term Compensation Awards Securities Underlying Options
		Salary(\$)	Bonus(\$)	
J. Todd Derbin	2004	\$168,270	\$45,000**	--
President, Chief Executive Officer, and Director	2003	\$150,000	\$60,000**	1,172,727
Dr. James Patton	2004	\$-*	--	29,583
Chairman of the Board of Directors	2003	\$-*	--	33,810

\*Dr. Patton was paid consulting fees by Advaxis of \$18,000 in 2003 and \$15,750 in 2004.

Mr. Patton's compensation related to his consulting agreement which terminated on November 2004.

\*\*Mr. Derbin's stock option award was based in his employment contract. His 2003 bonus of \$60,000 was paid in Common Stock of the Company on the basis of a volume of \$0.1452 per share and was two-third's of his maximum bonus of \$90,000. The basis for this bonus was the successful conclusion of several matters of great importance to the Company including:

- negotiating and executing an arrangement with GSK in 2003;
- extending the patent portfolio and moving it to the care of competent patent counsel;
- creating grant opportunities for the company;
- scaling up manufacturing;
- creating certain collaboration opportunities.

In determining Mr. Debin's bonus, the Board of Directors acted in part on a discretionary basis.

**Option Grants In Recent Fiscal Years**

The following table sets forth each grant of stock options during the years ended December 31, 2003 and 2004 to our current and former Chief Executive Officer under a predecessor stock option plan. The assumed 5% and 10% rates of stock price appreciation are provided in accordance with rules of the SEC and do not represent our estimate or projection of our common stock price. Actual gains, if any, on stock option exercises are dependent on the future performance of our common stock, overall market conditions and the option holders' continued employment through the vesting period. Unless the market price of our common stock appreciates over the option term, no value will be realized from the option grants made to these executive officers. The potential realizable values shown in the table are calculated by assuming that the estimated fair market value of our common stock on the date of grant increases by 5% and 10%, respectively, during each year of the option term.



The outstanding stock options described above became options for our common stock upon the Share Exchange.

### Individual Grants

Name	Year	Number Of Securities Underlying Options Granted	Percent Of Total Options Granted To Employees In Fiscal Year)	Exercise Price	Expiration Date	Potential Realizable Value At Assumed Annual Rates of Stock Price Appreciation For Option Term(\$)	
						5%	10%
J. Todd Derbin <sup>(1)</sup> President, Chief Executive Officer, and Director	2004 2003	-- --	-- --	-- --	-- --	-- --	-- --
Dr. James Patton Chairman of the Board of Directors	2004 2003	29,583 33,810	46.6% 53.3%	\$0.35 \$0.35	11/1/2012 11/1/2012	\$2,190 \$2,503	\$7,845 \$8,966

(1) The initial option grant was in the year 2002.

### Aggregate Option Exercises In Last Fiscal Year And Fiscal Year-End Option Values

The following table sets forth information concerning the options exercised by Advaxis' current and former Chief Executive Officer in the years ended December 31, 2003 and 2004 and the year-end number and value of unexercised options with respect to each of these executive officers.

Name	Year	Shares Acquired On Exercise	Value Realized <sup>(1)</sup>	Number Of Securities Underlying Unexercised Options At Fiscal Year-End <sup>(2)</sup>		Value Of Unexercised In-The-Money Options At Fiscal Year-End <sup>(3)</sup>	
				Exercisable	Unexercisable	Exercisable	Unexercisable
J. Todd Derbin President, Chief Executive Officer, and Director	2004 2003	0 0	0 0	586,382 293,191	586,382 879,575	51,015 0	51,015 0

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Dr. James	2004	0	0	29,583	0	0	0
Patton	2003	0	0	33,810	0	0	0
Chairman of the Board of Directors							

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- (1) Based on the fair market value of our common stock on the date of exercise, less the exercise price payable for such shares.
  - (2) Certain of the options are immediately exercisable for all the option shares as of the date of grant but any shares purchased are subject to repurchase by us at the original exercise price paid per share if the optionee ceases service with us before vesting in such shares.

- (3) Based on the fair market value of our common stock at fiscal year end of \$0.20 per share, determined by the board to be equal to our Private Placement price per share less the exercise price payable for such shares.

### **2004 Stock Option Plan**

In November 2004, our board of directors and stockholders adopted the 2004 Stock Option Plan (“Plan”). The Plan provides for the grant of options to purchase up to 2,381,525 shares of our common stock to employees, officers, directors and consultants. Options may be either “incentive stock options” or non-qualified options under the Federal tax laws. Incentive stock options may be granted only to our employees, while non-qualified options may be issued to non-employee directors, consultants and others, as well as to our employees.

The Plan is administered by “disinterested members” of the board of directors or the compensation committee, who determine, among other things, the individuals who shall receive options, the time period during which the options may be partially or fully exercised, the number of shares of common stock issuable upon the exercise of each option and the option exercise price.

Subject to a number of exceptions, the exercise price per share of common stock subject to an incentive option may not be less than the fair market value per share of common stock on the date the option is granted. The per share exercise price of the common stock subject to a non-qualified option may be established by the board of directors, but shall not, however, be less than 85% of the fair market value per share of common stock on the date the option is granted. The aggregate fair market value of common stock for which any person may be granted incentive stock options which first become exercisable in any calendar year may not exceed \$100,000 on the date of grant.

No stock option may be transferred by an optionee other than by will or the laws of descent and distribution, and, during the lifetime of an optionee, the option will be exercisable only by the optionee. In the event of termination of employment or engagement other than by death or disability, the optionee will have no more than three months after such termination during which the optionee shall be entitled to exercise the option, unless otherwise determined by the board of directors. Upon termination of employment or engagement of an optionee by reason of death or permanent and total disability, the optionee’s options remain exercisable for one year to the extent the options were exercisable on the date of such termination. No similar limitation applies to non-qualified options.

We must grant options under the Plan within ten years from the effective date of the Plan. The effective date of the Plan was November 12, 2004. Subject to a number of exceptions, holders of incentive stock options granted under the Plan cannot exercise these options more than ten years from the date of grant. Options granted under the Plan generally provide for the payment of the exercise price in cash and may provide for the payment of the exercise price by delivery to us of shares of common stock already owned by the optionee having a fair market value equal to the exercise price of the options being exercised, or by a combination of these methods. Therefore, if it is provided in an optionee’s options, the optionee may be able to tender shares of common stock to purchase additional shares of common stock and may theoretically exercise all of his stock options with no additional investment other than the purchase of his original shares.

Any unexercised options that expire or that terminate upon an employee’s ceasing to be employed by us become available again for issuance under the Plan.

### **Employment Agreements**

We have entered into an amended and restated employment agreement with J. Todd Derbin, dated December 20, 2004 pursuant to which Mr. Derbin is employed as our President and Chief Executive Officer. The effective date of the agreement is January 1, 2005. The term of the agreement is for one year and will be further renewed if mutually agreed to by Mr. Derbin and us. Mr. Derbin’s annual base salary shall be \$200,000; provided that it shall be increased

to \$225,000 or \$250,000 based upon certain milestones as set forth in the agreement. In addition, Mr. Derbin shall be entitled to bonuses in the form of equity and/or cash as set forth in the agreement and he shall be entitled to receive non-qualified stock options to purchase our common stock, the amount of which when added to his existing 1,172,767 options shall equal 5% of the our total issued and outstanding common stock, as of March 31, 2005. One-half of the options shall vest on the grant date and one-half of the options shall vest monthly over four years at a rate of 1/48<sup>th</sup> per month. The grant of the options is subject to us adopting a new stock option plan, which is subject to stockholder approval.

*Vafa Shahabit, Ph.D.* Dr. Shahabit has been Head of Director of Science effective March 1, 2005, terminable on 30 days. Her duties are to work on and/or manage research and development projects as specified by the Company. The compensation is \$100,000 per annum with a potential bonus of \$20,000. In addition, Dr. Shahabi will be granted 150,000 options.

*Dr. John Rothman, Ph.D.* Dr. Rothman has been hired as Vice President of Clinical Development effective March 7, 2005 for a term of one year ending February 28, 2006 and terminable on 30 days notice. His compensation is \$170,000 per annum, to increase to \$180,000 upon the closing of a \$15 million equity financing. Upon meeting incentives to be set by the Company, he will receive a bonus of up to \$45,000. In addition, Dr. Rothman will be granted 360,000 stock options.

#### **Compliance with Section 16(a) of the Securities Exchange Act of 1934**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who own more than ten percent of a registered class of our equity securities (collectively, "Reporting Persons") to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and our other equity securities. Reporting Persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file. To our knowledge, based solely on a review of the copies of such reports furnished to us, we believe that during calendar year ended December 31, 2004, all of the Reporting Persons complied with all applicable filing requirements, except for (i) the former officers and directors prior to November 12, 2004 who, to our knowledge, never filed Form 3s with the SEC, (ii) Messers. Appel and Flamm who haven't filed Form 4s with the SEC to reflect new option issuances, (iii) The Trustees of the University of Pennsylvania who were late in filing their Form 3 with the SEC and (iv) Harvest Advaxis LLC who has not filed a Form 3 with the SEC.

**PRINCIPAL AND MANAGEMENT STOCKHOLDERS**

The following table sets forth,

- each person who is known by us to be the owner of record or beneficial owner of more than 5% of our outstanding common stock;
  - each of our directors and each of our executive officers;
  - all of our directors and executive officers as a group; and
- the number of shares of common stock beneficially owned by each such person and such group and the percentage of the outstanding shares owned by each such person and such group.

As used in the table below and elsewhere in this prospectus, the term *beneficial ownership* with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following the date of this prospectus. Except as otherwise indicated, the stockholders listed in the table have sole voting and investment powers with respect to the shares indicated.

Except as otherwise noted below, the address of each of the persons in the table is 212 Carnegie Center, Suite 206, Princeton, New Jersey 08540.

<b><u>Name and Address</u></b>	<b><u>Number of Shares of Registrant Common Stock Beneficially Owned</u></b>	<b><u>Percentage of Class Beneficially Owned<sup>(1)</sup></u></b>
<b>Name and Address of Beneficial Owner</b>	<b>Shares of Common Stock Beneficially Owned</b>	<b>Percentage of Class Beneficially Owned</b>
J. Todd Derbin(1)(2)	1,837,348 (3)	4.81%
Roni Appel(1)(2)	3,041,622 (4)	8.22%
Scott Flamm(1)	2,914,989 (5)	7.90%
Dr. Steve Roth(1)	82,763 (6)	0.02%
Dr. James Patton(1)	2,913,476 (7)	7.92%
Dr. Thomas McKearn(1)	306,601 (8)	0.08%
The Trustees of the University of Pennsylvania Center for Technology Transfer, University of	6,339,282	17.2%

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3160 Chestnut Street, Suite  
200  
Philadelphia, PA 19104-6283

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Sunrise Equity Partners, LP 641 Lexington Ave-25fl New York, NY 10022	1,835,491 (9)	4.99%
Level Counter, LLC c/o Sunrise Securities Corp. 641 Lexington Ave-25fl New York, NY 10022	1,835,491 (10)	4.99%
Marilyn Adler c/o Sunrise Securities Corp. 641 Lexington Ave-25fl New York, NY 10022	1,835,491 (11)	4.99%
Nathan Low c/o Sunrise Securities Corp. 641 Lexington Ave-25fl New York, NY 10022	3,346,311 (12)	9.10%
Amnon Mandelbaum c/o Sunrise Securities Corp. 641 Lexington Ave-25fl New York, NY 10022	2,932,803 (13)	7.97%
Emigrant Capital Corp. 6 East 43 Street, 8th Fl. New York, NY 10017	1,838,783 (14)	4.99%
Harvest Advaxis LLC 30052 Aventura, Suite C Rancho Santa Margarita, CA 92688	3,832,753(15)	10.4%
All Directors and Officers as a Group (6 people)	11,096,799	28.95%

\* Based on 36,690,056 shares of common stock outstanding as of January 31, 2005.

- (1) Director
- (2) Officer
- (3) Reflects 295,766 shares of common stock, 1,172,767 options to purchase shares of common stock and 368,815 warrants to purchase shares of common stock.
- (4) Reflects 14,449 warrants to purchase shares of common stock and 2,522,166 shares of common stock owned by Mr. Appel but does not reflect 58,580 warrants to purchase shares of common stock because such warrants are not under the current circumstances, exercisable within the next 60 days. Also reflects 355,528 shares of common stock and 149,480 options and warrants to purchase shares of common stock beneficially owned by Carmel Ventures, Inc. of which Mr. Appel is a controlling person but does not reflect 355,528 warrants to purchase shares of common stock owned by Carmel Ventures, Inc. because such warrants are not under the current circumstances, exercisable within the next 60 days.
- (5) Reflects 125,772 shares of common stock and 122,751 options and warrants to purchase shares of common stock owned by Mr. Flamm but does not reflect 125,722 warrants to purchase shares of common stock because such warrants are not under the current circumstances, exercisable within the next 60 days. Also reflects 2,621,325 shares of common stock



- and 45,141 warrants to purchase shares of common stock beneficially owned by Flamm Family Partners LP of which Mr. Flamm is a partner.
- (6) Reflects options to purchase shares of common stock.
- (7) Reflects 56,349 options to purchase shares of common stock, 36,551 warrants to purchase shares of common stock and 2,820,576 shares of common stock but does not reflect 147,716 warrants to purchase shares of common stock because such warrants are not under the current circumstances, exercisable within the next 60 days.
- (8) Reflects 195,586 options and warrants to purchase shares of common stock and 111,015 shares of common stock.
- (9) Reflects 1,742,160 shares of common stock held by Sunrise Equity Partners, LP ("SEP") and warrants to purchase 93,331 shares of common stock, but does not include warrants to purchase 1,648,829 shares of common stock issuable upon exercise of warrants held by SEP because such warrants are not, under the current circumstances, exercisable within the next 60 days. The General Partner of SEP is Level Counter, LLC ("LC"), the managers of which are Nathan Low, Marilyn Adler and Amnon Mandelbaum (the "Managers"). Decisions regarding voting and disposition require the unanimous vote of all three managers. The 1,835,491 shares of common stock beneficially held by SEP also does not include: (1) 1,124,253 shares of common stock directly owned by Nathan Low or warrants directly owned by Mr. Low to purchase up to 761,971 shares of common stock; (2) 1,094,020 shares of directly owned by Amnon Mandelbaum or warrants directly owned by Mr. Mandelbaum to purchase up to 672,539 shares of common stock, and (3) shares of common stock held by limited partners of SEP or LC who may have a direct or indirect pecuniary interest, but have no authority to vote or dispose of the shares of common stock held by SEP. Does not reflect the 34,843 shares of common stock issuable as Penalty Shares.

- (10) Reflects 1,742,160 shares of common stock held by SEP and warrants to purchase 93,331 shares of common stock, but does not include warrants to purchase 1,648,829 shares of common stock issuable upon exercise of such warrants held by SEP because such warrants are not, under the circumstances, exercisable within the next 60 days. LC is the general partner of SEP and as such, is deemed to have beneficial ownership of the securities held by SEP for purposes of calculating percentage interest. Does not reflect the 34,843 shares of common stock issuable to SEP as Penalty Shares. However, LC disclaims beneficial interest in such shares except to the extent of its pecuniary interest therein.
- (11) Reflects 1,742,160 shares of common stock held by SEP and warrants to purchase 93,331 shares of common stock, but does not include warrants to purchase 1,648,829 shares of common stock issuable upon exercise of such warrants held by SEP because such warrants are not, under the circumstances, exercisable within the next 60 days. Does not reflect the 34,843 shares of common stock issuable to SEP as Penalty Shares. Ms. Adler is a manager of LC, the general partner of SEP, and as such, is deemed to have beneficial ownership of the securities held by SEP for purposes of calculating percentage interest. However, Ms. Adler disclaims beneficial interest in such shares except to the extent of her pecuniary interest therein.
- (12) Reflects 1,742,160 shares of common stock held by SEP and warrants to purchase 93,331 shares of common stock, but does not include warrants to purchase 1,648,829 shares of common stock issuable upon exercise of such warrants held by SEP because such warrants are not, under the circumstances, exercisable within the next 60 days. Does not reflect the 34,843 shares of common stock issuable to SEP as Penalty Shares. Mr. Low is a manager of LC, the general partner of SEP, and as such, is deemed to have beneficial ownership of the securities held by SEP for purposes of calculating percentage interest. However, Mr. Low disclaims beneficial interest in such shares except to the extent of his pecuniary interest therein. Also reflects 1,124,253 shares of common stock owned by Mr. Low but does not reflect warrants to purchase 761,971 shares of common stock issuable upon exercise of such warrants because such warrants are not, under the circumstances, exercisable within the next 60 days nor does it reflect 37,725 shares of common stock issuable to Mr. Low as Penalty Shares. Also includes 383,275 shares of common stock held by Sunrise Securities Corp., a corporation of which Mr. Low is sole stockholder and director, but does not include warrants to purchase 348,432 shares of common stock held by Sunrise Securities Corp. because such warrants are not, under the circumstances, exercisable within the next 60 days nor does it reflect 14,634 shares of common stock issuable to Sunrise Securities Corp. as Penalty Shares. Mr. Low's beneficial ownership does not include shares of common stock held by Sunrise Foundation Trust, a charitable trust of which Mr. Low is a trustee. Mr. Low disclaims beneficial ownership of such shares of common stock held by Sunrise Foundation Trust.
- (13) Reflects 1,742,160 shares of common stock held by SEP and warrants to purchase 93,331 shares of common stock, but does not include warrants to purchase 1,648,829 shares of common stock issuable upon exercise of such warrants held by SEP because such warrants are not, under the circumstances, exercisable within the next 60 days. Does not reflect the 34,843 shares of common stock issuable to SEP as Penalty Shares. Mr. Mandelbaum is a manager of LC, the general partner of SEP, and as such, is deemed to have beneficial ownership of the securities held by SEP for purposes of calculating percentage interest. However, Mr. Mandelbaum disclaims beneficial interest in such shares except to the extent of his pecuniary interest therein. Also reflects 1,094,020 shares of common stock owned by Mr. Mandelbaum but does not reflect warrants to purchase 672,539 shares of common stock issuable upon exercise of such warrants because such warrants are not, under the circumstances, exercisable within the next 60 days nor does it reflect 35,332 shares of common stock issuable to Mr. Mandelbaum as Penalty Shares.
- (14) Reflects 1,742,160 shares of common stock held by Emigrant Capital Corp. ("Emigrant") and warrants to purchase 16,623 shares of common stock, but does not include warrants to purchase 1,645,537 shares of common stock issuable upon exercise of warrants held by Emigrant because such warrants are not, under the current circumstances, exercisable within the next 60 days nor does it reflect 34,843 shares of common stock issuable to Emigrant as Penalty Shares. Mr. Howard Milstern is the Chairman and CEO and Mr. John Hart is the President of Emigrant.
- (15)

Reflects 3,832,753 shares of common stock but does not reflect warrants to purchase 3,832,753 shares of common stock because such warrants are not currently exercisable within the next 60 days. Mr. Robert Harvey is the manager of Harvest Advaxis LLC. It does not reflect 76,655 shares of common stock issuable to Harvest Advaxis LLC as Penalty Shares.

## **CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

Our policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred.

### **Consulting Agreement with Carmel Ventures, Inc.**

LVEP is owned by Scott Flamm, one of our directors and a principal shareholder. LVEP employs Mr. Flamm and Mr. Roni Appel, our Chief Financial Officer, director and a principal shareholder. Pursuant to a consulting agreement, dated as of January 19, 2005, and amended on April 15, 2005, LVEP is to provide financial management and strategic business development consulting services to us. The initial term of the agreement is until December 31, 2005 and thereafter the term of the agreement shall be automatically extended for one year periods unless we notify LVEP at least 60 days prior to the end of term of our intent not to extend. In consideration for providing the consulting services, LVEP received an initial payment of \$4,500 and shall receive \$7,000 per month during January, February and March 2005 and \$13,875 per month thereafter for the term of the agreement plus reimbursement of approved expenses in connection with providing the consulting services and will receive a payment at the end of 2005 equal to 60% of the bonus earned by the Chief Executive Officer of the Company. Additionally, LVEP shall receive options to purchase common stock equal to 3% of the outstanding shares of the Company as of March 31, 2005.

### **Consulting Agreement with LVEP Management, LLC**

LVEP is owned by Scott Flamm, one of our directors and a principal shareholder. LVEP employs Mr. Flamm and Mr. Roni Appel, our Chief Financial Officer, director and a principal shareholder. Pursuant to a consulting agreement, dated as of January 19, 2005, and amended on April 15, 2005 LVEP is to provide financial management and strategic business development consulting services to us. The initial term of the agreement is until December 31, 2005 and thereafter the term of the agreement shall be automatically extended for one year periods unless we notify LVEP at least 60 days prior to the end of term of our intent not to extend. In consideration for providing the consulting services, LVEP received an initial payment of \$4,500 and shall receive \$7,000 per month during January, February, and March 2005 and \$13,875 per month thereafter for the term of the agreement plus reimbursement of approved expenses in connection with providing the consulting services and will receive a payment at the end of 2005 equal to 60% of the bonus earned by the Chief Executive Officer of the Company. Additionally, LVEP shall receive options to purchase common stock equal to 3% of the outstanding shares of the Company as of March 31, 2005.

### **Amended and Restated Employment Agreement with J. Todd Derbin**

J. Todd Derbin is of Chief Executive Officer and a director. On December 20, 2004, we entered into an amended and restated employment agreement with J. Todd Derbin, pursuant to which Mr. Derbin is employed as our President and Chief Executive Officer. The effective date of the employment agreement is January 1, 2005. The term of the employment agreement is for one year and will be further renewed if mutually agreed to by Mr. Derbin and us. Mr. Derbin's annual base salary shall be \$200,000; provided that it shall be increased to \$225,000 or \$250,000 based upon certain milestones as set forth in the employment agreement. In addition, Mr. Derbin shall be entitled to bonuses in the form of equity and/or cash as set forth in the employment agreement and he shall be entitled to receive non-qualified stock options to purchase our common stock, the amount of which when added to his existing 1,172,767 options shall equal 5% of the our total issued and outstanding common stock, as of March 31, 2005. One-half of the options shall vest on the grant date and one-half of the options shall vest monthly over four years at a rate of 1/48<sup>th</sup> per month. The grant of the options is subject to us adopting a new stock option plan, which is subject to stockholder approval.



**Sentinel Consulting, Inc.**

Sentinel Consulting Inc. is owned by Robert Harvey, an observer to our Board and the manager of Harvest Advaxis LLC, one of our principal stockholders. Sentinel provided financial consulting, scientific validation and business strategy advice to us. The term of the agreement was for six months commencing as of September 5, 2004 with each party having the right to terminate it after four months under the agreement. We have paid Sentinel \$33,000 for services performed and we have the obligation to issue to them a warrant to purchase 191,638 shares of our common stock at an exercise price of an \$0.40 per share, plus 287,451 shares of our common stock, a retainer of \$5,000, a video preparation fee of \$10,000 and expenses of \$6,000 in connection with the preparation of a scientific review.

## SELLING STOCKHOLDERS

This prospectus relates to the resale from time to time of up to a total of 56,730,045 shares of common stock by selling stockholders, comprising:

- 37,099,460 shares of our common stock that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933; and
- 19,630,588 shares of common stock underlying warrants that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933.

The following table set forth certain information regarding the beneficial ownership of our common stock as to the selling stockholders and the shares offered by them in this prospectus. Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a selling stockholders and the percentage of ownership of that selling stockholder, shares of common stock underlying shares of convertible preferred stock, options or warrants held by that selling stockholder that are convertible or exercisable, as the case may be, within 60 days of January 31, 2005 are included. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other selling stockholder. Each selling stockholder's percentage of ownership in the following table is based upon 36,690,056 shares of common stock outstanding as of January 31, 2005 and not 37,099,460 shares of our common stock. An aggregate of 409,401 shares of common stock are issuable to certain selling stockholders as Penalty Shares pursuant to the terms of the Registration Rights Agreement, dated as of November 12, 2004, by and among the Company and certain stockholders and a Registration Rights Agreement, dated as of January 12, 2005, by and among the Company and a certain stockholder. Therefore, the following table includes a column to reflect the additional shares of common stock which certain selling stockholders are entitled to as Penalty Shares. However, such amounts are de minimus when calculating such selling stockholders' percentage ownership in the Company.

Except as described below, none of the selling stockholders within the past three years has had any material relationship with us or any of our affiliates:

- J. Todd Derbin has served as our Chief Executive Officer and a director since November 12, 2004;
- Roni Appel has served as our Chief Financial Officer and a director since November 12, 2004; Carmel Ventures, Inc., of which Mr. Appel is the principal stockholder has provided consulting services to us; LVEP by which Mr. Appel is employed, is providing consulting services to us;
- Scott Flamm has served as a director since November 12, 2004 and LVEP of which Mr. Flamm is a principal stockholder and an employee of, is providing consulting services to us;
  - Thomas McKearn has served as a director since November 12, 2004;
- Dr. James Patton has served as a director since November 12, 2004 and has served as a consultant to us in the past;
  - Dr. Yvonne Patton has served as a consultant;
- The Trustees of the University of Pennsylvania own the patents which we have an exclusive license;

- Sunrise Securities Corp. acted as placement agent in the Private Placement. Nathan Low, Amnon Mandelbaum, Marcia Kucher, Derek Caldwell, Richard Stone and David Goodfriend are all affiliated with or employed by Sunrise Securities Corp., the placement agent in the Private Placement. Sunrise Equity Partners, LP and Sunrise Foundation Trust are also affiliates of Sunrise Securities Corp.; and



- Dr. David Filer is a consultant for us and provided consulting services to the Sunrise Securities Corp.

The term “selling stockholders” also includes any transferees, pledges, donees, or other successors in interest to the selling stockholders named in the table below. To our knowledge, subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite such person’s name.

The selling stockholders named below are selling the securities. The table assumes that all of the securities will be sold in this offering. However, any or all of the securities listed below may be retained by any of the selling stockholders, and therefore, no accurate forecast can be made as to the number of securities that will be held by the selling stockholders upon termination of this offering. These selling stockholders acquired their shares by purchase exempt from registration under section 4(2) of the Securities Act of 1933 or Regulation D under the Securities Act of 1933. The selling stockholders acquired their shares in the ordinary course of business. We believe that the selling stockholders listed in the table have sole voting and investment powers with respect to the securities indicated. We will not receive any proceeds from the sale of the securities by the selling stockholders. No selling stockholders are broker-dealers or affiliates or employees of broker-dealers other than Sunrise Securities Corp., David Goodfriend, Amnon Mandelbaum, Marcia Kucher, Derek Caldwell, Richard Stone Nathan Low, Sunrise Equity Partners LP and Sunrise Foundation Trust. The securities included in this list include securities which would otherwise become saleable from time to time pursuant to Rule 144 as currently in effect.

Name	Total Shares Owned	Shares Registered	Penalty Shares	% Before Offering (not including Penalty Fees)	% After Offering (not including Penalty Fees)	Relationship (if any)
Adele Pfenninger 12 Spring Brook Road Annandale, NJ 08801	79,600 (1)	70,790 (1)	--	0.22%	0.02%	--
AI International Corporate (a) Holdings, Ltd. c/o FCIM Corp. 1 Rockefeller Plaza Suite 1730 New York, NY 10020	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
Alan Gelband Company (b) Defined Contribution Pension Plan and Trust 30 Lincoln Plaza New York, NY 10023	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
Alan Kestenbaum 18 Clover Drive Great Neck, NY 11021	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
Beret Family Partners LP (c)	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--

48 South Drive  
Great Neck, NY 11021

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Name	Total Shares Owned	Shares Registered	Penalty Shares	% Before Offering (not including Penalty fees)	% After Offering (not including Penalty Fees)	Relationship (if any)
Bridges & Pipes, LLC (d) 830 Third Avenue 14 <sup>th</sup> Floor New York, NY 10022	1,393,728 (4)	1,393,728 (4)	13,937	3.73%	0.0%	--
Bruce Fogel 218 Everglade Avenue Palm Beach, FL 33480	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
C. Leonard Gordon 551 Fifth Avenue New York, NY 10176	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
Carmel Ventures, Inc (e) 22 Ruth Lane Demarest, NJ 07627	860,537 (5)	711,057 (5)(a)	--	2.32%	0.41%	5(b)
Catherine Janus 4817 Creak Dr. Western Spring, IL 60558	118,832 (6)	105,767 (6)	--	0.32%	0.04%	--
Chaim Cymerman c/o Tomer Cymerman Paamoni 10, Apt. 19 Bavli, Tel Aviv Israel	196,371 (7)	174,593 (7)(a)	--	0.53%	0.06%	--
Charles Kwon 834 Monror Street Evanston, IL 60202	491,233 (8)	482,322 (8)(a)	3,484	1.33%	0.02%	--
Cranshire Capital, LP (f) 666 Dundee Road Sute 1901 Northbrook, IL 60602	1,045,296 (9)	1,045,296 (9)	10,453	2.81%	0.0%	--
Crestwood Holdings, LLC (g) c/o Ran Nizan 109 Boulevard Drive Danbury, CT 06810	360,253 (10)	337,978 (10)(a)	--	0.98%	0.06%	--
	348,432 (3)	348,432 (3)	3,484		0.0%	--
David Stone 228 St. Charles Avenue						

Suite 1024 New Orleans, LA 70130				0.95%		
David Tandler 401 East 60 <sup>th</sup> Street New York, NY 10022	696,864 (11)	696,864 (11)	6,969	1.88%	0.0%	--

Name	Total Shares Owned	Shares Registered	Penalty Shares	% Before Offering (not including Penalty Fees)	% After Offering (not including Penalty Fees)	Relationship (if any)
Design Investments, LTD (h) 9 Tanbark Circuit Suite 1442 Werrington Downs NSW 2747 Australia	696,864 (11)	696,864 (11)	6,969	1.88%	0.0%	--
Emigrant Capital Corp. (i) 6 East 43 <sup>rd</sup> Street 8 <sup>th</sup> Floor New York, NY 10017	3,484,320 (12)	3,484,320 (12)	38,843	9.07%	0.0%	--
Eugene Mancino Blau Mancino 12 Roszel Road, Suite C-101 Princeton, NJ 08540	355,099 (13)	212,544 (13)(a)	--	0.96%	0.39%	--
Fawdon Investments Ltd. (j) 4 Ibn Shaprut Street Jerusalem, Israel 92478	1,393,728 (4)	1,393,728 (4)	13,937	3.73%	0.0%	--
Flamm Family Partners, LP. (k) c/o Scott Flamm 70 West Road Short Hills, NJ 07078	2,666,466 (14)	2,657,556 (14)(a)	--	7.26%	0.02%	(14)(b)
Fred Berdon Co, LP (l) 717 Post Road Suite 105 Sacrsdale, NY 10583	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
Gina Ferarri 36 Stone Run Road Bedminster, NJ 07921	79,932 (15)	71,022 (15)(a)	--	0.22%	0.2%	--
Hal H. Beretz 48 South Drive Great Neck, NY 11021	522,648 (16)	522,648 (16)	5,226	1.41%	0.0%	--
	522,648 (16)	522,648 (16)	5,226		0.0%	--

Howard Kaye Family Fund (m) 2 Mohican Trail Scarsdale, NY 10583				1.41%		
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IRA FBO / Walter S. Grossman Pershing LLC Custodian (n) 277 North Ave. Westport, CT 06880	696,864 (11)	696,864 (11)	6,969	1.88%	0.0%	--
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Name	Total Shares Owned	Shares Registered	Penalty Shares	% Before Offering (not including Penalty Fees)	% After Offering (not including Penalty Fees)	Relationship (if any)
Itai Portnio 26 Yakinton St. Haifa, Isreal 34406	157,608 (17)	14,186 (17)(a)	--	0.43%	0.05%	--
J. Todd Derbin 840 Pretty Brook Road Princeton, NJ 08540	1,837,348 (18)	591,532 (18)(a)	--	4.81%	3.28%	(18)(b)
James Patton 1937 Swedesford Malvern, PA 19355	3,061,192 (19)	2,968,291(19)(a)	--	8.29%	0.25%	(19)(b)
James Paul c/o Fulwider Patton Howard Hughes Center 6060 Center Drive, 10 <sup>th</sup> Floor Los Angeles, CA 90045	39,215 (20)	34,861 (20)(a)	--	0.11%	0.01%	--
Jonas Grossman 59 Huratio St. New York, NY 10014	80,640 (21)	71,731 (21)(a)	--	0.22%	0.02%	--
Kerry Propper 59 Huratio St. New York, NY 10014	201,600 (22)	179,326 (22)(a)	--	0.55%	0.06%	--
Lilian Flamm c/o Scott Flamm 70 West Road Short Hills, NJ 07078	197,328 (23)	197,328 (23)	--	0.54%	0.0%	--
Marilyn Mendell 1203 River Road, Apt. Penthouse 4 Edgewater, NJ 07020	284,500 (24)	253,316 (24)(a)	--	0.77%	0.08%	--
Mary Ann Ryan Francis 1115 Beanaqt Ave. Seaside Park, NJ 08752	79,071 (25)	70,360 (25)(a)	--	0.22%	0.02%	--
MEA Group, LLC (o) 145 Talmadge Road Edison, NJ 08817	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
	157,608 (17)	140,186 (17)(a)	--		0.05%	--

Mordechai Mashiach  
8 Shlomzion Hamalka  
Haifa, Isreal 34406

0.43%

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<b>Name</b>	<b>Total Shares Owned</b>	<b>Shares Registered</b>	<b>Penalty Shares</b>	<b>% Before Offering (not including Penalty Fees)</b>	<b>% After Offering (not including Penalty Fees)</b>	<b>Relationship (if any)</b>
New Bank Ltd (p) Levinstein Tower #21 <sup>st</sup> 23 Menahem Begin Road Tel Aviv, Israel	1,393,728 (4)	1,393,728 (4)	13,937	3.73%	0.0%	--
Open Ventures LLC (q) 127 West Chestnut Hill Ave. Philadelphia, PA 19118	17,422	17,422	--	0.05%	0.0%	--
Peggy Fern 1548 Herlong Court Rock Hill, SC 29732	79,712 (26)	70,081 (26)(a)	--	0.22%	0.02%	--
Penn Footware Retirement Trust (r) Line & Grove Streets PO Box 87 Nanticoke, PA 18634	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
Richard Yelovich 603 Milleson Lane West Chester, PA 19380	151,289	151,289	--	0.41%	0.0%	--
Roni Appel 22 Ruth Lane Demarest, NJ 07627	2,595,193 (27)	2,580,745 (27)(a)	--			