

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)

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)

*Copies to:*

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**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:

## CALCULATION OF REGISTRATION FEE

<u>Title of each class of securities to be registered</u>	<u>Amount to be Registered</u> <sup>(1)</sup>	<u>Proposed maximum offering price per unit</u> <sup>(2)</sup>	<u>Proposed maximum aggregate offering price</u> <sup>(2)</sup>	<u>Amount of registration fee</u>
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.

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.
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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.

## 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.

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.

	Period from March 1, 2002 (inception) to December 31,	Year ended December 31,	Ten Months Ended October 31,		Three Months Ended January 31, (unaudited)	
	2002	2003	Unaudited 2003	2004	2004	2005
<b>Statement of Operations Data:</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)

<b>Balance Sheet Data:</b>	December 31,	December 31,	October 31	January 31, (unaudited)
	2002	2003	2004	2005
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

## 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

(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.

## 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,” “expect,” “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.

Statement of Operations Data:	Period from March 1, 2002 (inception) to December 31,	Year ended December 31,	Ten Months Ended October 31,		Three Months Ended January 31, (unaudited)	
	2002	2003	Unaudited 2003	2004	2004	2005
	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)

Balance Sheet Data:	December 31,	December 31,	October 31	January 31, (unaudited)
	2002	2003	2004	2005
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

## 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 become 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

- 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:

- 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;

- 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, primarily by preferential movement of the antigen sequence in to the intracellular protein processing system of antigen processing cells such as macrophages and dendritic cells.

## 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 fess 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 opportunitites, 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 entereed 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 maintainence 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.

## **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 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 Healthware Solutions. From June 2000 to June 2003, Dr. Patton served as a director of LifeStar Response. He earned his B.S. from the University of Michigan, his Medical Doctorate from Medical College of Pennsylvania, and his M.B.A. from 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.

## 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
		Salary(\$)	Bonus(\$)	Securities Underlying Options
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.

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

<b>Name</b>	<b>Year</b>	<b>Shares Acquired On Exercise</b>	<b>Value Realized<sup>(1)</sup></b>	<b>Number Of Securities Underlying Unexercised Options At Fiscal Year-End<sup>(2)</sup></b>		<b>Value Of Unexercised In-The-Money Options At Fiscal Year-End<sup>(3)</sup></b>	
				<b>Exercisable</b>	<b>Unexercisable</b>	<b>Exercisable</b>	<b>Unexercisable</b>
J. Todd Derbin President, Chief Executive Officer, and Director	2004	0	0	586,382	586,382	51,015	51,015
	2003	0	0	293,191	879,575	0	0
Dr. James Patton Chairman of the Board of Directors	2004	0	0	29,583	0	0	0
	2003	0	0	33,810	0	0	0

(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.

<u>Name and Address</u>	<u>Number of Shares of Registrant Common Stock Beneficially Owned</u>	<u>Percentage of Class Beneficially Owned<sup>(1)</sup></u>
<u>Name and Address of Beneficial Owner</u>	<u>Shares of Common Stock Beneficially Owned</u>	<u>Percentage of Class Beneficially Owned</u>
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 Pennsylvania 3160 Chestnut Street, Suite 200 Philadelphia, PA 19104-6283	6,339,282	17.2%



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%	--
Beretz Family Partners LP (c) 48 South Drive Great Neck, NY 11021	174,216 (2)	174,216 (2)	1,742	0.47%	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)
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%	--
David Stone 228 St. Charles Avenue Suite 1024 New Orleans, LA 70130	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
David Tendler 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 Bedmingter, 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%	--
Howard Kaye Family Fund (m) 2 Mohican Trail Scarsdale, NY 10583	522,648 (16)	522,648 (16)	5,226	1.41%	0.0%	--
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%	--



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 Yakintov 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%	--
Mordechai Mashiach 8 Shlomzion Hamalka Haifa, Isreal 34406	157,608 (17)	140,186 (17)(a)	--	0.43%	0.05%	--

Name	Total Shares Owned	Shares Registered	Penalty Shares	% Before Offering (not including Penalty Fees)	% After Offering (not including Penalty Fees)	Relationship (if any)
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)	--	7.06%	0.04%	(27)(b)
RP Capital, LLC (s) 10900 Wilshire Blvd. Suite 500 Los Angeles, CA 90024	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
Scott Flamm c/o Scott Flamm 70 West Road Short Hills, NJ 07078	374,296 (28)	251,545 (28)(a)	--	1.01%	0.33%	(28)(b)
Shai Stern 43 Maple Aenue Cedarhurst, NY 11516	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
SRG Capital, LLC (t) 120 Broadway 40 <sup>th</sup> Floor New York, NY 10271	696,864 (11)	696,864 (11)	6,969	1.88%	0.0%	--
Sunrise Equity Partners, LP (u) 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	3,484,320 (12)	3,484,320 (12)	34,843	9.07%	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)
Thomas McKearn 6040 Lower Mountain Road New Hope, PA 18938	374,876 (29)	269,839 (29)(a)	--	1.02%	0.29%	(29)(b)
Titan Capital Management, LLC (TCMP3 Partners) (v) 7 Centure Drive Suite 201 Parsippany, NJ 07054	696,864 (11)	696,864 (11)	6,969	1.88%	0.0%	--
Tracy Yun 90 LaSalle St., Apt. #13G New York, NY 10027	60,197	60,197	--	0.16%	0.0%	--
Trinita, LLC (w) c/o Morten Kielland 22 Painters Lane Chesterbrook, PA 19087	151,289	151,289	--	0.41%	0.0%	--
The Trustees of the University of Pennsylvania Center for Technology Transfer University of Pennsylvania 3160 Chestnut Street Suite 200 Philadelphia, PA 19104-6283 Attn: Managing Director	6,339,282	6,339,282	--	17.28%	0.0%	(41)
William Kahn 7903 Longmeadow Road Baltimore, MD 21208	151,517	151,517	--	0.41%	0.0%	--
Yair Talmor 517 Old Chappaqua Road Briarcliff Manor, NY 10510	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
Yoav Millet 950 Third Avenue New York, NY 10022	174,216 (2)	174,216 (2)	1,742	0.47%	0.0%	--
Yvonne Paterson 514 South 46 St. Philadelphia, PA 19143	873,412(30)	704,365	--	2.37%	0.46%	
Amnon Mandelbaum c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	1,766,559 (31)	1,766,559 (31)	35,332	4.73%	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)
David Goodriend c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	194,193 (32)	194,193 (32)	3,884	0.53%	0.0%	--
David Filer 165 East 32 Street New York, NY 10016	382,772 (33)	382,772 (33)	5,704	1.04%	0.0%	(32)(a)
Marcia Kucher c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	4,140 (34)	4,140 (34)	83	0.01%	0.0%	--
Nathan Low c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	1,886,224 (35)	1,886,224 (35)	37,725	5.04%	0.0%	--
Derek Caldwell c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	153,658 (36)	153,658 (36)	3,074	0.42%	0.0%	--
Sunrise Securities Corp. (x) 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	731,707(37)	731,707(37)	14,634	1.98%	0.0%	(37)(a)
Richard Stone c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	307,317(38)	307,317(38)	6,146	0.83%	0.0%	--
Sunrise Foundation Trust (y) c/o Sunrise Securities Corp. 641 Lexington Avenue 25 <sup>th</sup> Floor New York, NY 10022	71,497(38)(a)	71,497	1,430	0.19%	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)
Martin Trust Agreement U/A/ DTD 11/05/01 Peter L. Martin TTE 3757 Wedbster St, Apt 203 San Francisco, CA 94123	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
A. Heifetz Technologies Ltd. (z) 22 Kanfey Nesharim St Jerusalem, Israel 95464	348,432 (3)	348,432 (3)	3,484	0.95%	0.0%	--
Balestra Spectrum Partners, LLC (aa) 1185 Avenue of the Americas 32 <sup>nd</sup> Floor New York, NY 10036	1,045,296 (9)	1,045,296 (9)	10,453	2.81%	0.0%	--
Reitler Brown Holdings, LLC (bb) 800 Third Avenue 21 <sup>st</sup> Floor New York, NY 10022	60,000 (39)	60,000 (39)	--	0.16%	0.0%	(39)(a)
Harvest Advaxis LLC (cc) 30052 Aventura, Suite C Rancho Santa Margarita, CA 92688	7,665,506 (40)	4,665,506 (40)	76,655	18.92%	0.0%	--
Miles Wynn P.O. Box 440842 Aurora , CO 80044	696,700	696,700	--	1.90%	0.0%	--
Teresa Waz 3679 S. Dawson St. Aurora, CO 80444	26,900	26,900	--	0.07%	0.0%	--
Ormonde Frew 19996 E. Greenwood Drive Aurora, CO 80013	12,000	12,000	--	0.03%	0.0%	--
Ralph Grills 4042 S. Atchison Way Aurora, CO 80014	12,000	12,000	--	0.03%	0.0%	--
Daniel Unrein 281 S. Leyden St. Denver, CO 80220	2,500	2,500	--	0.01%	0.0%	--
Frederick Malkhe 4105 E. Florida Ave. Suite 100 Denver, CO 80222	2,500	2,500	--	0.01%	0.0%	--

- (a) Rima Salam has voting and disposition rights on behalf of A1 International Corporate Holdings, Ltd.
- (b) Alan Gelbard has voting and disposition rights on behalf of Alan Gelband Company Defined Contribution pension plan and Trust.
- (c) Hal Beretz has voting and disposition rights on behalf of Beretz Family Partners LLP.
- (d) David Fuchs has voting and disposition rights on behalf of Bridges & Pipes LLC.
- (e) Roni Appel has voting and disposition rights on behalf of Carmel Ventures, Inc.
- (f) Mitchell P. Kopin, president of Downsview Capital Inc., the general partner of Cranshire Capital, L.P, has voting and disposition rights.
- (g) Ran Nizan has voting and disposition rights on behalf of Crestwood Holdings, LLC.
- (h) Haim Rolnitsky has voting and disposition rights on behalf of Design Investments Ltd.
- (i) Howard Milstein and John Hart have voting and disposition rights on behalf of Emigrant Capital Corp.
- (j) Joseph Franck has voting and disposition rights on behalf of Fawdan Investments Ltd.
- (k) Scott Flamm has voting and disposition rights on behalf of Flamm Family Partners LP.
- (l) Frederick Berdon has voting and disposition rights on behalf of Fred Berdon Co., LP.
- (m) Howard Kaye, the managing partner, has voting and disposition rights on behalf of Kay Family Fund.
- (n) Pershing IMS has voting and disposition rights on behalf of IRA FBO / Walter S. Grossman.
- (o) Albert Chabot has voting and disposition rights on behalf of MEA Group
- (p) Yacov Reizman and Leon Recanati have voting and disposition rights on behalf of New Bank Ltd.
- (q) Shoshana Loeb has voting and disposition rights on behalf of Open Ventures, LLC.
- (r) Jeff Davidowitz has voting and disposition rights on behalf of Penn Footwear Retirement Trust.
- (s) Eric Richardson has voting and disposition rights on behalf of RP Capital, LLC.
- (t) Edwin Mecabe and Tai May Lee jointly have voting and disposition rights on behalf of SRB Capital LLC.
- (u) Nathan Low, Marilyn Adler and Amnon Mandelbaum are the managers of Level Counter, LLC, the general partner of Sunrise Equity Partners, L.P. The unanimous vote of such managers is required for voting and disposition rights.
- (v) Walter Schenker and Steven Slawson have voting and disposition rights on behalf of Titan Capital Management LLC.
- (w) Morten Kiellan has voting and disposition rights on behalf of Trinita, LLC.
- (x) Nathan Low has voting and disposition rights on behalf of Sunrise Securities Corp.
- (y) Nathan Low is a trustee.
- (z) Avit Heifetz has voting and disposition rights on behalf of A. Heifetz Technologies Ltd.
- (aa) James L. Melcher has voting and disposition rights on behalf of Balestra Spectrum Partners, LLC.
- (bb) Robert Brown, Scott Rosenblatt, Edward G. Reitler and John Watkins have voting and disposition rights on behalf of Reitler Brown Holdings, LLC.
- (cc) Robert Harvey has voting and disposition rights on behalf of Harvest Advaxis,, LLC.

- (1) Reflects 35,395 shares of common stock 44,205 warrants to purchase shares of common stock.
- (2) Reflects 87,108 shares of common stock and 87,108 warrants to purchase shares of common stock.
- (3) Reflects 174,216 shares of common stock and 174,216 warrants to purchase shares of common stock.
- (4) Reflects 696,864 shares of common stock and 696,864 warrants to purchase shares of common stock.
- (5) Reflects 355,528 shares of common stock, 413,441 warrants to purchase shares of common stock and 91,567 options exercisable for shares of common stock.
- (5)(a) Reflects 355,528 shares of common stock and 355,528 warrants to purchase shares of common stock
- (5)(b) Carmel Ventures, Inc. has performed consulting services for us and is owned by Roni Appel, our chief financial officer, director and principal shareholder.
- (6) Reflects 52,833 shares of common stock and 52,883 warrants to purchase shares of common stock.
- (7) Reflects 87,297 shares of common stock and 109,074 warrants to purchase shares of common stock.
- (7)(a) Reflects 87,297 shares of common stock and 87,297 warrants to purchase shares of common stock.
- (8) Reflects 271,260 shares of common stock and 219,973 warrants to purchase shares of common stock.
- (8)(a) Reflects 271,260 shares of common stock and 211,063 warrants to purchase shares of common stock.
- (9) Reflects 522,648 shares of common stock and 522,648 warrants to purchase shares of common stock.
- (10) Reflects 244,933 shares of common stock and 115,320 warrants to purchase shares of common stock.
- (10)(a) Reflects 266,933 shares of common stock and 93,046 warrants to purchase shares of common stock.
- (11) Reflects 348,432 shares of common stock and 348,432 warrants to purchase shares of common stock.
- (12) Reflects 1,742,160 shares of common stock and 1,742,160 warrants to purchase shares of common stock.
- (13) Reflects 106,272 shares of common stock and 248,827 warrants to purchase shares of common stock.
- (13)(a) Reflects 106,272 shares of common stock and 106,272 warrants to purchase shares of common stock.
- (14) Reflects 2,585,094 shares of common stock and 45,141 warrants to purchase shares of common stock.
- (14)(a) Reflects 2,621,325 shares of common stock and 36,231 warrants to purchase shares of common stock.
- (14)(b) The general partner of Flamm Family Partners is Scott Flamm a director and principal shareholder.
- (15) Reflects 35,511 shares of common stock and 44,421 warrants to purchase shares of common stock.
- (15)(a) Reflects 35,511 shares of common stock and 35,511 warrants to purchase shares of common stock.
- (16) Reflects 261,324 shares of common stock and 261,324 warrants to purchase shares of common stock.
- (17) Reflects 70,093 shares of common stock and 87,515 warrants to purchase shares of common stock.
- (17)(a) Reflects 70,093 shares of common stock and 70,093 warrants to purchase shares of common stock.
- (18) Reflects 295,766 shares of common stock and 1,172,767 options to purchase shares of common stock and 368,815 shares of common stock issuable upon exercise of warrants.
- (18)(a) Reflects 295,766 shares of common stock and 295,766 warrants to purchase shares of common stock.
- (18)(b) Mr. Derbin is one of our directors and the chief executive officer.
- (19) 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 currently exercisable within the next 60 days.
- (19)(a) Reflects 2,820,576 shares of common stock and 14,7716 warrants to purchase shares of common stock.
- (19)(b) Dr. Patton is one of our directors.
- (20) Reflects 17,430 shares of common stock and 21,785 warrants to purchase shares of common stock.
- (20)(a) Reflects 17,430 shares of common stock and 17,430 warrants to purchase shares of common stock.
- (21) Reflects 35,865 shares of common stock and 44,775 warrants to purchase shares of common stock.
- (21)(a) Reflects 35,865 shares of common stock and 35,865 warrants to purchase shares of common stock.
- (22) Reflects 89,663 shares of common stock and 111,937 warrants to purchase shares of common stock.
- (22)(a) Reflects 89,663 shares of common stock and 89,663 warrants to purchase shares of common stock.
- (23) Reflects 98,664 shares of common stock and 98,664 warrants to purchase shares of common stock.
- (24) Reflects 126,658 shares of common stock and 157,842 warrants to purchase shares of common stock.
- (24)(a) Reflects 126,658 shares of common stock and 126,658 warrants to purchase shares of common stock.

- (25) Reflects 35,180 shares of common stock and 43,981 warrants to purchase shares of common stock.
- (25)(a) Reflects 35,180 shares of common stock and 35,180 warrants to purchase shares of common stock.
- (26) Reflects 35,401 shares of common stock and 44,311 warrants to purchase shares of common stock.
- (26)(a) Reflects 35,401 shares of common stock and 35,401 warrants to purchase shares of common stock.
- (27) Reflects 2,522,164 shares of common stock and 73,029 warrants to purchase shares of common stock..
- (27)(a) Reflects 2,522,164 shares of common stock and 58,580 warrants to purchase shares of common stock
- (27)(b) Mr. Appel is one of our directors and our chief financial officer and owner of Carmel Ventures, Inc., one of our stockholders and is employed by LVEP Management, LLC one of our consultants.
- (28) Reflects 125,772 shares of common stock, 156,956 warrants to purchase shares of common stock and 91,567 options.

- (28)(a) Reflects 125,772 shares of common stock and 125,772 warrants to purchase shares of common stock.
- (28)(b) Mr. Flamm is one of our directors and also the general partner of Flamm Family Partners, one of our stockholders and is the beneficial owner of LVEP Management, LLC one of our consultants.
- (29) Reflects 179,290 shares of common stock, 82,763 options and 112,823 warrants to purchase shares of common stock.
- (29)(a) Reflects 179,290 shares of common stock and 90,549 warrants to purchase shares of common stock.
- (29)(b) Mr. McKearn is one of our directors.
- (30) Reflects 704,365 shares of common stock and 169,048 options to purchase shares of common stock.
- (31) Reflects 1,094,020 shares of common stock warrants to purchase 672,539 shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (32) Reflects 119,466 shares of common stock and 74,727 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (33) Reflects 97,561 shares of common stock and 97,561 warrants to purchase shares of common stock, which securities were purchased in the private placement. In addition, includes 187,650 warrants to purchase common stock, which securities were received as compensation for consulting services rendered to Sunrise Securities Corp., the Company's Placement Agent.
- (34) Reflects 2,070 shares of common stock and 2,070 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of Sunrise Securities Corp. as Placement Agent. Dr. Filer is a consultant to Sunrise Securities Corp.
- (35) Reflects 1,124,253 shares of common stock owned by Mr. Low and warrants to purchase 761,971 shares of common stock owned by Mr. Low, all of which securities were received as compensation in the ordinary course of selling Stockholder's employer, business of Sunrise Capital as Placement Agent.
- (36) Reflects 80,488 shares of common stock and 73,170 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (37) Reflects 383,275 shares of common stock and 348,432 warrants to purchase shares of common stock. Nathan Low is the sole director and stockholder, with 100% beneficial ownership and voting and disposition rights.
- (37)(a) Our placement agent in connection with the Private Placement discussed in this prospectus.
- (38) Reflects 160,976 shares of common stock and 146,341 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (38)(a) Sunrise Foundation Trust is a charitable trust of which Nathan Low, owner of Sunrise Securities Corp., is a trustee.
- (39) Reflects 60,000 warrants to purchase shares of common stock.
- (39)(a) Reitler Brown Holdings, LLC is an affiliate of our legal counsel in connection with this prospectus.
- (40) Reflects 3,832,753 shares of common stock and warrant to purchase 3,832,753 shares of common stock.
- (41) We license our intellectual property from Penn through an exclusive license.
- (32) Reflects 119,466 shares of common stock and 74,727 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (33) Reflects 97,561 shares of common stock and 285,211 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of Sunrise Securities Corp. as Placement Agent.
- (34) Reflects 2,070 shares of common stock and 2,070 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of Sunrise Securities Corp. as Placement Agent. Dr. Filer is a consultant to Sunrise Securities Corp.
- (35) Reflects 1,124,253 shares of common stock owned by Mr. Low and warrants to purchase 761,971 shares of common stock owned by Mr. Low, all of which securities were received as compensation in the ordinary course of business of Sunrise Capital as Placement Agent.
- (36) Reflects 80,488 shares of common stock and 73,170 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (37) Reflects 383,275 shares of common stock and 348,432 warrants to purchase shares of common stock. Nathan Low is the sole director and stockholder, with 100% beneficial ownership and voting and disposition rights.
- (37)(a) Our placement agent in connection with the Private Placement discussed in this prospectus.
- (38) Reflects 160,976 shares of common stock and 146,341 warrants to purchase shares of common stock, all of which securities were received as compensation in the ordinary course of business of the selling Stockholder's employer, Sunrise Securities Corp. as Placement Agent.
- (38)(a) Sunrise Foundation Trust is a charitable trust of which Nathan Low, owner of Sunrise Securities Corp., is a trustee.
- (39) Reflects 60,000 warrants to purchase shares of common stock.
- (39)(a) Reitler Brown Holdings, LLC is an affiliate of our legal counsel in connection with this prospectus.
- (40) Reflects 3,832,753 shares of common stock and warrant to purchase 3,832,753 shares of common stock.

## Blue Sky

Thirty-five states have what is commonly referred to as the "standard manual exemption" for secondary trading of securities such as those to be resold by selling stockholders under this registration statement. In these states, so long as we obtain and maintain a listing in one of the commonly accepted standard manuals e.g. Standard and Poor's Corporate Manual, and the manual sets forth certain information: (1) the names of our officers and directors, (2) our balance sheet, and (3) our profit and loss statement for either the fiscal year preceding the balance sheet or for the most recent fiscal year of operations, secondary trading can occur without any filing, review or approval by state regulatory authorities in these states. These states are: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Delaware, Hawaii, Idaho, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Texas, Utah, Washington, West Virginia, and Wyoming. We cannot secure this listing, and thus this qualification, until after this registration statement is declared effective. Once we secure this listing, secondary trading can occur in these states without further action.



We currently do not intend to and may not be able to qualify securities for resale in other states which require shares to be qualified before they can be resold by our stockholders; provided however that we intend to take appropriate action to qualify securities for resale in the State of New York.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act of 1933.

Because selling stockholders may be deemed to be “underwriters” within the meaning of the Securities Act of 1933, they will be subject to the prospectus delivery requirements of the Securities Act of 1933. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act of 1933 may be sold under Rule 144 rather than under this prospectus. Each selling stockholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of the date which is three years after this registration has been declared effective by the SEC, or such earlier date as of which all of the common stock registered for resale hereunder has been sold. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholder or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

## DESCRIPTION OF CAPITAL STOCK OF THE COMPANY

### General

At the date hereof we are authorized by our articles of incorporation to issue an aggregate of 500,000,000 shares of common stock, par value \$0.001 per share and 5,000,000 shares of "blank check" preferred stock, par value \$0.001 per share. 36,690,056 shares of common stock are outstanding and held of record by 83 stockholders and no shares of convertible preferred stock will be outstanding.

### Common Stock

Holders of common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. There is no cumulative voting for the election of directors. Subject to the prior rights of any class or series of preferred stock which may from time to time be outstanding, if any, holders of common stock are entitled to receive ratably, dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution, or winding up, are entitled to share ratably in all assets remaining after payment of liabilities and payment of accrued dividends and liquidation preferences on the preferred stock, if any. Holders of common stock have no preemptive rights and have no rights to convert their common stock into any other securities. The outstanding common stock is validly authorized and issued, fully-paid and nonassessable.

The shares of common stock offered in this prospectus have been fully paid and not liable for further call or assessment. Holders of the common stock do not have cumulative voting rights, which means that the holders of more than one half of the outstanding shares of common stock, subject to the rights of the holders of the preferred stock, if any, can elect all of our directors, if they choose to do so. In this event, the holders of the remaining shares of common stock would not be able to elect any directors. Except as otherwise required by Colorado law, and subject to the rights of the holders of preferred stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy.

### Preferred Stock

We are authorized to issue up to 5,000,000 shares of "blank check" preferred stock. Preferred stock may be issued in one or more series and having the rights, privileges and limitations, including voting rights, conversion privileges and redemption rights, as may, from time to time, be determined by the board of directors. Preferred stock may be issued in the future in connection with acquisitions, financings, or other matters as the board of directors deems appropriate. In the event that any shares of preferred stock are to be issued, a certificate of designation containing the rights, privileges and limitations of such series of preferred stock shall be filed with the Secretary of State of the State of Colorado. The effect of such preferred stock is that, subject to Federal securities laws and Colorado law, the board of directors alone, may be able to authorize the issuance of preferred stock which could have the effect of delaying, deferring, or preventing a change in control of the Company without further action by the stockholders, and may adversely affect the voting and other rights of the holders of the common stock. The issuance of preferred stock with voting and conversion rights may also adversely affect the voting power of the holders of common stock, including the loss of voting control to others.

### Stock Symbol; No Trading of common stock

Currently there is no market for our securities, however Vfinance Investment has filed a form 15c2ll with NASD to become a market maker.

We have applied for trading on the OTC Bulletin Board. At this time there is no symbol.

## **Transfer Agent and Registrar**

The transfer agent and registrar for the common stock is Securities Transfer Corporation, 2591 Dallas Parkway, Suite 102, Frisco, TX 75034.

## **Directors' Limitation of Liability**

Our articles of incorporation and by-laws include provisions to (1) indemnify the directors and officers to the fullest extent permitted by the Colorado Revised Statutes, including circumstances under which indemnification is otherwise discretionary and (2) eliminate the personal liability of directors and officers for monetary damages resulting from breaches of their fiduciary duty, except for liability for breaches of the duty of loyalty, acts, or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, violations under Section 7-108-704 of Colorado Law, or for any transaction from which the director derived an improper personal benefit. We believe that these provisions are necessary to attract and retain qualified persons as directors and officers.

We will enter into an indemnification agreement with each of our directors which provides that we will indemnify our directors and advance expenses to our directors, to the extent permitted by the laws of the State of Colorado.

We have directors and officers liability insurance in an amount of \$1 million.

Insofar as indemnification for liability arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons as stated in the foregoing provisions or otherwise, we have been advised that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

## SHARES OF THE COMPANY ELIGIBLE FOR FUTURE SALE

Prior to the date of this prospectus, there has been a limited public market for our common stock. Sales of substantial numbers of shares of our common stock in the public market following this Offering, or the perception that such sales may occur, could adversely affect prevailing market prices of our shares.

Assuming no exercise of options outstanding, or up 671,994 warrants to purchase shares of our common stock, and assuming exercise of 19,630,588 warrants to purchase shares of our common stock, there are 56,730,045 shares of our common stock issued and outstanding as of the date of this prospectus. These shares of common stock will be deemed to be “*restricted securities*” under Rule 144. Restricted securities may only be sold in the public market pursuant to an effective registration statement under the Act or pursuant to an exemption from registration under Rule 144, Rule 701 or Rule 904 under the Act. These rules are summarized below.

### Eligibility of Restricted Shares for Sale in the Public Market

As of the date of this prospectus no shares may be eligible for resale, 46,586,560 shares of common stock may become eligible for resale under Rule 144 on November 12, 2005, 1,671,080 shares of common stock may be eligible for resale under Rule 144 on December 8, 2005, 1,069,491 shares of common stock may be eligible for resale under Rule 144 on January 4, 2006, 7,665,606 shares of common stock may be eligible for resale under Rule 144 on January 12, 2006, and 409,401 shares of common stock may be eligible for resale under Rule 144 on May 10, 2006, in each case subject to volume, manner of sale and other limitations under Rule 144.

All shares of Common Stock of shareholders whose shares are included in the foregoing calculations are included in the shares of Common Stock being registered in this Registration Statement.

### Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of common stock for at least one year is entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1.0% of the number of shares of common stock outstanding, which is approximately 366,900 shares of common stock; or
- the average weekly trading volume of the shares of common stock during the four calendar weeks preceding the filing of a notice on Form 144 in connection with the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. In addition, under Rule 144(k) as currently in effect, a person:

- who is not considered to have been one of our affiliates at any time during the 90 days preceding a sale; and
- who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate,

is entitled to sell his shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

## Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants, or advisors (other than affiliates) who purchased shares of common stock from us under a compensatory stock option plan or other written agreement before the closing of the Share Exchange is entitled to resell these shares. These shares can be resold 90 days after the effective date of the Share Exchange in reliance on Rule 144, without having to comply with restrictions, including the holding period, contained in Rule 144. However, the 2004 Plan has a lock-up provision and shares issued under it are not eligible for resale at this time. Pursuant to such lock-up provision any common stock or other equity securities issued or issuable upon exercise of an option may not be sold, transferred or disposed of until the earlier of (i) the date that this registration statement has been filed with and declared effective by the SEC, and (ii) November 12, 2005, 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 such lock-up provision to the same extent as if they had originally been a party hereto.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act of 1934, along with the shares acquired upon exercise of these options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above, beginning 90 days after the date of this prospectus, may be sold:

- by persons other than affiliates subject only to the manner of sale provisions of Rule 144; and
- by affiliates under Rule 144 without compliance with its one year minimum holding period requirement.

## Options

We intend to file one or more registration statements on Form S-8 under the Act to register 2,381,525 shares of common stock reserved for issuance under our stock option plans. The registration statement on Form S-8 will become effective automatically upon filing. As of the date of this prospectus, options to purchase 2,182,894 shares of common stock were issued and outstanding, of which options to purchase approximately 1,400,988 shares of common stock had vested and had not been exercised. Shares of common stock issued upon exercise of a share option and registered under the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates and the lock-up provision described above, be available for sale in the open market immediately.

## Lock Up of Certain Shares

We have secured the agreement of all persons who received their shares of common stock by reason of securities ownership in Advaxis prior to the Share Exchange to not sell, transfer, pledge or otherwise dispose of such shares during the period from 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 date hereof, 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. A total of 17,734,163 shares of Common Stock and 2,808,434 shares of Common Stock underlying exercisable warrants are subject to such agreement.

## PLAN OF DISTRIBUTION

The selling stockholders, and any of their pledgees, assignees and successors-in-interest, may from time to time, sell any or all of their shares of our common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits Investors;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales (other than short sales established prior to the effectiveness of the Registration Statement to which this Prospectus is a part)
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, if available, rather than under this prospectus.

Broker-dealers engaged by selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each selling stockholder does not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the registrable securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common Stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon us being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act of 1933, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out in this prospectus, and (vi) other facts material to the transaction. In addition, upon us being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act of 1933. Each selling stockholder has represented and warranted to us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act of 1933.

## LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Frasca, Joiner, Goodman and Greenstein, PC.

## EXPERTS

The financial statements appearing in this prospectus and registration statement have been audited by Goldstein Golub Kessler LLP, independent accountants; to the extent and for the periods indicated in their report appearing elsewhere herein, and are included in reliance upon such report and upon the authority of such firms as experts in accounting and auditing.

## ADDITIONAL INFORMATION

We filed with the SEC a registration statement on Form SB-2 under the Securities Act of 1933 for the shares of common stock in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits that were filed with the registration statement. Statements contained in this prospectus about the contents or any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules that were filed with the registration statement may be inspected without charge at the Public Reference Room maintained by the SEC at 450 Fifth Street, N.W., Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 800-SEC-0330. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov).

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, and in accordance with the Securities Exchange Act of 1934, we file annual, quarterly and special reports, and other information with the SEC. These periodic reports, and other information are available for inspection and copying at the regional offices, public reference facilities and website of the SEC referred to above.



# FINANCIAL STATEMENTS

<b>Report of Independent Registered Public Accounting Firm</b>	F-2
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## **Financial Statements:**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of  
Advaxis, Inc.

We have audited the accompanying balance sheets of Advaxis, Inc. (a development stage company) as of December 31, 2002 and 2003 and October 31, 2004, and the related statements of operations, shareholders' equity (deficiency), and cash flows for the period from March 1, 2002 (inception) to December 31, 2002, the year ended December 31, 2003, the period from January 1, 2004 to October 31, 2004, and the period from March 1, 2002 (inception) to October 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the Standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Advaxis, Inc. as of December 31, 2002 and 2003 and October 31, 2004, and the results of its operations and its cash flows for the period from March 1, 2002 (inception) to December 31, 2002, the year ended December 31, 2003, the period from January 1, 2004 to October 31, 2004 and the period from March 1, 2002 (inception) to October 31, 2004 in conformity with United States generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses from operations, has a working capital deficiency and has a shareholders' deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 1. These financial statements do not include any adjustments that may result from the outcome of this uncertainty.

GOLDSTEIN GOLUB KESSLER LLP  
New York, New York

April 21, 2005

**ADVAXIS, INC.**  
**(a development stage company)**  
**BALANCE SHEET**

	2002	December 31, 2003	October 31, 2004	January 31, 2005 (unaudited)
<b>ASSETS</b>				
Current Asset - cash	\$ 204,382	\$ 47,160	\$ 32,279	\$ 3,217,430
Intangible Assets		277,243	469,804	666,447
Other Assets				2,450
<b>Total Assets</b>	<b>\$ 204,382</b>	<b>\$ 324,403</b>	<b>\$ 502,083</b>	<b>\$ 3,886,327</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)</b>				
Current Liabilities:				
Accounts payable	\$ 85,825	\$ 1,018,936	\$ 823,152	\$ 435,280
Notes payable, current portion		25,408	\$ 605,190	258,237
<b>Total current liabilities</b>	85,825	1,044,344	1,428,342	693,517
Notes Payable, net of current portion	40,000	86,794	413,237	230,000
<b>Total liabilities</b>	125,825	1,131,138	1,841,579	923,517
Commitments and Contingencies				
Shareholders' Equity (Deficiency):				
Common stock - \$0.001 par value; authorized 500,000,000 shares, issued and outstanding 15,557,723 at December 31, 2002 and 2003 and October 31, 2004 and 36,690,046 shares at January 31, 2005	15,598	15,598	15,598	36,690
Additional paid-in capital	229,895	254,348	303,547	4,830,116
Deficit accumulated during the development stage	(166,936)	(1,076,681)	(1,658,641)	(1,903,996)
<b>Shareholders' equity (deficiency)</b>	78,557	(806,735)	(1,339,496)	2,962,810
<b>Total Liabilities and Shareholders' Equity (Deficiency)</b>	<b>\$ 204,382</b>	<b>\$ 324,403</b>	<b>\$ 502,083</b>	<b>\$ 3,886,327</b>

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

**ADVAXIS, INC.**  
**(a development stage company)**  
**STATEMENT OF OPERATIONS**

	Period from March 1, 2002 (inception) to December 31, 2002	Year ended December 31, 2003	Ten Month Period ended October 31, 2003 (unaudited)	Ten Month Period ended October 31, 2004	Period from March 1, 2002 (inception) to October 31, 2004	Three-month period ended January 31, 2004 (unaudited)	Three-month period ended January 31, 2005 (unaudited)	Period from March 1, 2002 (inception) to January 31, 2005 (unaudited)
Revenue		\$ 4,000	\$ 3,600	\$ 116,406	\$ 120,406	\$ 400		\$ 120,406
Research and development expenses	\$ 50,899	491,508	446,324	125,942	668,349	86,842	\$ 218,951	887,300
General and administrative expenses	117,003	405,568	375,403	524,368	1,046,939	45,399	26,175	1,073,114
Interest expense		17,190	8,288	4,229	21,419	10,655	2,968	24,387
Other income	966	521	506	57	1,544	30	2,739	4,283
Net loss	(166,936)	(909,745)	(825,907)	(538,076)	(1,614,757)	(142,466)	(245,355)	(1,860,112)
Dividends attributed to preferred stock				43,884	43,884			43,884
Net loss applicable to common stock	\$ (166,936)	\$ (909,745)	\$ (825,907)	\$ (581,960)	\$ (1,658,641)	\$ (142,466)	\$ (245,355)	\$ (1,903,996)
Basic and diluted net loss per share	\$ (0.01)	\$ (0.06)	\$ (0.05)	\$ (\$0.04)	\$ (\$0.11)	\$ (0.01)	\$ (0.01)	\$ (0.11)
Weighted-average number of shares, basic and diluted	15,597,723	15,597,723	15,597,723	15,597,723	15,597,723	15,597,723	31,181,332	16,941,389

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

**STATEMENT OF SHAREHOLDERS' EQUITY (DEFICIENCY)**

**Period from March 1, 2002 (inception) to January 31, 2005**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Shareholders' Equity (Deficiency)
	Number of Shares Outstanding	Amount	Number of Shares Outstanding	Amount			
Preferred stock issued	3,418.18	\$ 235,000					\$ 235,000
Common stock issued			40,000	\$ 40	\$ (40)		
Options granted to consultants and professionals					10,493		10,493
Net loss						\$ (166,936)	(166,936)
Retroactive restatement to reflect recapitalization on November 12, 2004	(3,418.18)	(235,000)	15,597,723	15,558	219,442		
Balance at December 31, 2002	- 0 -	- 0 -	15,597,723	15,598	229,895	(166,936)	78,557
Note payable converted into preferred stock	232.27	15,969					15,969

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

Options granted to consultants and professionals					8,484		8,484
Net loss						(909,745)	(909,745)
Retroactive restatement to reflect recapitalization on November 12, 2004	(232.27)	(15,969)			15,969		
Balance at December 31, 2003	- 0 -	- 0 -	15,597,723	15,598	254,348	(1,076,681)	(806,735)
Stock dividend on preferred stock	638.31	43,884				(43,884)	
Net loss						(538,076)	(538,076)
Options granted to consultants and professionals					5,315		5,315
Retroactive restatement to reflect recapitalization on November 12, 2004	(638.31)	(43,884)			43,884		
Balance at October 31, 2004	- 0 -	- 0 -	15,597,723	15,598	303,547	(1,658,641)	(1,339,496)
(Unaudited):							
Common Stock issued to Placement Agent on recapitalization			752,600	753	(753)		
Effect of recapitalization			752,600	752	(752)		
Options granted to consultants and professionals							
Conversion of Note payable to Common Stock			2,136,441	2,136	611,022		613,158
Issuance of Common Stock for cash, net of shares to Placement Agent			17,450,693	17,451	4,335,549		4,353,000
Issuance Costs					(329,673)		(329,673)
Net loss						(245,355)	(245,355)

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

Restatement to reflect recapitalization on November 12, 2004 including cash paid of \$44,940							(88,824)		(88,824)				
Balance at January 31, 2005	\$	- 0 -	\$	- 0 -	36,690,057	\$	36,690	\$	4,830,116	\$	(1,903,996)	\$	2,962,810

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

**ADVAXIS, INC.**  
**(a development stage company)**  
**STATEMENT OF CASH FLOWS**

	Period from March 1, 2002 (inception) to December 31, 2002	Year ended December 31, 2003	Tenth Month Period ended October 31 2003	Tenth Month Period ended October 31 2004	Period from March 1, 2002 (inception) to October 31, 2004	Three-month period ended January 31, 2004	Three-month period ended January 31, 2005	Period from March 1, 2002 (inception) to January 31, 2005
			(unaudited)			(unaudited)	(unaudited)	(unaudited)
Cash flows from operating activities:								
Net loss	\$ (166,936)	\$ (909,745)	(825,907)	(538,076)	(1,614,757)	\$ (142,466)	\$ (245,355)	\$ (1,860,112)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:								
Value assigned to options given as payment to consultants and professionals	10,493	8,484		5,315	24,292	8,484		24,292
Amortization expense		3,171		15,818	18,989	800	6,817	25,806
Accrued interest on notes payable							7,968	7,968
Increase in Other Assets							(2,450)	(2,450)
Increase (decrease) in accounts payable	85,825	933,111	840,037	80,307	1,099,243	102,910	(356,756)	742,487
<b>Net cash provided by (used in) operating activities</b>	<b>(70,618)</b>	<b>35,021</b>	<b>14,130</b>	<b>(436,636)</b>	<b>(472,233)</b>	<b>(30,272)</b>	<b>(589,776)</b>	<b>(1,062,009)</b>
CASH FLOWS USED IN INVESTING ACTIVITIES:								
Cash paid on acquisition of Great Expectations							(44,940)	(44,940)
Cost of Intangible Assets		(277,243)	(217,133)	(124,469)	(401,712)	(30,228)	(203,460)	(605,172)
Net cash used in Investing Activities		(277,243)	(217,133)	(124,469)	(401,712)	(30,228)	(248,400)	(650,112)
Cash flows from financing activities:								
Proceeds from notes payable	40,000	85,000		546,224	671,224	87,203		671,224
Net proceeds on issuance of preferred stock	235,000				235,000			235,000
Net Proceeds on Issuance of Common Stock							4,023,327	4,023,327
<b>Cash provided by financing activities</b>	<b>275,000</b>	<b>85,000</b>		<b>546,224</b>	<b>906,224</b>	<b>87,203</b>	<b>4,023,327</b>	<b>4,929,551</b>
Net increase (decrease) in cash	204,382	(157,222)	(203,003)	(14,881)	32,279	26,703	3,185,151	3,217,430
Cash at beginning of period		204,382	204,382	47,160		1,379	32,279	
Cash at end of period	\$ 204,382	\$ 47,160	\$ 1,379	\$ 32,279	\$ 32,279	\$ 28,082	\$ 3,217,430	\$ 3,217,430

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.



	Period from March 1, 2002 (inception) to December 31, 2002	Year ended December 31, 2003	Tenth Month Period ended October 31, 2003	Tenth Month Period ended October 31, 2004	Period from March 1, 2002 (inception) to December 31, 2003	Three months ended January 31, 2005	Three months ended January 31, 2004	Period from March 1, 2002 (Inception) January 31, 2005
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:								
Common Stock issued to founders	\$ 40				\$ 40			\$ 40
Notes Payable and Accrued Interest Converted to Preferred Stock		\$ 15,969	\$ 15,969		\$ 15,969			\$ 15,969
Stock Dividend on Preferred Stock				\$ 43,884	\$ 43,884			\$ 43,884
Notes Payable and Accrued Interest Converted to Common							\$ 631,158	\$ 613,158
Intangible Assets Acquired with Notes Payable				\$ 360,000	\$ 360,000			\$ 360,000

The accompanying notes and the report of independent registered public accounting firm should be read in conjunction with the financial statements.

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and  
2004 is unaudited)

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1. **PRINCIPAL  
BUSINESS  
ACTIVITY AND  
SUMMARY OF  
SIGNIFICANT  
ACCOUNTING  
POLICIES:**

Advaxis, Inc. (the "Company") was incorporated in 2002 and is a biotechnology company researching and developing new cancer-fighting techniques.

The Company is in the development stage and its operations are subject to all of the risks inherent in an emerging business enterprise. The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As shown in the financial statements, the Company has incurred losses from operations, and has a working capital deficit of \$971,776 and \$1,396,063, and a shareholders' deficiency of \$806,735 , and \$1,339,496 at December 31, 2003 and October 31, 2004 , respectively. Management has raised (see Note 8) and will continue to raise additional funds through equity and is working to develop technologies that will generate revenue that will allow the Company to continue as a going concern. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

In accordance with Securities and Exchange Commission (SEC) 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, the Company 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.

The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits.

Intangible assets, which consist primarily of legal costs in obtaining trademarks and patents, are being amortized on a straight-line basis over 15 and 17 years, respectively.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition exceeds its carrying amount. The amount of impairment loss, if any, is measured as the difference between the net book value of the asset and its estimated fair value.

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and  
2004 is unaudited)

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Basic loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the periods. Diluted earnings per share gives effect to dilutive options, warrants and other potential common stock outstanding during the period. Potential common stock has not been included in the computation of diluted loss per share, as the effect would be antidilutive.

Deferred income taxes are provided for the differences between the bases of assets and liabilities for financial reporting and income tax purposes. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the use of estimates by management. Actual results could differ from these estimates.

The estimated fair value of the notes payable approximates the carrying amount based on the rates available to the Company for similar debt.

Accounts payable consists entirely of trade accounts payable.

Research and development costs are charged to expense as incurred.

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

**NOTES TO FINANCIAL STATEMENTS**  
**(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)**

The Company has elected to apply APB Opinion No. 25 and related interpretations in accounting for its stock options granted to employees and has adopted the disclosure-only provisions of SFAS No. 123. Had the Company elected to recognize compensation cost based on the fair value of the options granted at the grant date as prescribed by SFAS No. 123, the Company's net loss would have been as follows:

	March 1, 2002 (date of inception) to December 31, 2002	Year ended December 31, 2003	10 months ended October 31, 2003	10 months ended October 31, 2004	3 months ended January 31 2004	3 months ended January 31, 2005
Net Loss as reported	\$ (166,936)	\$ (909,745)	\$ (825,907)	\$ (538,076)	\$ (142,466)	\$ (245,355)
Deduct stock option compensation expense determined under fair value based method	(8,566)	(32,923)	(30,199)	(70,019)	(22,612)	(18,573)
<b>Adjusted Net Loss</b>	<b>\$ (175,502)</b>	<b>\$ (942,668)</b>	<b>\$ (856,106)</b>	<b>\$ (608,095)</b>	<b>\$ (165,078)</b>	<b>\$ (263,928)</b>
Net Loss per share as reported	\$ (0.01)	\$ (0.06)	\$ (0.05)	\$ (0.04)	\$ (0.01)	\$ (0.01)
Net Loss per share pro forma	\$ (0.01)	\$ (0.06)	\$ (0.05)	\$ (0.04)	\$ (0.01)	\$ (0.01)

The Company accounts for nonemployee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments in accordance with the guidance provided in the consensus opinion of the Emerging Issues Task Force ("EITF") Issue 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction With Selling Goods or Services*.

The accompanying unaudited interim financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and the requirements of item 310(b) of Regulation S-B. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. The results of operations for the three-month period ended January 31, 2005 are not necessarily indicative of the results of operations expected for the year ended October 31, 2005.

In the opinion of management, the accompanying unaudited interim financial statements for the nine-month periods ended September 30, 2004 and 2003 include all adjustments (consisting only of those of a normal recurring nature) necessary for a fair statement of the results of the interim period.

**NOTES TO FINANCIAL STATEMENTS**  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)

2. **INTANGIBLE ASSETS:** Intangible assets consist of the following:

	December 31, 2003	October 31, 2004
Trademarks	\$ 8,243	\$ 8,243
Patents		117,377
License	269,000	360,000
Less: Accumulated Amortization		(15,818)
	\$ 277,243	\$ 469,804

During the ten-month period ended October 31, 2004, the Company renegotiated certain payables with its attorney which reduced intangible assets by \$98,090.

Estimated amortization expense is as follows:

Year ending October 31,	
2005	\$ 24,281
2006	24,281
2007	24,281
2008	24,281
2009	24,281

During the three-month period ended January 31, 2005, the Company acquired \$203,460 of new patents. Amortization expense during the period amounted to \$6,817.

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)

3. NOTES PAYABLE:

Notes payable consist of the following:

	December 31, 2003	December 31, 2002	October 31 2004
Note payable with interest at 6% per annum, due on December 31, 2005. The amount is mandatorily convertible at the time of the closing of the Company's contemplated \$2,000,000 equity financing into the same class of shares issued at the equity financing at a conversion price per share equivalent to the price per share in the equity financing. Upon closing of an equity financing which is less than \$2,000,000, the holder has the right to convert, at the holder's option, into the same class of shares issued at the equity financing at a conversion price per share equivalent to the price per share in the equity financing.	\$ 10,060		\$ 605,190
Note payable with interest at 8% per annum, due on November 10, 2008.	10,112		10,647
Note payable with interest at 8% per annum, due on December 17, 2008.	40,122		42,590
Note payable with interest at 6% per annum, due on December 31, 2004. The amount is mandatorily convertible at the time of the closing of the Company's contemplated \$2,000,000 equity financing into the same class of shares issued at the equity financing at a conversion price per share equivalent to the price per share in the equity financing. Upon closing of an equity financing which is less than \$2,000,000, the holder has the right to convert, at the holder's option, into the same class of shares issued at the equity financing at a conversion price per share equivalent to the price per share in the equity financing.	25,408		
Notes payable with no interest, due on December 15, 2006.			130,000
Notes payable with no interest, due on December 15, 2007.			230,000

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)

(continued)

	December 31,		October 31
	2003	2002	2004
Note payable with interest at 6% per annum, due on June 30, 2005. The amount is convertible at the holder's option into Series A convertible preferred stock at a price per share of \$68.75.	\$ 26,500	\$ 25,000	
Note payable with interest at 6% per annum, due and payable on June 30, 2005. The amount is convertible at the holder's option into Series A convertible preferred stock at a price per share of \$68.75. The full amount of this note plus accrued interest of \$969 was converted into 232.27 shares of Series A preferred stock on September 22, 2003.		15,000	
	112,202	40,000	1,018,427
Less current portion	25,408		605,190
	\$ 86,794	\$ 40,000	\$ 413,237

Aggregate maturities of notes payable at October 31, 2004 are as follows:

Year ending December 31,

2005	605,190
2006	130,000
2007	230,000
2008	53,237
	\$ 1,018,427

**NOTES TO FINANCIAL STATEMENTS**  
**(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)**

4. **STOCK OPTIONS:** The Company has adopted the Advaxis, Inc. 2002 Stock Option Plan (the "Plan"), which allows for grants up to 8,000 shares of the Company's common stock. The Plan shall be administered and interpreted by the Company's board of directors.

Stock option activity during the periods indicated is as follows:

	Options Granted	Weighted- average Exercise Price
Granted from the period March 1, 2002 (inception) to December 31, 2002	4,351	\$ 73.63
Outstanding at December 31, 2002	4,351	73.63
Granted	1,777	97.47
Outstanding at December 31, 2003	6,464	\$ 78.91
Granted	350	\$ 117.32
Forfeited	(750)	\$ 68.75
Outstanding at October 31, 2004	6,064	\$ 80.95
Vested and exercisable at October 31, 2004	3,917	\$ 87.63

At October 31, 2004, the weighted exercise prices and weighted-average remaining contractual life of outstanding options were \$80.95 and 7.70 years, respectively.

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants in 2004, 2003 and 2002: dividend yield of 0%; average risk-free interest rates of 6%; volatility of 0%; and an expected life of 10 years in each year.

Also under the Plan, the Company has granted 3,430 options to purchase the Company's common stock that are being accounted for under variable plan accounting because these options have an exercise price that is subject to a one-time price adjustment following the next round of equity financing. Accordingly, each period, increases in the stock price of the Company will result in a charge to operations for the increase in the Company's stock price multiplied by the number of these options still outstanding. However, there has been no fluctuation in the Company's stock price from inception to December 31, 2003 and, as such, no charge has been taken on the accompanying statement of operations.



NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)

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On November 12, 2004, in connection with the recapitalization (see Note 8), the above options were canceled, and employees and consultants were granted options of Great Expectations. The pro forma disclosures in Note 1 are presented for the options outstanding prior to the recapitalization. The cancellation and replacement had no accounting consequence since the aggregate intrinsic value of the options immediately after the cancellation and replacement was not greater than the aggregate intrinsic value immediately before the cancellation and replacement, and the ratio of the exercise price per share to the fair value per share was not reduced. Additionally, the original options were not modified to accelerate vesting or extend the life of the new options.

5. **SHAREHOLDERS' EQUITY:** Prior to the recapitalization (see Note 8), the Company had convertible preferred stock with \$.001 par value and 50,000 shares authorized. 6,000 of those shares were designated as Series A and 3,418.18, 3,650.45, and 3,640.45 were issued and outstanding at December 31, 2002, December 31, 2003 and October 31, 2004, respectively. The Company also had 100,000 shares authorized of \$.001 par value common stock with 40,000 shares issued and outstanding at December 31, 2002 and 2003, and at October 31, 2004.

The preferred stock and common stock amounts were retroactively restated to reflect the effects of the recapitalization on November 12, 2004 (see Note 8).

6. **COMMITMENTS AND CONTINGENCIES:** Pursuant to multiple consulting agreements and a licensing agreement, the Company is contingently liable for the following:

The Company is obligated to pay \$35,500 to two consultants upon receiving financing of \$1,000,000 or greater.

The Company is obligated to pay \$20,000 to two consultants upon receiving financing of \$500,000 or greater and an additional \$20,000 upon receiving financing of \$2,000,000 or greater.

The Company is obligated to pay \$91,000 to two consultants upon receiving financing of \$4,000,000 or greater.

Under a licensing agreement, the Company has agreed to pay \$525,000 over a four-year period as a royalty after the first commercial sale of a product under the license. The Company is also obligated to pay annual license maintenance fees ranging from \$25,000 to \$125,000 per year after the first commercial sale of a product under the license. The Company is also obligated to pay up to \$660,000 to the licensor upon receiving financing. The amount due is contingent upon the size of the financing.

**NOTES TO FINANCIAL STATEMENTS**  
**(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and**  
**2004 is unaudited)**

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As of October 31, 2004, the Company has an employment agreement with a key executive through December 31, 2004. The agreement shall be automatically renewed for one-year periods unless the Company or the key executive gives the other party written consent of its intent not to renew at least 30 days prior to the end of the term of the contract. The agreement provides for an annual base salary of \$150,000, which will be adjusted to \$225,000 to \$250,000 per annum once the Company closes on its next round of equity financing.

The Company is also obligated under two employment agreements to pay approximately \$220,000 per annum upon the closing of the next round of equity financing.

**NOTES TO FINANCIAL STATEMENTS**  
**(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)**

7. **INCOME TAXES:** The Company has a net operating loss carryforward of approximately \$1,800,000 at October 31, 2004 available to offset taxable income through 2023.

The tax effects of loss carryforwards give rise to a deferred tax asset and a related valuation allowance as follows:

	<b>December 31, 2003</b>	<b>October 31, 2004</b>
Net operating losses	\$ 640,000	\$ 720,000
Less valuation allowance	(640,000)	(720,000)
<b>Deferred tax asset</b>	<b>\$ - 0 -</b>	<b>\$ - 0 -</b>

The difference between income taxes computed at the statutory federal rate of 34% and the provision for income taxes relates to the following:

	Period from 1-Mar-02 (inception) to December 31, 2002	Year ended December 31, 2003	Ten-month period ended October 31, 2004	three-month period ended January 31, 2004	three-month period ended January 31, 2005
Provision at federal statutory rate	34%	34%	34%	34%	34%
Valuation allowance	(34)	(34)	(34)	(34)	(34)
	-0-%	-0-%	-0-%	-0-%	-0-%

8. **SUBSEQUENT EVENTS:** On November 12, 2004, Great Expectations and Associates, Inc. ("Great Expectations") acquired the Company through a share exchange and reorganization (the "Recapitalization"), pursuant to which the Company became a wholly owned subsidiary of Great Expectations. Great Expectations acquired (i) all of the issued and outstanding shares of common stock of the Company and the Series A preferred stock of the Company in exchange for an aggregate of 15,597,723 shares of authorized, but theretofore unissued, shares of common stock, no par value, of Great Expectations; (ii) all of the issued and outstanding warrants to purchase the Company's common stock, in exchange for warrants to purchase 584,885 shares of Great Expectations; and (iii) all of the issued and outstanding options to purchase the Company's common stock in exchange for an aggregate of 2,381,525 options to purchase common stock of Great Expectations, constituting approximately 96% of the common stock of Great Expectations prior to the issuance of shares of common stock of Great Expectations in the private placement described below. Prior to the closing of the Recapitalization, Great Expectations performed a 200-for-1 reverse stock split, thus reducing the issued and outstanding shares of common stock of Great Expectations from 150,520,000 shares to 752,600 shares. Additionally, 752,600 shares of common stock of Great Expectations were issued to the financial advisor in connection with the Recapitalization. Pursuant to the Recapitalization, there are 17,102,923 common shares outstanding in Great Expectations.

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and  
2004 is unaudited)

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As a result of the transaction, the former shareholders of Advaxis are the controlling shareholders of the Company. Additionally, prior to the transaction, Great Expectations had no substantial assets. Accordingly, the transaction is treated as a recapitalization of a public shell, rather than a business combination. The historical financial statements of Advaxis are now the historical financial statements of the Company. Historical shareholders' equity (deficiency) of Advaxis has been restated to reflect the recapitalization, and include the shares received in the transaction.

Pro forma information has not been presented since the transaction is not a business combination.

November 12, 2004, the Company completed an initial closing of a private placement offering (the "Private Placement"), whereby it 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, to purchase 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, the Company granted to each investor certain registration rights and anti-dilution rights. Also, in November 2004, the Company converted approximately \$618,000 of aggregate principal promissory notes and accrued interest outstanding into Units.

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

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

NOTES TO FINANCIAL STATEMENTS  
(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)

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

On January 12, 2005, the Company completed a second private placement offering whereby it 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 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. Upon the closing of this second private placement offering the Company issued to the investor 3,832,753 shares of common stock and warrants to purchase up to an aggregate of 3,832,753 shares of common stock.

The aggregate sale from the four private placements was \$4,353,000, which was netted against transaction costs of \$329,673 for net proceeds of \$4,023,327.

Pursuant to the Recapitalization and the first closing of the private placement, there are 2,381,525 options to purchase the Company's common stock outstanding. These options have a 10-year life and vest ratably over a four-year period. A summary of the options outstanding are as follows:

Options	Exercise Price
1,966,939	\$ 0.1952
14,087	\$ 0.2839
35,639	\$ 0.2870
227,509	\$ 0.3549
137,351	\$ 0.4259
2,381,525	

Pursuant to the Recapitalization and the first closing of the private placement, there are 14,951,292 warrants to purchase the Company's common stock outstanding. A summary of the warrants outstanding are as follows:

**NOTES TO FINANCIAL STATEMENTS**  
**(information related to the ten-month period ended October 31, 2003 and the three-month periods ended January 31, 2005 and 2004 is unaudited)**

Amount	Exercise Price	Expiration
2,543,553	\$ 0.20	2009
35,218	\$ 0.28	2011
142,555	\$ 0.29	2007
2,038,328	\$ 0.29	2009
10,191,638	\$ 0.40	2009
14,951,292		

On December 20, 2004, the Company entered into an Amended and Restated Employment Agreement with J. Todd Derbin, its current chief executive officer and president ("Employment Agreement"). Pursuant to the terms of the Employment Agreement, Mr. Derbin shall serve as the Company's chief executive officer and president for a period of one year commencing on January 1, 2005. The Employment Agreement may be extended, in writing, by the Company and Mr. Derbin. Mr. Derbin's salary shall be \$200,000, provided that it shall be increased to \$225,000 or \$250,000 based upon certain milestones of the Company 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 common stock of the Company (the "Options"), the amount of which when added to his existing 1,172,767 options shall equal 5% of the total issued and outstanding common stock of the Company, 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 the Company adopting a 2005 Stock Option Plan, which is subject to stockholder approval.

The Company entered into an employment agreement with Dr. Vafa Shahabi PhD to become Head of Director of Science effective March 1, 2005, terminable on 30 days notice. The compensation is \$100,000 per annum with a potential bonus of \$20,000. In addition, Dr. Shahabi will be granted 150,000 options.

The Company entered into an employment agreement with Dr. John Rothman, Ph.D to become 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.

**56,320,114 Shares**

**ADVAXIS, INC.**

**Common Stock**

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**PROSPECTUS**

**\_\_\_\_\_ , 2005**

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Until [\_\_\_\_\_], 2005, all dealers that buy, sell, or trade the common stock, may be required to deliver a prospectus, regardless of whether they are participating in this offering. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### INDEMNIFICATION OF DIRECTORS AND OFFICERS

Our articles of incorporation and by-laws include provisions to (1) indemnify the directors and officers to the fullest extent permitted by the Colorado Revised Statutes, including circumstances under which indemnification is otherwise discretionary and (2) eliminate the personal liability of directors and officers for monetary damages resulting from breaches of their fiduciary duty, except for liability for breaches of the duty of loyalty, acts, or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, violations under Section 7-108-704 of Colorado Law, or for any transaction from which the director derived an improper personal benefit. We believe that these provisions are necessary to attract and retain qualified persons as directors and officers.

We will enter into an indemnification agreement with each of our directors which provides that we will indemnify our directors and advance expenses to our directors, to the extent permitted by the laws of the State of Colorado.

We have directors and officers liability insurance in an amount not less than \$1 million.

Insofar as indemnification for liability arising under the Act may be permitted to our directors, officers and controlling persons as stated in the foregoing provisions or otherwise, we have been advised that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

#### OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, if any, payable by the Registrant relating to the sale of common stock being registered. All amounts are estimates except the SEC registration fee.

SEC registration fee	\$	6,628.94*
Printing and engraving expenses	\$	10,000*
Legal fees and expenses	\$	25,000*
Accounting fees and expenses	\$	5,000*
Transfer agent and registrar's fees and expenses	\$	10,000*
Miscellaneous expense	\$	3,371.06*
Total	\$	60,000*

\* Estimates only.

#### RECENT SALES OF UNREGISTERED SECURITIES

During the last three years, we have issued unregistered securities to the persons, as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(2) thereof and/or Regulation D promulgated thereunder. All recipients had adequate access, though their relationships with us, to information about us.



We issued on November 12, 2004 pursuant to the Share Exchange, 16,350,323 shares of our common stock, 2,381,525 options to purchase shares of common stock and 584,885 warrants to purchase shares of common stock.

We issued on November 12, 2004 pursuant to the conversion of \$595,000 principal amount of outstanding promissory notes, 2,136,441 shares of our common stock and warrants to purchase 2,136,441 shares of our common stock.

On November 12, 2004 in connection with the first closing of the Private Placement we issued 12,248,798 shares of our common stock and 12,229,966 warrants to purchase shares of our common stock.

On November 12, 2004 we issued a warrant to purchase 60,000 shares of common stock to RB Holdings, LLC, an affiliate of Reitler Brown & Rosenblatt LLC in connection with legal services rendered.

On December 8, 2004, in connection with the second closing of the Private Placement we issued 834,843 shares of our common stock and 836,237 warrants to purchase shares of our common stock.

On January 4, 2005, in connection with the third and final closing of the Private Placement we issued 534,299 shares of our common stock and 535,192 warrants to purchase shares of our common stock.

On January 12, 2005, in connection with the closing of a second private placement offering, we issued 3,832,752 shares of our common stock and 3,832,752 warrants to purchase shares of our common stock.

## EXHIBITS

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION OF EXHIBIT</u>
Exhibit 3.1	Amended and Restated Articles of Incorporation. Incorporated by reference to Exhibit 3.1 to Report on Form 8K filed with the SEC on December 27, 2004.
Exhibit 3.2	Amended and Restated Bylaws. Incorporated by reference to Exhibit 3.1 to Report on Form 8K filed with the SEC on December 27, 2004.
Exhibit 4.1	Form of Warrant issued to purchasers. Incorporated by reference to Exhibit 4.1 to Report on Form 8K filed with the SEC on November 18, 2004.
Exhibit 4.2	Form of Warrant issued to Placement Agent. Incorporated by reference to Exhibit 4.2 to Report on Form 8K filed with the SEC on November 18, 2004.
Exhibit 5.1	Opinion of Frascogna, Joiner, Goodman and Greenstein, PC

- Exhibit 10.1 Share and Exchange Agreement, dated as of August 25, 2004, by and among the Company, Advaxis and the shareholders of Advaxis. Incorporated by reference to Exhibit 10.1 to Report on Form 8K filed with the SEC on November 18, 2004.
- Exhibit 10.2 Form of Securities Purchase Agreement, by and among the Company and the purchasers listed as signatories thereto. Incorporated by reference to Exhibit 10.2 to Report on Form 8K filed with the SEC on November 18, 2004.
- Exhibit 10.3 Form of Registration Rights Agreement, by and among the Company and the persons listed as signatories thereto. Incorporated by reference to Exhibit 10.3 to Report on Form 8K filed with the SEC on November 18, 2004.
- Exhibit 10.4 Form of Standstill Agreement, by and among the Company and persons listed on Schedule 1 attached thereto. Incorporated by reference to Exhibit 10.4 to Report on Form 8K filed with the SEC on November 18, 2004.
- Exhibit 10.5 Amended and Restated Employment Agreement, dated December 20, 2004, by and between the Company and J.Todd Derbin. Incorporated by reference to Exhibit 10.1 to Report on Form 8K filed with the SEC on December 23, 2004.
- Exhibit 10.6 2004 Stock Option Plan of the Company. Incorporated by reference to Exhibit 10.1 to Report on Form 8K filed with the SEC on December 27, 2004.
- Exhibit 10.7 License Agreement, dated as of June 17, 2002, by and between Advaxis and The Trustees of the University of Pennsylvania\*.
- Exhibit 10.8 Non-Exclusive License and Bailment, dated as of March 17, 2004, between The Regents of the University of California and Advaxis, Inc.
- Exhibit 10.9 Consultancy Agreement, dated as of January 19, 2005, by and between LVEP Management, LLC. and the Company.
- Exhibit 10.10 Government Funding Agreement, dated as of April 5, 2004, by and between David Carpi and Advaxis, Inc.
- Exhibit 10.11 Amended and Restated Consulting and Placement Agreement, dated as of May 28, 2003, by and between David Carpi and Advaxis, Inc., as amended
- Exhibit 10.12 Consultancy Agreement, dated as of January 22, 2005, by and between Dr. Yvonne Paterson and Advaxis, Inc.
- Exhibit 10.13 Consultancy Agreement, dated as of March 15, 2003, by and between Dr. Joy A. Cavagnaro and Advaxis, Inc.

Exhibit 10.14	Grant Writing Agreement, dated June 19, 2003, by and between DNA Bridges, Inc. and Advaxis, Inc.
Exhibit 10.15	Consulting Agreement, dated as of July 2, 2004, by and between Sentinel Consulting Corporation and Advaxis, Inc.
Exhibit 10.16	Agreement, dated July 7, 2003, by and between Cobra Biomanufacturing PLC and Advaxis, Inc.*
Exhibit 10.17	Securities Purchase Agreement, dated as of January 12, 2005, by and between the Company and Harvest Advaxis LLC. Incorporated by reference to Exhibit 10.1 to Report on Form 8K filed with the SEC on January 18, 2005.
Exhibit 10.18	Registration Rights Agreement, dated as of January 12, 2005, by and between the Company and Harvest Advaxis LLC. Incorporated by reference to Exhibit 10.2 to Report on Form 8K filed with the SEC on January 18, 2005.
Exhibit 10.19	Letter Agreement, dated as of January 12, 2005 by and between the Company and Robert T. Harvey. Incorporated by reference to Exhibit 10.3 to Report on Form 8K filed with the SEC on January 18, 2005.
Exhibit 10.20	Consultancy Agreement, dated as of January 15, 2005, by and between Dr. David Filer and the Company.
Exhibit 10.21	Consultancy Agreement, dated as of January 15, 2005, by and between Pharm-Olam International Ltd. and the Company.
Exhibit 10.22	Agreement, dated February 1, 2004, by and between Strategic Growth International Inc. and the Company.
Exhibit 10.23	Letter Agreement, dated February 10, 2005, by and between Richard Berman and the Company.
Exhibit 10.24	Employment Agreement, dated February 8, 2005, by and between Vafa Shahabi and the Company.
Exhibit 10.25	Employment Agreement, dated March 1, 2005, by and between John Rothman and the Company.
Exhibit 10.26	Clinical Research Services Agreement, dated April 6, 2005, between Pharm-Olam International Ltd. and the Company.*
Exhibit 10.27	Amendment to Consultancy Agreement, dated as of April 4, 2005, between LVEP Management LLC and the Company.
Exhibit 10.28	Royalty Agreement, dated as of May 11, 2003, by and between Cobra Manufacturing PLC and the Company.
Exhibit 14.1	Code of Ethics. Incorporated by reference to Exhibit 14.1 to Report on Form 8K filed with the SEC on November 18, 2004.
Exhibit 21.1	Advaxis, Inc., a Delaware corporation
Exhibit 23.1	Consent of Goldstein Golub Kessler LLP
Exhibit 23.2	Consent of Frasca, Joiner, Goodman and Greenstein, PC (included in Exhibit 5.1 above)
Exhibit 24.1	Power of Attorney (Included on the signature page)

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\* Confidential Treatment sought.

## UNDERTAKINGS

The undersigned small business issuer hereby undertakes to:

(1) For determining any liability under the Securities Act of 1933, treat the information omitted from this form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the small business issuer under Rule 424(b) (1), or (4) or 497(h) under the Securities Act of 1933 as part of this registration statement as of the time the SEC declared it effective.

(2) For determining any liability under the Securities Act of 1933, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in this registration statement, and that offering of the securities at that time as the initial BONA FIDE offering of those securities.

The undersigned small business issuer hereby undertakes with respect to the securities being offered and sold in this offering:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this Registration Statement to:

(a) Include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(b) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(c) Include any additional or changed material information on the plan of distribution.

(2) For determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering.

(3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

Insofar as indemnification by the undersigned small business issuer for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Princeton, Mercer County, State of New Jersey, on the 9th day of June, 2005.

**ADVAXIS, INC.**

By: /s/ J. Todd Derbin

\_\_\_\_\_  
J. Todd Derbin  
Chief Executive Officer

**POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
/s/ J. Todd Derbin _____ J. Todd Derbin	Chief Executive Officer and Director (Principal Executive Officer)	June 9, 2005
* _____ Roni Appel	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	June 9, 2005
* _____ Scott Flamm	Director	June 9, 2005
* _____ Thomas McKearn	Director	June 9, 2005
* _____ James Patton	Director	June 9, 2005
* _____ Steven Roth	Director	June 9, 2005
*by: /s/ J. Todd Derbin _____ J. Todd Derbin Attorney-in-fact		

## Frascona, Joiner, Goodman and Greenstein, P.C.

Oliver E. Frascona  
 Gary S. Joiner  
 Jonathan A. Goodman  
 Gregg A. Greenstein  
 G. Roger Bock  
 Joyce M. Bergmann

of Counsel  
 Joseph Adams Cope  
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June 8, 2005

Karen J. Radakovich  
 Miriam Abrams Goodman  
 Cynthia M. Mazzano  
 Janice R. Hill  
 David A. Farns  
 William A. Robinson  
 Eric R. Jaworski  
 Kevin A. Cain  
 B.J. Sanchez

Advaxis, Inc.  
 212 Carnegie Center  
 Suite 206  
 Princeton, NJ 08540

RE: Amendment No. 4 to Registration Statement on Form SB-2

Gentlemen:

We have acted as special counsel to Advaxis, Inc., a Colorado corporation (the "Company") with respect to Colorado law in connection with the above Registration Statement on Form SB-2 of the Company, as amended ("Registration Statement") relating to shares of its Common Stock (the "Shares"), namely: (i) outstanding shares of Common Stock held by certain shareholders of the Company, and (ii) shares of Common Stock to be offered upon exercise of certain outstanding Warrants.

We have reviewed a copy of the Company's Amended and Restated Articles of Incorporation on file with the Colorado Secretary of State, as well as copies of its By-laws, as amended, the Warrants, the minutes of the relevant corporate proceedings and such other documents as we deemed pertinent to this opinion.

We have assumed the accuracy of the information set forth in the Registration Statement without an independent investigation.

Based on the foregoing, it is our opinion that the Shares when offered by means of the prospectus which is part of the Registration Statement will be legally issued, fully paid and nonassessable.

We hereby consent to the reference to our firm under the caption "Legal Matter" in the prospectus and the filing of this opinion as an exhibit to the Registration Statement.

Sincerely yours,

*Frascona, Joiner, Goodman & Greenstein, P.C.*  
 Frascona, Joiner, Goodman and Greenstein, P.C.

**LICENSE AGREEMENT**

**BETWEEN**

**ADVAXIS, INC.**

**(COMPANY)**

**AND**

**THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA**

**(PENN)**

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**EFFECTIVE DATE: JUNE 17, 2002**

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## LICENSE AGREEMENT

This License Agreement ("AGREEMENT") is between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation, with offices located at 3700 Market Street, Suite 300, Philadelphia, Pennsylvania 19104-3147 ("PENN") and Advaxis, Inc., a corporation organized and existing under the laws of Delaware ("COMPANY"), having a place of business at 250 West Lancaster Avenue, Ste 100, Paoli, PA 19301.

This AGREEMENT shall be and become effective on the date (the "EFFECTIVE DATE") on which COMPANY raises two-hundred fifty thousand dollars (\$250,000) of equity capital or convertible debt, whereupon the COMPANY shall be deemed to have exercised its rights under the Option (as defined below).

### BACKGROUND

A. PENN owns issued and pending U.S. and foreign patent applications based upon information in PENN Dockets D751, H1219, H1219 - CIP, J1598, M2244, M2244 - CIP, N2483 (which was joined with M2244), O2876 and O2883 naming Dr. Yvonne Paterson and colleagues of PENN's School of Medicine, as inventors; and,

B. PENN and COMPANY have entered into a Exclusive Negotiation and Option Agreement (the "Option") with an effective date of March 15, 2002 and extendable upon agreement of the parties, which grants COMPANY exclusive rights to negotiate for a license to such pending U.S. and foreign patents and patent applications; and,

C. COMPANY desires to fund further research by Dr. Paterson relating to therapeutic vaccines based on LLO-antigen fusion proteins under a sponsored research agreement between PENN and COMPANY; and,

D. COMPANY desires to obtain the exclusive right and license to use and exploit the intellectual property developed by Dr. Paterson, et al, as described in Attachment 1, in accordance with the DEVELOPMENT PLAN (as defined below); and,

E. PENN has determined that commercial exploitation of the intellectual property developed by Dr. Paterson in accordance with the terms of this AGREEMENT is in the best interest of PENN and is consistent with its educational and research missions; and,

NOW, THEREFORE, in consideration of the promises and covenants contained in this AGREEMENT and intending to be legally bound, the parties agree as follows:

### 1. DEFINITIONS

1.1 AFFILIATE means; any legal entity directly or indirectly controlling, controlled by or under common control with COMPANY that has executed a Joinder Agreement substantially in the form of Attachment 2 or such other form as PENN and COMPANY may hereafter agree in writing. For purposes of this AGREEMENT, "control" means the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities of a legal entity, or the right to receive more than fifty percent (50%) of the profits or earnings of a legal entity, or the right to control the policy decisions of a legal entity.

1.2 CALENDAR QUARTER means each three calendar month period beginning on January 1, April 1, July 1 and October 1, or any portion thereof, arising during the term of this AGREEMENT.

1.3 DEVELOPMENT PLAN means a plan for the development and/or marketing of the PENN PATENT RIGHTS and/or PENN LICENSED PRODUCTS that reasonably demonstrates COMPANY's capability to bring such patent rights, technical information and/or products to practical application, as more fully described in ~~the~~ Attachment 3, consisting of the following:

1.3.1 development activities to be undertaken, including proposed dates of completion of all major milestones to develop and commercialize PENN LICENSED PRODUCTS;

1.3.2 a list of all government regulatory approvals, including the nature of submissions and government agencies involved in pre-market clearance;

1.3.3 a list of current competitors and their competitive products, including competitors' known plans for further development of competing technologies; and

1.3.4 anticipated dates of first SALE of each PENN LICENSED PRODUCT described in the DEVELOPMENT PLAN.

1.4 FAIR MARKET VALUE means the cash consideration which COMPANY, an AFFILIATE, or any sublicensee would realize from an unaffiliated, unrelated buyer in an arm's length sale of an identical item sold in the same quantity and at the same time and place of the transaction.

1.5 FIELD OF USE means therapeutic use in humans and other mammals.

1.6 NET SALES means the consideration or FAIR MARKET VALUE attributable to the SALE of any PENN LICENSED PRODUCT(S), less the qualifying costs set forth below that are directly attributable to such SALE and actually identified on the invoice and borne by COMPANY, an AFFILIATE, or any sublicensee. Such qualifying costs shall be limited to the following:

1.6.1 Discounts, in amounts customary in the trade, for quantity purchases, prompt payments and for wholesalers and distributors.

1.6.2 Credits or refunds, not exceeding the original invoice amount, for claims or returns.

1.6.3 Prepaid outbound transportation expenses and transportation insurance premiums.

1.6.4 Sales and use taxes and other fees, duties, and imports imposed by any governmental agency.

1.7 PENN LICENSED PRODUCT(S) means products which are made, made for, used or sold by COMPANY, an AFFILIATE, or any sublicensees and which: (1) in the absence of this AGREEMENT would infringe at least one Valid Claim or (2) use a process or machine covered by a Valid Claim.

1.8 PENN PATENT RIGHTS means all patents represented by or issuing from those United States patent applications listed in Attachment 1, including continuation, divisional and re-issue applications and any foreign counterparts and extensions of the foregoing.

1.9 PRIMARY STRATEGIC FIELD shall be Cancer, including Cancer caused by infection.

1.10 SALE means any bona fide transaction for which consideration is in fact received by COMPANY or AFFILIATE or any sublicensee hereunder or expected for the sale, use, lease, transfer or other disposition of PENN LICENSED PRODUCT(S). A SALE shall be deemed completed at the time COMPANY, an AFFILIATE, or any sublicensee invoices, ships, or receives payment for such PENN LICENSED PRODUCT(S), whichever occurs first.

1.11 SECONDARY STRATEGIC FIELDS includes (a) Infectious Disease, (b) Allergy, (c) Autoimmune Disease, and (d) any other therapeutic indications for which PENN LICENSED PRODUCT(S) are developed.

1.12 SPONSORED RESEARCH AGREEMENT means a sponsored research agreement between PENN and COMPANY providing for the conduct of certain research consistent with this AGREEMENT, all on terms and conditions acceptable to PENN and COMPANY.

1.13 VALID CLAIM means any pending, issued or granted claim of the PENN PATENT RIGHTS that has not been surrendered, abandoned or declared invalid or unenforceable by an unappealed and unappealable decision of a court of competent jurisdiction.

## 2. LICENSE GRANT

2.1 PENN grants to COMPANY for the term of this AGREEMENT an exclusive, world-wide right and license, with the right to grant sublicenses, to make, have made, use, import, sell and offer for sale PENN LICENSED PRODUCT(S) in the FIELD OF USE. Except for Section 2.6, no other rights or licenses are granted. Intellectual property created or conceived during the performance of the SPONSORED RESEACH AGREEMENT shall be governed by the SPONSORED RESEARCH AGREEMENT.

2.2 This license grant is exclusive except that PENN may use and permit other not-for profit organizations to use the PENN PATENT RIGHTS for educational and research purposes.

2.3 COMPANY acknowledges that pursuant to Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, the United States government retains certain rights in intellectual property funded in whole or part under any contract, grant or similar agreement with a Federal agency. Pursuant to these laws, the government may impose certain requirements regarding such intellectual property, including but not limited to the requirement that products resulting from such intellectual property sold in the United States must be substantially manufactured in the United States. This license grant is expressly subject to all applicable United States government rights as provided in the above-mentioned laws and any regulations issued under those laws, as those laws or regulations may be amended from time to time.

2.4 The right to sublicense granted to COMPANY under this AGREEMENT is subject to the following conditions:

2.4.1 In each such sublicense, COMPANY must prohibit the sublicense from further sublicensing and require that the sublicensee is subject to the terms and conditions of the license granted to COMPANY pursuant to Section 2.1 of this AGREEMENT, the limitations thereon set forth in Sections 2.2 , 2.3 and 2.4 as well as sublicensee's compliance with Sections 3.4.4, 5.5, 5.9 and 9, and COMPANY shall impose upon its sublicensees obligations comparable to those obligations imposed upon COMPANY pursuant to Sections 8.2 and 8.4 of this Agreement. COMPANY may submit a written request to PENN to obtain the right to allow a sublicensee to further sublicense on a case by case basis. Such right to allow a sublicensee to further sublicense PENN PATENT RIGHTS shall not be unreasonably withheld provided that COMPANY can validate to PENN's satisfaction that such sublicensee has the financial and resource capabilities to develop and commercialize PENN PATENT RIGHTS and further, such sublicensee agrees that any sub-sublicense shall be subject to the terms and conditions of the license granted to COMPANY under this AGREEMENT.

2.4.2 Within thirty (30) days after COMPANY enters into any sublicense, COMPANY shall deliver to PENN a complete copy of the sublicense written in the English language. PENN's receipt of the sublicense shall not constitute an approval of the sublicense or a waiver of any of PENN's rights or COMPANY's obligations under this AGREEMENT.

2.4.3 In the event of a DEFAULT under Section 5.3 hereunder all payments then or thereafter due to COMPANY from its AFFILIATES or sublicensees in connection with rights granted to such third party pursuant to this Agreement shall upon notice from PENN to any such AFFILIATE or sublicensee become owed directly to PENN for the account of COMPANY; provided however, that PENN shall remit to COMPANY the amount by which such payments exceed the amounts owed by COMPANY to PENN.

2.4.4 In the event that COMPANY enters into sublicenses, COMPANY remains primarily liable to PENN for all of COMPANY'S duties and obligations contained in this AGREEMENT, and any act or omission of a sublicensee which would be a breach of this AGREEMENT if performed by COMPANY shall be deemed to be a breach by COMPANY of this AGREEMENT.

2.5 Promptly after the date of execution of this AGREEMENT, PENN and COMPANY shall in good faith negotiate the terms of, and enter into, the SPONSORED RESEARCH AGREEMENT; provided, however, that neither PENN nor COMPANY shall be obligated to enter into the SPONSORED RESEARCH AGREEMENT on terms that are not acceptable to such party in all respects.

2.6 PENN grants to COMPANY a series of exclusive options during [ \* ] following the EFFECTIVE DATE of this AGREEMENT to obtain exclusive licenses to new inventions on therapeutic vaccines: (1) involving the use of listeria vectors and/or listeria antigen and/or PEST-containing fusion proteins in the FIELD OF USE and (2) developed by, under the supervision of, or in collaboration with Dr. Yvonne Paterson; to the extent of PENN's ownership interest in any resulting intellectual property. Each option shall be granted at [ \* ] to COMPANY by PENN, and shall extend for a period of (a) [ \* ] from the date of disclosure of such new inventions if the disclosure was made on or before 12.31.2004, or (b) [ \* ] from the date of disclosure of such new inventions if the disclosure was made after 12.31.2004 but before the [ \* ] anniversary of the EFFECTIVE DATE. Such license agreement shall include a license initiation fee of [ \* ], shall be substantially similar in form to this AGREEMENT and shall include no financial terms that [ \* ] in this AGREEMENT. All fees, excluding the license initiation fee and royalty payments, shall be fully creditable against payments made by COMPANY to PENN under this AGREEMENT.

2.7 PENN grants to COMPANY a series of exclusive options during [ \* ] following the EFFECTIVE DATE of this AGREEMENT to obtain exclusive licenses to new inventions on therapeutic vaccines: (1) involving the use of listeria vectors and/or listeria antigen and/or PEST-containing fusion proteins in the FIELD OF USE; and (2) developed by, under the supervision of, or in collaboration with Dr. Fred Frankel; to the extent of PENN's ownership interest in any resulting intellectual property. Each option shall be granted at [ \* ] to COMPANY by PENN, and shall extend for a period of (a) [ \* ] from the date of disclosure of such new inventions if the disclosure was made on or before 12.31.2004, or (b) [ \* ] from the date of disclosure of such new inventions if the disclosure was made after 12.31.2004 but before the [ \* ] anniversary of the EFFECTIVE DATE. Upon exercise of option by COMPANY, PENN and COMPANY agree to negotiate in good faith a comprehensive license agreement within ninety (90) days of COMPANY's exercise of its option. Such license agreement shall include a license initiation fee of [ \* ] fully creditable against license maintenance fees and shall be substantially similar in form to this AGREEMENT, with financial terms not to exceed those in this AGREEMENT.

### 3. FEES AND ROYALTIES

#### 3.1 LICENSE INITIATION FEE AND ROYALTIES

3.1.1 In partial consideration of the exclusive license granted to COMPANY, COMPANY shall pay to PENN a non-refundable license initiation fee of [ \* ] within thirty (30) days of the date COMPANY receives in the aggregate [ \* ] in equity financing. The initiation fee paid to PENN pursuant to this Section shall be [ \* ].

3.1.2 In further consideration of the License, COMPANY shall perform its obligations under that certain Stock Purchase Agreement dated April 19, 2002, between COMPANY and PENN (“STOCK PURCHASE AGREEMENT”), a copy of which is attached as Attachment 4.

3.1.3. In further consideration of the exclusive license granted to COMPANY, COMPANY must pay to PENN, on a quarterly basis, royalties on the annual, worldwide NET SALES of PENN LICENSED PRODUCTS as follows:

- [ \* ]% on NET SALES in countries with pending or issued patents; and
- [ \* ]% on NET SALES in countries without pending or issued patents.

However, in the event that the PENN royalty rates represent greater than [ \* ] of any royalty payable to COMPANY by a sublicensee (on a country-by-country basis in regard to patent status), PENN’s royalty rate shall be reduced to [ \* ] of such sublicense royalties; provided, however, that at no time will the aggregate royalty due to PENN for any Calendar Quarter be less than [ \* ] of worldwide NET SALES of PENN LICENSED PRODUCTS.

3.1.4. Following the first commercial SALE of a each PENN LICENSED PRODUCT, COMPANY must pay to PENN non-refundable minimum royalties in advance on the following dates and in the corresponding amounts:

Date Payment Becomes Due	Amount
the first January 1 <sup>st</sup> arising after the first commercial SALE	\$( * )
the second January 1 <sup>st</sup> arising after the first commercial SALE	\$( * )
the third and fourth January 1 <sup>st</sup> arising after the first commercial SALE	\$( * )

The obligation to pay such Minimum Royalties will not, in respect of each PENN LICENSED PRODUCT, extend beyond January 1<sup>st</sup> of the [ \* ] year following the first commercial sale of that PENN LICENSED PRODUCT. A minimum royalty payment paid under this Section 3.1.5 shall serve as an advance payment against royalties due under Section 3.1.3 during the period for which such minimum royalty payment was paid.

3.1.5 COMPANY will pay PENN, on a quarterly basis, a percentage of any sublicense initiation fee or any other non-royalty payments received by COMPANY from sublicensees of PENN PATENT RIGHTS as follows:

If Sublicense Becomes Effective Anytime:	Percent of Sublicense Fees
On or before the 1 <sup>st</sup> Anniversary of the EFFECTIVE DATE	[ * ]%
After the 1 <sup>st</sup> and on or before the 2 <sup>nd</sup> Anniversary of the EFFECTIVE DATE	[ * ]%
After the 2 <sup>nd</sup> and on or before 3 <sup>rd</sup> Anniversary of the EFFECTIVE DATE	[ * ]%
After the 3 <sup>rd</sup> and on or before the 4 <sup>th</sup> Anniversary of the EFFECTIVE DATE	[ * ]%
After the 4 <sup>th</sup> Anniversary of the EFFECTIVE DATE	[ * ]%

Such sublicense payments include but are not limited to: i) upfront cash payments made to COMPANY in consideration of the sublicense, but excluding funds paid to COMPANY for research and development purposes and equity investments in COMPANY at FAIR MARKET VALUE, and excluding equity received by COMPANY in affiliates, joint venture partners and sublicensees; ii) "premium" over the fair market value of equity investments in COMPANY, where "premium" is defined as the amount by which cash amounts received by COMPANY for a particular equity security exceed the fair market value of such security and, notwithstanding the definition of FAIR MARKET VALUE set forth in Section 1.4 above, the fair market value of securities shall, for purposes of this Section 3.1.5(ii), be the average of the final "bid" and "ask" price of COMPANY's securities as of the close of business on the last business day prior to the date such securities are transferred to COMPANY if such securities are publicly traded or, in the event that such securities are not traded in the public market, the fair market value, as of the date of such securities are issued to the sublicensee, shall be established in good faith by the COMPANY Board of Directors; and iii) the fair market value of non-cash consideration received by COMPANY from a sublicensee (excluding equity received by COMPANY in sublicensee), where such fair market value, notwithstanding the definition of FAIR MARKET VALUE set forth in Section 1.4 above, is determined as of the date such consideration is received by COMPANY and equals the fair market value determined in good faith by the COMPANY Board of Directors

3.1.6 NET SALES of any PENN LICENSED PRODUCT shall not be subject to more than one assessment of the scheduled royalty; such assessment shall be the highest applicable royalty. Where any PENN LICENSED PRODUCT is the subject of a SALE by the COMPANY or any AFFILIATE but the COMPANY concludes in good faith that, in the ordinary course of business, the same PENN LICENSED PRODUCT will be the subject of a subsequent SALE by the COMPANY or any AFFILIATE for an amount greater than the consideration paid for the previous SALE, the COMPANY may exclude consideration paid for the previous SALE from NET SALES until the date arising ninety (90) days after the date of the previous SALE;. If a subsequent SALE for an amount greater than the consideration paid for the previous SALE arises prior to such date, then the consideration paid for the previous SALE shall be permanently excluded from NET SALES; if there is no subsequent SALE for an amount greater than the consideration paid for the previous SALE prior to such date, then the consideration paid for the previous SALE shall be included in NET SALES, but shall still be credited against any subsequent SALE of the same PENN LICENSED PRODUCT for a higher price.

### 3.2 MILESTONE PAYMENTS

The following milestone payments are non-refundable, non-creditable, and payable to PENN by COMPANY within forty-five (45) days following the achievement of the following milestones as follows:

3.2.1 [ \* ] shall be due for first commercial SALE of the first PENN LICENSED PRODUCT in the PRIMARY STRATEGIC FIELD. Such payment shall be payable as follows: [ \* ] shall be paid within forty-five (45) days of the date of the first commercial SALE, [ \* ] shall be paid on the first Anniversary of the first commercial SALE; and [ \* ] shall be paid on the second Anniversary of the date of the first commercial SALE.

3.2.2 [ \* ] shall be due and payable within forty-five (45) days following the date of the first commercial SALE of a PENN LICENSED PRODUCT in a SECONDARY STRATEGIC FIELD; provided, however, that this fee shall [ \* ] for each of the SECONDARY STRATEGIC FIELDS in which PENN LICENSED PRODUCTS are sold.

### 3.3 DILIGENCE AND MAINTENANCE FEES

#### 3.3.1 Financial Due Diligence

3.3.1.1 COMPANY shall, within twelve (12) months of the EFFECTIVE DATE, raise at least [ \* ] in equity financing or convertible debt from reputable investors.

3.3.1.2 COMPANY shall, within thirty-six (36) months of the EFFECTIVE DATE, raise at least an additional [ \* ] in equity financing or convertible debt from reputable investors.

#### 3.3.3 Developmental Due Diligence.

3.3.3.1 COMPANY will use commercially reasonable efforts to develop, commercialize, and market PENN LICENSED PRODUCTS as soon as practical, consistent with the terms of the DEVELOPMENT PLAN and any DEVELOPMENT PLAN PROGRESS REPORTS provided pursuant to Section 3.6.1 of this AGREEMENT. The DEVELOPMENT PLAN will be prepared by COMPANY and delivered to PENN prior to the EFFECTIVE DATE.

3.3.3.2 COMPANY agrees to commit resources (including relevant resources dedicated by sublicensees and strategic or collaboration partners and including research grants for Dr. Paterson) during the term of this AGREEMENT to the development and commercialization of PENN LICENSED PRODUCTS in the PRIMARY STRATEGIC FIELD in amounts not less than the following:



Anniversary of EFFECTIVE DATE	Required Diligence Expenditure
First	\$[ * ]
Second	\$[ * ]
Third	\$[ * ]
Fourth	\$[ * ]
Fifth and thereafter	\$[ * ]

Notwithstanding the above, COMPANY shall be not be obligated to make any due diligence expenditures at any time after the date the COMPANY first becomes obligated to pay minimum royalties pursuant to Section 3.1.5. In the event that total expenditures for the development and commercialization of PENN LICENSED PRODUCTS do not meet or exceed the amounts set forth above, COMPANY must pay to PENN the difference between the mandated amount listed above and the actual amount expended by COMPANY and/or its sublicensees, strategic or collaboration partner(s). Funds invested in development in a given year that are in excess of the above amounts shall be creditable up to \$[ \* ] against the diligence requirements of the following year.

3.3.3.3 SECONDARY STRATEGIC FIELDS: By [ \* ] of the EFFECTIVE DATE, COMPANY must either (i) initiate research and development programs for the SECONDARY STRATEGIC FIELDS of infectious disease, allergy, and autoimmune disease, at an initial annual expense level of at least [ \* ] per field, or (ii) partner with or grant one or more third parties rights for the commercial development of PENN LICENSED PRODUCTS in one or more of such SECONDARY STRATEGIC FIELDS.

3.3.3.4 In the event COMPANY develops PENN LICENSED PRODUCTS in any SECONDARY STRATEGIC FIELDS pursuant to Section 3.3.3.3, part (i), the parties will negotiate in good faith due diligence requirements for subsequent years for such SECONDARY STRATEGIC FIELD under development at that time. If COMPANY fails to complete either part (i) or (ii) as described in Section 3.3.3.3 above for such SECONDARY STRATEGIC FIELD(S) by [ \* ] anniversary of the EFFECTIVE DATE, COMPANY will forfeit all rights for development of commercial products in such SECONDARY STRATEGIC FIELDS, and rights will return to PENN for such SECONDARY STRATEGIC FIELD(S). PENN will thereafter be free to enter into agreements for such forfeited rights with any third party for commercial development in the respective SECONDARY STRATEGIC FIELD(S).

3.3.6 COMPANY must pay to PENN annual license maintenance fees, according to the following schedule:

Due Date:	Amount:
1 <sup>st</sup> anniversary of EFFECTIVE DATE	\$[ * ]
2 <sup>nd</sup> anniversary of EFFECTIVE DATE	\$[ * ]
3 <sup>rd</sup> anniversary of EFFECTIVE DATE	\$[ * ]
4 <sup>th</sup> anniversary of EFFECTIVE DATE	\$[ * ]
5 <sup>th</sup> anniversary of EFFECTIVE DATE	\$[ * ]
6 <sup>th</sup> anniversary of EFFECTIVE DATE and each anniversary thereafter	\$[ * ]

provided, however, that such fees shall not be payable on any anniversary of the EFFECTIVE DATE arising at any time after the first commercial SALE of a PENN LICENSED PRODUCT.

### 3.4 REPORTS AND RECORDS

3.4.1 On each December 1 arising during the term of this AGREEMENT, COMPANY must provide PENN with written progress reports; (each a "DEVELOPMENT PLAN PROGRESS REPORT"), setting forth COMPANY'S progress regarding its efforts to develop and commercialize PENN LICENSED PRODUCTS, including activities of AFFILIATES and sublicensees, for the preceding year. COMPANY shall also notify PENN within thirty (30) days of the first commercial SALE by the COMPANY, an AFFILIATE, or any sublicensee of each PENN LICENSED PRODUCT. Each DEVELOPMENT PLAN PROGRESS REPORT shall include, without limitation:

3.4.1.1 The date of the DEVELOPMENT PLAN PROGRESS REPORT and the time covered by such report.

3.4.1.2 Major activities and accomplishments completed by COMPANY, any AFFILIATE or any sublicensee since the last DEVELOPMENT PLAN PROGRESS REPORT.

3.4.1.3 Significant research and development projects currently being performed by COMPANY, any AFFILIATE, or any sublicensee and projected dates of completion.

3.4.1.4 Future development activities expected to be undertaken by COMPANY, any AFFILIATE, or any sublicensee during the next reporting period.

3.4.1.5 Current development stage (e.g., pre-clinical, Phase I, Phase II or Phase II) of each PENN LICENSED PRODUCT and targeted date of NDA approval, if any.

3.4.1.6 Significant changes to the DEVELOPMENT PLAN, including the reasons for the changes.

3.4.1.7 Summary of development efforts related to PENN PATENT RIGHTS being performed by third parties including the nature of the relationship between the COMPANY and such third parties.

3.4.2 COMPANY must deliver to PENN within forty-five (45) days after the end of each CALENDAR QUARTER a report, certified by the chief financial officer of COMPANY, setting forth the calculation of the royalties due to PENN for such CALENDAR QUARTER, including, without limitation:

- 3.4.2.1 Number of PENN LICENSED PRODUCTS involved in SALES, listed by country.
- 3.4.2.2 Gross consideration for SALES of PENN LICENSED PRODUCTS, including all amounts invoiced, billed, or received.
- 3.4.2.3 Qualifying costs, as defined in Section 1.5, listed by category of cost.
- 3.4.2.4 NET SALES of PENN LICENSED PRODUCTS listed by country.
- 3.4.2.5 Royalties owed to PENN, listed by category, including without limitation earned, sublicensee-derived, and minimum royalty categories.
- 3.4.2.6 Earned royalty amounts credited against minimum royalty payments.

3.4.3 COMPANY must pay the royalties due under Sections 3.1 and 3.3 within forty-five (45) days following the last day of the CALENDAR QUARTER in which the royalties accrue. COMPANY must send with the royalties the report described in Section 3.4.1.

3.4.4 COMPANY must maintain and cause its AFFILIATES and any sublicensees to maintain, complete and accurate books and records which enable the royalties, fees, and payments payable under this AGREEMENT to be verified. The records for each CALENDAR QUARTER must be maintained for five (5) years after the submission of each report provided pursuant to Section 3.4.2. Upon reasonable prior notice to COMPANY, COMPANY must provide an independent auditor appointed by PENN and reasonably acceptable to COMPANY with access to all books and records relating to the SALES of PENN LICENSED PRODUCTS by COMPANY and its AFFILIATES or any sublicensees in order to conduct a review or audit of those books and records. Access to these books and records pertaining to NET SALES must be made available following the date of the first product sale and then no more than once every three (3) years following each audit during the term of this AGREEMENT, during normal business hours, and on two (2) occasions during the three (3) year period immediately following expiration or termination of this AGREEMENT. If a review or audit of the [ \* ] or more, COMPANY must reimburse to PENN its actual out-of-pocket costs of employing its auditors in connection with such review or audit. Notwithstanding the foregoing, COMPANY agrees to conduct, at its expense, an independent audit of SALES and royalties at least every five (5) years once annual SALES of a PENN LICENSED PRODUCT are greater than [ \* ]. The audit shall address, at a minimum, the amount of gross sales by or on behalf of COMPANY during the audit period, the amount of funds owed to PENN under this AGREEMENT, and whether the amount owed has been paid to PENN and is reflected in the records of the COMPANY. A report by the auditors shall be submitted promptly to PENN upon completion.

3.4.5 COMPANY shall provide to PENN, at least as frequently as they are distributed to the Board of Directors and/or management of COMPANY, copies of: all Board and managerial reports that relate to the PENN PATENT RIGHTS and PENN LICENSED PRODUCTS; and all business plans, projections and financial statements that are distributed to the Board of Directors and/or management.

### 3.5 CURRENCY, PLACE OF PAYMENT, INTEREST, PAYMENT OF EXPENSES

3.5.1 All dollar amounts referred to in this AGREEMENT are expressed in United States dollars. All payments to PENN under this AGREEMENT must be made in United States dollars by check payable to "The Trustees of the University of Pennsylvania" and sent to the following address:

The Trustees of the University of Pennsylvania  
[ \* ]

For electronic transfer, all payments should be sent to the following address:

[ \* ]

3.5.2 If COMPANY receives revenues from SALES of PENN LICENSED PRODUCTS in currency other than United States dollars, such revenues shall, for purposes of calculating NET SALES, be converted into United States dollars at the conversion rate for the foreign currency as published in the eastern edition of The Wall Street Journal as of the last business day of the CALENDAR QUARTER in which such NET SALES were accrued.

3.5.3 Amounts that are not paid when due shall accrue interest from the due date until paid, at a rate equal to [ \* ] per month (or the maximum allowed by law, if less).

## 4. CONFIDENTIALITY

4.1 CONFIDENTIAL INFORMATION means and includes all technical information, inventions, developments, discoveries, software, know-how, methods, techniques, formulae, data, processes and other proprietary ideas, whether or not patentable or copyrightable, that PENN identifies as confidential or proprietary at the time it is delivered or communicated to COMPANY.

4.2 COMPANY agrees to maintain in confidence and not to disclose to any third party any CONFIDENTIAL INFORMATION of PENN. COMPANY agrees to ensure that its employees have access to CONFIDENTIAL INFORMATION only on a need-to-know basis and are obligated in writing to abide by COMPANY's obligations under this AGREEMENT. The foregoing obligation shall not apply to:

4.2.1 information that is known to COMPANY or independently developed by COMPANY prior to the time of disclosure, in each case, to the extent evidenced by written records promptly disclosed to PENN upon receipt of the CONFIDENTIAL INFORMATION;

4.2.2 information disclosed to COMPANY by a third party that has a right to make such disclosure;

4.2.3 information that becomes patented, published or otherwise part of the public domain as a result of acts by PENN or a third person obtaining such information as a matter of right; or

4.2.4 information that is required to be disclosed by order of United States governmental authority or a court of competent jurisdiction; provided that COMPANY must use best efforts to obtain confidential treatment of such information by the agency or court.

4.2.5 information disclosed by COMPANY to a third party under the normal course of business, provided that COMPANY discloses such information under confidentiality agreements that are substantially in the form of Attachment 6 or such other form as PENN may from time-to-time approve.

4.3 PENN shall not be obligated to accept any confidential information from COMPANY. PENN shall use best efforts not to disclose confidential information of COMPANY that is received by PENN's Center for Technology Transfer from COMPANY to any third party (subject to the exceptions analogous to those in Section 4.2). PENN bears no institutional responsibility for maintaining the confidentiality of any CONFIDENTIAL INFORMATION other than (i) reports provided pursuant to Sections 3.4.1. and 3.4.2 and (ii) any information disclosed to PENN's auditor pursuant to Section 3.4.4.

4.4 PENN acknowledges that COMPANY is free to enter into confidentiality agreements with any faculty members or other employees or students of PENN provided such agreements are acceptable to the relevant faculty members, employees or students and are substantially in the form of Attachment 6 or such other form as PENN may from time-to-time approve.

## **5. TERM AND TERMINATION**

5.1 This AGREEMENT, unless sooner terminated as provided in this AGREEMENT, terminates upon the later of: (a) expiration of the last to expire or become abandoned of the PENN PATENT RIGHTS; or (b) twenty (20) years after the EFFECTIVE DATE.

5.2 COMPANY may, upon sixty (60) days written notice to PENN, terminate this AGREEMENT by doing all of the following:

5.2.1 ceasing to make, have made, use, import, sell and offer for sale all PENN LICENSED PRODUCTS; and

5.2.2 terminating all sublicenses, and causing all AFFILIATES and sublicensees to cease making, having made, using, importing, selling and offering for sale all PENN LICENSED PRODUCTS; and

5.2.3 paying all monies owed to PENN under this AGREEMENT and the SPONSORED RESEARCH AGREEMENT, if any.

5.3 PENN may terminate this AGREEMENT if any of the following events of default (“DEFAULT”) occur:

5.3.1 COMPANY is late in paying to PENN royalties, expenses, or any other monies due under this AGREEMENT and COMPANY does not pay PENN in full within ninety (90) days of written demand for such payment; or

5.3.2 COMPANY, experiences a Trigger Event (as defined below); or

5.3.3 COMPANY, or any AUTHORIZED AFFILIATE is in material breach of this AGREEMENT and such breach is not cured within ~~ninety~~ ~~(90)~~ sixty (60) days after written notice of the breach is provided to COMPANY.

5.4 Trigger Event means any of the following:

5.4.1 If COMPANY,

5.4.1.1 becomes insolvent, bankrupt or generally fails to pay its debts as such debts become due;

5.4.1.2 is adjudicated insolvent or bankrupt; admits in writing its inability to pay its debts; or shall suffer a custodian, receiver or trustee for it or substantially all of its property to be appointed and, if appointed without its consent, not be discharged within thirty (30) days; or

5.4.1.3 makes an assignment for the benefit of creditors; or suffers proceedings under any law related to bankruptcy, insolvency, liquidation or the reorganization, readjustment or the release of debtors to be instituted against it and, if contested by it, not dismissed or stayed within ten (10) days;

5.4.2 If proceedings under any law related to bankruptcy, insolvency, liquidation, or the reorganization, readjustment or the release of debtors are instituted or commenced by COMPANY;

5.4.3 If any order for relief is entered relating to any of the proceedings described in Sections 5.4.1 or 5.4.;

5.4.4 If COMPANY shall call a meeting of its creditors with a view to arranging a composition or adjustment of its debts;

5.4.5 If any sublicensee experiences an event comparable to a TRIGGER EVENT or is in material breach of its sublicense and fails to cure such material breach within sixty (60) days of COMPANY's written notice thereof, and (i) such sublicensee is either (x) responsible for a material amount of NET SALES or (y) primarily responsible for research and/or development activities relating to any contemplated PENN LICENSED PRODUCT described in the DEVELOPMENT PLAN and anticipated to result in commercial SALES having a positive material effect on NET SALES, and (ii) COMPANY fails to use commercially reasonable efforts to exercise its termination rights under the relevant sublicense;

5.4.6 If any AFFILIATE experiences an event comparable to a TRIGGER EVENT and (i) such AFFILIATE is either (x) responsible for a material amount of NET SALES or (y) primarily responsible for research and/or development activities relating to any contemplated PENN LICENSED PRODUCT described in the DEVELOPMENT PLAN and anticipated to result in commercial SALES having a positive material effect on NET SALES, and (ii) COMPANY fails to use commercially reasonable efforts to exercise its termination rights under any applicable agreements between COMPANY and such AFFILIATE implicating the rights granted to COMPANY under this AGREEMENT or otherwise deprive such AFFILIATE of any responsibility for the development or commercialization of PENN LICENSED PRODUCTS; or

5.4.7 If, without PENN's express prior written consent, COMPANY grants a sublicense to, or otherwise subsequently conducts material business implicating COMPANY's rights, duties and obligations under this AGREEMENT with, any Affiliate or sublicensee whose agreement or commercial relationship with COMPANY was previously terminated by COMPANY as contemplated in Sections 5.4.5 or 5.4.6 above.

5.5 In the event of a termination under Section 5.3 above, all duties of PENN and all rights (but not duties) of COMPANY under this AGREEMENT immediately terminate without the necessity of any action being taken either by PENN or by COMPANY. Upon and after any termination of this Agreement, COMPANY, any AFFILIATE, and any sublicensee shall refrain from further manufacture, sale, marketing, importation and/or distribution of PENN LICENSED PRODUCT(s). If, upon a termination of this agreement by PENN, a sublicensee is not in breach of its sublicense agreement and did not cause the Trigger Event, then PENN shall agree to negotiate in good faith with sublicensee a license agreement having commercially-reasonable terms.

5.6 Upon termination of this AGREEMENT, COMPANY must, at PENN's request, return to PENN all CONFIDENTIAL INFORMATION in respect of which COMPANY is RECIPIENT, together with any data generated by COMPANY during the term of this AGREEMENT which will facilitate the further development of the Technology licensed to COMPANY hereunder (the "NEW COMPANY DATA"). Upon termination of this AGREEMENT, COMPANY agrees to negotiate in good faith a license granting to potential licensees identified by PENN rights in the NEW COMPANY DATA on commercially reasonable terms.

5.7 COMPANY's obligation to pay all monies owed but not yet paid under this AGREEMENT shall survive termination of this AGREEMENT. In addition, the provisions of Sections 3.4.2, 3.4.3, 3.4.4 and 3.5, Articles 4 - Confidentiality, Article 5 - Term and Termination, Article 8 - Disclaimer of Warranties; Indemnification, Article 9 - Use of PENN's Name; and Article 10 - Additional Provisions shall survive such termination in accordance with their respective terms.

5.8 Upon termination of this AGREEMENT, COMPANY shall cause physical inventories to be taken immediately of: (a) all completed PENN LICENSED PRODUCT(s) on hand under the control of COMPANY, any AFFILIATES, or any sublicensees; and (b) such PENN LICENSED PRODUCT(s) as are in the process of manufacture and component parts thereof as of the date of termination of this AGREEMENT, which inventories shall be reduced to writing. COMPANY shall deliver copies of such written inventories, verified by an officer of COMPANY forthwith to PENN. PENN shall have 45 forty-five (45) days after receipt of such verified inventories within which to challenge the inventory and request an audit. Upon five (5) days written notice to COMPANY, PENN and its agents shall be given access during business hours to the premises of COMPANY and/or AFFILIATES or sublicensees for the purpose of conducting an audit. Upon the termination of this AGREEMENT, COMPANY shall, at its own expense forthwith remove and promptly upon PENN's request, efface or destroy all references to PENN from all advertising or other materials used in the promotion of COMPANY's business or the business of any AFFILIATE or sublicensee and COMPANY, its AFFILIATES, and any sublicensee shall not thereafter represent in any manner that it has rights in or to the PENN PATENT RIGHTS or PENN LICENSED PRODUCT(s).

5.9 Notwithstanding the foregoing, if this AGREEMENT terminates other than pursuant to Section 5.4.1 or 5.4.2, COMPANY shall have a period of six (6) months to sell off its inventory of PENN LICENSED PRODUCT(s) existing on the date of termination of this AGREEMENT and shall pay royalties to PENN with respect to such PENN LICENSED PRODUCT(s) within thirty (30) days following the expiration of such six-month period ("Sell Off Right").

## **6. PATENT MAINTENANCE AND REIMBURSEMENT**

6.1 Subject to this Article 6, PENN controls the prosecution and maintenance of PENN PATENT RIGHTS. COMPANY must reimburse PENN for all documented attorneys fees, expenses, official fees and other charges incurred after the EFFECTIVE DATE of the option and incident to the preparation, prosecution maintenance and licensing of PENN PATENT RIGHTS. COMPANY's obligation to reimburse such costs shall commence as of the date COMPANY closes an initial [ \* ] or greater financing round; reimbursements shall be paid within thirty (30) days after COMPANY'S receipt of invoices for such fees, expenses and charges

6.2 COMPANY shall reimburse PENN for all historically accrued patent and licensing expenses, attorneys fees, official fees and all other charges incident to the preparation, prosecution and maintenance of the PENN PATENT RIGHTS that were incurred before the EFFECTIVE DATE of the Option (March 15, 2002) within thirty (30) days after the date of closing of an initial [ \* ] or greater financing round. Such historically accrued expenses are estimated by PENN at approximately [ \* ] but will not be greater than [ \* ].



6.3 Notwithstanding Section 6.1, COMPANY [ \* ]. In that event, PENN shall be the client of the attorney, and COMPANY may directly manage the prosecution of the PENN PATENT RIGHTS through a Client and Billing Agreement attached hereto as Attachment 7 (the "CLIENT AND BILLING AGREEMENT"). COMPANY shall bear all costs of prosecution of the PENN PATENT RIGHTS. PENN shall be copied on all correspondence related to the prosecution of the PENN PATENT RIGHTS between COMPANY and the selected attorney, and retains the right to advise COMPANY regarding patent prosecution. PENN and COMPANY shall in good faith cooperate to implement the prosecution and maintenance of PENN PATENT RIGHTS in accordance with the CLIENT AND BILLING AGREEMENT and COMPANY must promptly pay for all ongoing attorneys fees, expenses, official fees and all other charges incident to the preparation, prosecution and maintenance of the PENN PATENT RIGHTS after the EFFECTIVE DATE of this AGREEMENT in accordance with such CLIENT AND BILLING AGREEMENT.

6.4 COMPANY hereby covenants and agrees that it shall in good faith prosecute PENN PATENT RIGHTS in all countries set forth in Attachment 7 (the "REQUIRED TERRITORIES"); [ \* ]; If COMPANY refuses such expenditures under the CLIENT AND BILLING AGREEMENT, or does not reimburse PENN for expenses related to PENN PATENT RIGHTS, COMPANY'S rights in the relevant PENN PATENT RIGHTS granted under Section 2.1 of this AGREEMENT shall, thereafter terminate on a patent-by-patent basis. Thereafter, (i) PENN will, be free, at its discretion and expense, to either abandon such applications or patents or to continue such preparation, prosecution and/or maintenance activities; and (ii) PENN may, license such PENN PATENT RIGHTS to any third party upon such terms and conditions as PENN deems appropriate.

6.5 If COMPANY should desire to abandon any of the PENN PATENT RIGHTS (whether an already issued patent or an application therefor) in any countries other than those countries in the REQUIRED TERRITORIES, COMPANY shall give PENN at least [ \* ] advance written notice of its intention and, upon the written request of the PENN within said [ \* ], shall alternatively consent to termination of the license granted pursuant to Section 2.1 in respect only of those PENN PATENT RIGHTS COMPANY desires to abandon. Upon such limited termination of the license, the other provisions of this Agreement shall be deemed terminated with regard to such PENN PATENT RIGHTS only and COMPANY shall have no further rights or obligations in respect of the same or subsequently accrued proceeds thereof; provided, however, that (i) PENN covenants that it shall not assert such PENN PATENT RIGHTS (whether by way of infringement or otherwise) against COMPANY, or any AFFILIATES or sub-licensees of the PENN PATENT RIGHTS without COMPANY's express prior written consent; and (ii) if any third parties continue to hold rights in such PENN PATENT RIGHTS under any license or other binding agreement previously entered into by or under the authority of COMPANY, its AFFILIATES or sublicensees, then both of COMPANY's and PENN's rights and obligations under this Agreement and in respect of proceeds from such third party agreements shall survive such termination, but PENN shall be under no obligation to COMPANY or any third parties to file, prosecute, maintain, defend or enforce PENN PATENT RIGHTS in respect of which the license has been terminated pursuant to this Section 6.5.

6.6 Nothing in Sections 6.4 or 6.5 above, shall prevent COMPANY from abandoning or surrendering any of the PENN PATENT RIGHTS, or from canceling or amending any claim of any of the PENN PATENT RIGHTS, without giving rise to any rights under Sections 6.4 or 6.5, provided that such abandonment, surrender, cancellation or amendment is, in COMPANY's sole reasonable discretion, necessary or appropriate in the ordinary course of the prosecution, maintenance and enforcement of the PENN PATENT RIGHTS. For the purposes of Sections 6.4 and 6.5, COMPANY's election not to pursue applications for patents or other rights in respect of the PENN PATENT RIGHTS in any countries, territories and regions in which, or in accordance with any treaties, conventions or other multi-national agreements under which, any applications for patents or other rights in respect of the PENN PATENT RIGHTS could in good faith lawfully be applied for or otherwise prosecuted, shall not constitute or be construed to constitute abandonment of any PENN PATENT RIGHTS.

6.7 COMPANY may at its sole discretion (i) apply for and obtain such extension, term restoration or comparable addition to the life of the affected PENN PATENT RIGHTS and (ii) apply for and obtain such supplemental protection certificates for the approved product or process covered by the PENN PATENT RIGHTS, all to the extent the same are available pursuant to the applicable laws and regulations of the jurisdiction where such regulatory approval is given. Nothing herein shall be construed to obligate COMPANY to in fact seek extension or restoration of any PENN PATENT RIGHTS or supplemental protection for any PENN LICENSED PRODUCTS. Where COMPANY applies for and obtains supplemental protection or comparable treatment for any PENN LICENSED PRODUCT, then, subject to continued payment by COMPANY of its royalty obligations under this AGREEMENT, this AGREEMENT shall not expire pursuant to Section 5.1(a) prior to the date of termination of such supplemental protection or comparable treatment.

6.8 Notwithstanding the other provisions of this Article 6, COMPANY shall in good faith confer with, and regularly keep PENN apprised of, its patent prosecution, maintenance, enforcement and defense strategy and plans and shall in good faith consider PENN's comments regarding such strategy and plans including, without limitation, the following:

6.8.1 Providing to PENN, promptly upon PENN's request, copies of any office actions or proposed responses to office actions affecting PENN PATENT RIGHTS.

6.8.2 Providing to PENN, promptly upon PENN's request, copies of any written communications alleging infringement of, or responding to allegations of infringement of, the PENN PATENT RIGHTS by third parties and any pleadings, motions, briefs or other substantive papers filed by COMPANY or any third parties or proposed to be filed by COMPANY, in connection with any litigation, arbitration or regulatory proceedings (including interference and opposition proceedings).

## 7. INFRINGEMENT AND LITIGATION

7.1 PENN and COMPANY are responsible for notifying each other promptly of any infringement of PENN PATENT RIGHTS which may come to their attention. PENN and COMPANY shall consult one another in a timely manner concerning any appropriate response to the infringement.

7.2 COMPANY may prosecute such infringement at its own expense. COMPANY must not settle or compromise any such suit in a manner that imposes any obligations or restrictions on PENN or grants any rights to the or the PENN PATENT RIGHTS, without PENN's prior written permission. Financial recoveries from any such litigation will first be applied to reimburse COMPANY for its litigation expenditures with additional recoveries being paid to COMPANY, subject to a royalty due PENN based on the provisions of Article 3.

7.3 COMPANY's rights under Section 7.2 are subject to the continuing right of PENN to intervene at PENN's own expense and join COMPANY in any claim or suit for infringement of the PENN PATENT RIGHTS. Any consideration received by COMPANY in settlement of any claim or suit shall be shared between PENN and COMPANY in proportion with their share of the litigation expenses in such infringement action.

7.4 Subject to COMPANY'S obligations under Section 6.7 above, COMPANY shall be free to determine at its sole discretion when, if at all, and how to assert and prosecute infringement claims relating to PENN PATENT RIGHTS where such determinations are based upon *bona fide* strategic issues such as COMPANY'S concerns regarding challenges to the validity of the PENN PATENT RIGHTS. If COMPANY elects at its sole discretion not to prosecute or otherwise abate any infringement for non-strategic reasons, COMPANY shall so notify PENN, and PENN may thereafter prosecute such infringement at its own expense. In such event, financial recoveries will be entirely retained by PENN.

7.5 In any action to enforce any of the PENN PATENT RIGHTS, either party, at the request and expense of the other party shall cooperate to the fullest extent reasonably possible. This provision shall not be construed to require either party to undertake any activities, including legal discovery, at the request of any third party except as may be required by lawful process of a court of competent jurisdiction.

7.6 For so long as this Agreement is effective, PENN may not itself assert, or authorize others to assert, claims of infringement of the PENN PATENT RIGHTS against third parties without COMPANY'S express prior written consent.

## 8. DISCLAIMER OF WARRANTIES; INDEMNIFICATION

8.1 THE PENN PATENT RIGHTS, PENN LICENSED PRODUCTS AND ALL OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" BASIS AND PENN MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT THERETO. BY WAY OF EXAMPLE BUT NOT OF LIMITATION, PENN MAKES NO REPRESENTATIONS OR WARRANTIES (i) OF COMMERCIAL UTILITY; (ii) OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; OR (iii) THAT THE USE OF THE PENN PATENT RIGHTS, PENN LICENSED PRODUCTS AND ALL TECHNOLOGY LICENSED UNDER THIS AGREEMENT WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK OR OTHER PROPRIETARY RIGHTS OF OTHERS. PENN SHALL NOT BE LIABLE TO COMPANY, COMPANY'S SUCCESSORS OR ASSIGNS OR ANY THIRD PARTY WITH RESPECT TO: ANY CLAIM ARISING FROM COMPANY'S USE OF THE PENN PATENT RIGHTS, PENN LICENSED PRODUCTS AND ALL TECHNOLOGY LICENSED UNDER THIS AGREEMENT OR FROM THE MANUFACTURE, USE OR SALE OF PENN LICENSED PRODUCTS. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CLAIM FOR LOSS OF PROFITS, LOSS OR INTERRUPTION OF BUSINESS, OR FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND REGARDLESS OF THE CAUSE OF ACTION OR THEORY OF LIABILITY UPON WHICH SUCH CLAIM IS BASED, AND WHETHER OR NOT THE PARTY AGAINST WHOM SUCH CLAIM IS MADE WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

8.2 COMPANY must defend, indemnify and hold harmless PENN, its trustees, officers, agents and employees (individually, an "Indemnified Party", and collectively, the "Indemnified Parties"), from and against any and all liability, loss, damage, action, claim or expense suffered or incurred by the Indemnified Parties (including attorney's fees) (individually, a "Liability", and collectively, the "Liabilities") that results from or arises out of third-party claims made in connection with: (a) the development, use, manufacture, promotion, sale or other disposition of any PENN PATENT RIGHTS or PENN LICENSED PRODUCTS by COMPANY, its assignees, AFFILIATES, sublicensees, vendors or other third parties; (b) any breach by COMPANY of this AGREEMENT, as well as any Liabilities resulting from the enforcement by an Indemnified Party of this Section. Without limiting the foregoing, COMPANY must defend, indemnify and hold harmless the Indemnified Parties from and against any Liabilities resulting from:

8.2.1 any product liability or other claim of any kind made by a third party and related to the use by a third party of a PENN LICENSED PRODUCT that was manufactured, sold or otherwise disposed by COMPANY, its assignees, AFFILIATES, sublicensees, vendors or other third parties;

8.2.2 a claim by a third party that the PENN PATENT RIGHTS or the design, composition, manufacture, use, sale or other disposition of any PENN LICENSED PRODUCT infringes or violates any patent, copyright, trademark or other intellectual property rights of such third party; and

8.2.3 claims made by third parties (including governmental agencies) in connection with clinical trials or studies conducted by or on behalf of COMPANY relating to the PENN PATENT RIGHTS or PENN LICENSED PRODUCTS, including, without limitation, any claim by or on behalf of a human subject of any such clinical trial or study.

8.3 COMPANY is not permitted to settle or compromise any claim or action giving rise to Liabilities in a manner that imposes any restrictions or obligations on PENN or grants any rights to the PENN PATENT RIGHTS or PENN LICENSED PRODUCTS without PENN's prior written consent. If COMPANY fails or declines to assume the defense of any such claim or action within thirty (30) days after notice thereof, PENN may assume the defense of such claim or action for the account and at the risk of COMPANY for indemnification, and any Liabilities related thereto shall be conclusively deemed a liability of the party responsible for indemnification. The indemnification rights of PENN or any other Indemnified Parties are in addition to all other rights which such Indemnified Party may have at law or in equity or otherwise.

#### 8.4 INSURANCE

8.4.1 Within 90 days of the EFFECTIVE DATE of this AGREEMENT, COMPANY must procure and maintain a policy or policies of comprehensive general liability insurance, including broad form and contractual liability, in a minimum amount of \$2,000,000 combined single limit per occurrence and in the aggregate as respects personal injury, bodily injury and property damage arising out of COMPANY's performance under this AGREEMENT.

8.4.2 COMPANY must, upon commencement of clinical trials involving PENN LICENSED PRODUCTS, procure and maintain a policy or policies of product liability insurance in a minimum amount of \$3,000,000 combined single limit per occurrence and in the aggregate as respects bodily injury and property damage arising out of COMPANY's performance under this AGREEMENT.

8.4.3 The policy or policies of insurance described in this Section 8.4 [must be issued by an insurance carrier with an AM Best rating of "A" or better and] must name PENN as an additional insured with respect to COMPANY's performance of this AGREEMENT. COMPANY must provide PENN within thirty (30) days of the EFFECTIVE DATE with certificates evidencing the insurance coverage required herein. Such certificates must provide that COMPANY's insurance carrier(s) notify PENN in writing at least 30 days prior to cancellation or material change in coverage.

8.4.4 PENN may periodically review the adequacy of the minimum limits specified above and reserves the right to require COMPANY to adjust the liability coverages, provided such adjustments do not require COMPANY to obtain coverages in excess of those customarily obtained by entities incurring comparable risks in comparable industries. The specified minimum insurance amounts do not constitute a limitation on COMPANY's obligation to indemnify PENN under this AGREEMENT.

#### 9. USE OF PENN'S NAME

COMPANY and its employees and agents must not use and COMPANY must not permit its AFFILIATES or sublicensees to use PENN's name or any adaptation thereof, or any PENN seal, logotype, trademark, or service mark, or the name, mark, or logotype of any PENN representative or organization in any way without the prior written consent of PENN.

**10. ADDITIONAL PROVISIONS**

10.1 Nothing in this AGREEMENT shall be deemed to establish a relationship of principal and agent between PENN and COMPANY, nor any of their agents or employees for any purpose whatsoever, nor shall this AGREEMENT be construed as creating any other form of legal association or arrangement which would impose liability upon one party for the act or failure to act of the other party.

10.2 COMPANY is not permitted to assign this AGREEMENT or any part of it, either directly or by merger or other operation of law, without the prior written consent of PENN, which consent shall not be unreasonably withheld. A withholding of PENN's consent shall be considered as reasonable in the event that the acquiring party of the assignee of this license is not reputable or is not capable of developing the PENN PATENT RIGHTS in the FIELD OF USE. Any prohibited assignment of this AGREEMENT or the rights hereunder shall be null and void. No assignment relieves COMPANY of responsibility for the performance of any accrued obligations which it has prior to such assignment.

10.3 A waiver by either party of a breach of any provision of this AGREEMENT will only be valid if express, in writing and signed by an authorized representative of the waiving party and will not constitute a waiver of any subsequent breach of that provision or a waiver of any breach of any other provision of this AGREEMENT.

10.4 Notices, payments, statements, reports and other communications under this AGREEMENT shall be in writing and shall be deemed to have been received as of the date sent if sent by public courier (e.g. Federal Express) or by Express Mail, receipt requested, and addressed as follows:

If for PENN:

University of Pennsylvania  
Center for Technology Transfer  
[ \* ]

with a copy to:

Office of General Counsel  
University of Pennsylvania

If for COMPANY:

Advaxis, Inc.  
250 West Lancaster Ave., Ste. 100  
Paoli, PA 19301  
Attn: Mr. James P. Patton

with a copy to:

Pryor Cashman Sherman & Flynn  
410 Park Avenue, 10th Floor  
New York, NY 10022  
Attn: Selig D. Sacks, Esq.

Either party may change its official address upon written notice to the other party.

10.5 This AGREEMENT shall be construed and governed in accordance with the laws of the Commonwealth of Pennsylvania, without giving effect to conflict of law provisions. In the event that a party to this AGREEMENT perceives the existence of a dispute with the other party concerning any right or duty provided for herein, the parties will, as soon as practicable, confer in an attempt to resolve the dispute. If the parties are unable to resolve such dispute amicably, then the parties hereby submit to the exclusive jurisdiction of and venue in the courts located in the Eastern District of the Commonwealth of Pennsylvania with respect to any and all disputes concerning the subject of this AGREEMENT.

10.6 PENN and COMPANY shall not discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or because he or she is a disabled veteran or a veteran of the Vietnam Era.

10.7 COMPANY must comply with all prevailing laws, rules and regulations that apply to its activities or obligations under this AGREEMENT. Without limiting the foregoing, it is understood that this AGREEMENT may be subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, articles and information, including the Arms Export Control Act as amended in the Export Administration Act of 1979, and that the parties' obligations are contingent upon compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by COMPANY that COMPANY shall not export data or commodities to certain foreign countries without prior approval of such agency. PENN neither represents that a license is not required nor that, if required, it will issue.

10.8 If any provision of this AGREEMENT shall be held to be illegal, invalid or unenforceable, then such illegality, invalidity or unenforceability shall attach only to such provision and shall not in any manner affect or render illegal, invalid or unenforceable any other provision of this AGREEMENT, and this AGREEMENT shall be carried out as if any such illegal, invalid or unenforceable provision were not contained herein.

10.9 This AGREEMENT embodies the entire agreement of the parties with respect to the matters herein contained, and supercedes all prior oral or written agreements relating thereto except to the extent expressly addressed in the STOCK PURCHASE AGREEMENT or the STOCKHOLDER'S AGREEMENT. Any modification of this AGREEMENT must be in writing and signed by an authorized representative of each party.

IN WITNESS WHEREOF, the parties, intending to be legally bound, have caused this AGREEMENT to be executed by their duly authorized representatives.

**THE TRUSTEES OF THE  
UNIVERSITY OF PENNSYLVANIA**

**ADVAXIS, INC.**

/s/ Louis P. Berneman

/s/ J. Todd Derbin

TYPED NAME: Louis P. Berneman  
TITLE: Managing Director  
Center for Technology Transfer

TYPED NAME: J. Todd Derbin  
TITLE:

DATE:

DATE:

**ATTACHMENT 1 - List of Intellectual Property**

[ \* ]

**ATTACHMENT 2 - - Required Territories**

[ \* ]





**Determination of Manufacturing  
Parameters, Process Development  
and cGMP Production of *Listeria  
monocytogenes* for Advaxis, Inc.**

**July 7, 2003**

**Reference No. O422**

making tomorrow's medicines

Cobra Biomanufacturing Plc  
The Science Park,  
Keele,  
U.K.  
ST5 5SP

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## Executive Summary

Advaxis has developed a recombinant attenuated *L. monocytogenes* for vaccination against HPV E7 expressing tumors. Advaxis will require the production of approximately [ \* ] cfu of *L. monocytogenes* non-cGMP preclinical material and [ \* ] cfu for clinical trial use produced following cGMP guidelines. The program will involve the following phases:

### Phase I

- Transfer of current *Listeria* culture and analysis methods
- Two month feasibility study and process development program
- Animal component free growth media recommendation
- Analytical methods development and host characterization methods

### Phase II

- cGMP Master Cell Bank production
- Toxicology material
- Manufacture of clinical material
- Development of product stability tests
- Quality assurance review
- Bulk product release for fill/finish

To achieve these goals, Advaxis will require the collaboration of a partner with:

- Specialized facilities for plasmid DNA manufacture
- Experience in plasmid DNA manufacture according to cGMP
- Successful track record producing material for clinical trials in the USA
- Experience in meeting regulatory requirements in facilities and documentation

*Cobra has both the expertise and the facilities available to meet the project deliverables required by Advaxis in the timescales attached.*

### **Cobra Biomanufacturing Plc**

Cobra is a full service, world class Contract Manufacturing Organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotechnology industries. Cobra provides contract services spanning pre-clinical to early Phase III scale production and supply of biological products. These services include the cGMP manufacture of DNA, recombinant protein, viruses, mammalian cell products and cell banking.

Currently, four clinical trials in the USA are being conducted using products manufactured at Cobra. Additionally, there are clinical trials in Europe, Africa, China, and Australia using products manufactured at Cobra.

Cobra has a Type II Drug Master File (DMF) lodged with the FDA covering DNA manufacture. We were last inspected by the MCA in August 2002 and found to be cGMP compliant. Cobra provides a comprehensive analytical and documentation package for regulatory filing.

## **Introduction**

Cobra Biomanufacturing is a full service, world class Contract Manufacturing Organization that manufactures and supplies DNA-based therapeutics for the pharmaceutical and biotechnology industries. Cobra provides contract services spanning pre-clinical to early Phase III scale production and supply of biological products. These services include the cGMP manufacture of DNA, recombinant protein, viruses, mammalian cell products and cell banking. The company also undertakes process development programs for recombinant protein and gene therapy products.

## **Company History**

Cobra was founded in 1992 as a start up biotechnology company specializing in gene therapy and has been operating from facilities at the Keele Science Park for the past 8 years. The manufacturing division was originally established in order to expedite Cobra Therapeutics own R & D programs. Investments were made in cGMP manufacturing facilities and the development of technology for scaleable manufacture of DNA and protein based pharmaceuticals. In 1998 the manufacturing division began to offer cGMP manufacturing services to the pharmaceutical industry. Cobra Therapeutics became a wholly owned subsidiary of ML Laboratories in 2000.

In June 2002, following a successful IPO on London's AIM, Cobra Biomanufacturing was established as an *independent* company with an exclusive focus on custom manufacturing of bio therapeutics.

Cobra's corporate objective is to continue to grow as a major contract supplier of DNA, virus and protein based therapeutics for clinical trials and of licensed biopharmaceutical products for commercial sale.

## **Manufacture of DNA Therapeutics for Clinical Trials**

Cobra has established a worldwide reputation in the manufacture of plasmid DNA therapeutics and is supporting clinical trials in the USA, Europe, Africa, China, and Australia.

Every project undergoes a technology transfer of your existing expression system to utilize our scale-up expertise before initiating the cGMP manufacturing program. During the evaluation stage genetic stability and relative productivity will be determined in shake flask experiments. The fermenter productivity of the transformed host strain will then be evaluated in a scale down (5L) evaluation. This initial optimisation is to achieve the maximum productivity in the fermentation, ensure yield and product purity throughout the purification process. It is essential for the identification of potential difficulties with your plasmid. The process development work is necessary because in our experience there can often be a 5-10 fold difference in productivity between strains (even with similar plasmid backbones) and genetic instability is observed with some plasmids. By assessing the plasmid at the beginning of the program, we can accurately estimate the yields of clinical material that you will obtain.

Cobra has substantial experience working with Kanamycin and Tetracycline resistant plasmids and has also developed and been granted patents covering an antibiotic-free plasmid DNA manufacturing process, the Operator Repressor Titration (ORT) System. A Type II DMF (Drug Master File) has been lodged with the FDA covering DNA manufacture.

### **Facilities**

Cobra has over 11,000 square feet of space used for a process development facility, separate QA/QC laboratories, and dedicated cGMP manufacturing facilities. The existing cGMP manufacturing facility includes 4,500 square feet of EU Grade C Clean Room space required for key stages in the manufacture of biopharmaceutical products. The cGMP facility has two microbial production suites. The [ \* ] fermenter suite ([ \* ] working volume) is for Phase I and II clinical trial material. There is a [ \* ] fermenter ([ \* ] working volume) that is used to provide an inoculum for the larger fermenter. The [ \* ] fermenter suite ([ \* ] working volume) is for Phase II and III clinical trial material.

Additionally, there are two virus production suites with [ \* ] and [ \* ] fermenters ([ \* ] and [ \* ] working volume) utilising adenovirus and baculovirus expression systems for manufacture of Phase I and II clinical trial material.

### **Quality**

Cobra is committed to conducting its manufacturing activities in accordance with appropriate current Good Manufacturing Practice (cGMP) and Good Control Laboratory Practice (GLP) regulations and/or guidelines. The latest inspection from the UK Medicines Control Agency (MCA) was in August 2002 with a compliance statement received several weeks later. Cobra's QA group ensures that the products manufactured by the division meet appropriate standards of safety, quality, and efficacy. The QA group oversees manufacture at all stages and is responsible for testing, release, storage, and arranges shipment of the drug product. Overseas shipping and safe passage through Customs is easily co-ordinated and sub-contracted to BioCair, Inc or World Courier.

### **Key Personnel**

Cobra's belief that quality individuals result in quality products is reflected in the key personnel that will be involved in the manufacture of Advaxis' *L. monocytogenes* for clinical trials.

**Julian Hanak B.Sc. (Hons), MSc., Director of Production**

After gaining an honours degree in Biochemistry at University College London, Julian obtained an MSc at the University College of North Wales and then trained in cell culture and microbial fermentation at the National Institute of Medical Research. He then moved to the Bioproducts Laboratory (Elstree) where his duties involved the pilot scale production of human monoclonal antibodies for clinical trials. He was also responsible for running a sterile fill operation and supervising the commissioning of a new cGMP production suite.

In 1992, Julian moved to Zeneca Pharmaceuticals where he was involved with the process development of several immunotherapy products and the development of virus expression systems for protein production. He joined Cobra in 1994 and took over responsibility for production in 1995.

**Geoff Sharpe BSc., PhD., CChem, MRSC., Director of Quality Assurance**

Geoff has over 25 years experience in pharmaceutical biotechnology with over 12 years experience in Quality Assurance. After having gained a degree in Applied Chemistry at Liverpool, Geoff trained as a research chemist working for ICI Corporate Laboratory. He later worked at the ICI Corporate Bioscience Group and went on to complete a PhD in molecular biology at Leicester University.

In 1991 he transferred to ICI Pharmaceuticals (now AstraZeneca) where he was involved with the cloning and expression of recombinant proteins and managed the corporate DNA sequencing laboratory. In 1993, he moved to Zeneca Pharmaceuticals. In the pharmaceutical department Geoff managed a team involved in the development, manufacture, and release of both small molecule and biotechnology based therapeutics. In 1996 he joined Cobra as their Quality Assurance Manager and has been trained as a Qualified Person under Article 23 of Directive 75/319/EEC.

**Amanda Weiss BSc., MSc., Section Head Fermentation**

Amanda was trained at the University of Birmingham, Centre for Biochemical Engineering before joining Cobra in 1996 as a fermentation scientist. Amanda has expertise in microbial and mammalian cell culture, scale-up design and large-scale manufacture of biopharmaceuticals. She was also involved with the exemplification and publication of Cobra's ORT technology. Amanda has successfully managed the fermentation aspect of Cobra's manufacturing operations for over 5 years.

**Tony Hitchcock BSc, Section Head Microbial Products**

Tony has over 19 years' experience in the large-scale manufacture of biopharmaceuticals. Tony has held positions in the Blood Products Laboratory (Elstree) and at Zeneca Pharmaceuticals in the protein process development department. Tony was a founding staff member of Cobra and has been responsible for the development of much of Cobra's DNA manufacturing technology. Tony has published several papers in the field and is an inventor on two families of Cobra's process patents.

**Roy Cowell BSc. (Hons), CChem, MRSC, Section Head Quality Control**

Roy has 16 years' experience of analytical development and quality control of pharmaceuticals within the associated regulatory framework. Ten years employed by Zeneca (now AstraZeneca) Pharmaceuticals working on new chemical entities and candidate biotherapeutics and six years employed at Cobra working on candidate DNA products. Roy is currently undergoing training leading to eligibility for Qualified Person status.

**Joy Manley BSc, Senior QA Microbiologist**

Joy is currently responsible for developing, validating, and applying suitable testing regimes that help to assure clean room suitability and equipment cleanliness. New test methods are designed and validated for plant systems and for cleaning as required. Both standard and novel microbiological methods are developed and used to characterize cell banks. She has experience in working with microorganisms from both pharmaceutical and clinical backgrounds, previously working for Fisons and The Public Health Laboratory.

**David Thatcher, Chief Executive**

David was trained as a protein chemist at the Universities of Newcastle on Tyne and Edinburgh. In 1981 he moved to Biogen SA in Geneva where he worked on the isolation of recombinant cytokines. In 1985 he became Director of Process Development of Biogen, Inc. in Cambridge, MA, where he was responsible for the development of large-scale processes for the production of gamma interferon, GM-CSF and several other products.

In 1988 he left Biogen and joined Zeneca Pharmaceuticals as head of their Protein Production Lab where he was responsible for the production of a number of biopharmaceutical products for clinical evaluation. In 1994 he joined Cobra and has been responsible for managing the evolution of Cobra's manufacturing technology and developing the contract manufacturing business into an independent company with a successful initial public offering.

## Quotation O422

Description

Price

### Phase I

[ \* ]

### Phase II

[ \* ]

#### Notes:

##### Stage I

1. Execution of Material Transfer Agreement. Advaxis methods for recombinant *Listeria* culture and analysis will be transferred to Cobra. This will include plasmid isolation, plasmid and host identity, plasmid and host stability, cryopreservation, and protocol for plasmid isolation.
2. Characterization and strain history of the untransformed *L. monocytogenes* will be addressed by Advaxis. Advaxis will also be responsible for plasmid sequence and/or detailed restriction maps. Host and plasmid information is required for the GMO risk assessment. A letter from Dr. Paterson addressing the mobility of *L. monocytogenes* is requested.
3. Advaxis will supply [ \* ] vials of a transformed research cell bank (mid log phase) of *L. monocytogenes* with documentation sufficient to make the research bank suitable for generation of the cGMP Master Cell Bank.
4. A two-month feasibility study will be undertaken to determine the growth kinetics of *Listeria* (latest harvest point) in various growth media. The study will also involve bioreactor growth, analysis of log phase, determination of yield, and number of cell doublings in vivo before maintenance of virulence is lost. We suggest running Stage II at the same time as Stage I to reduce the timeline to cGMP manufacture.

##### Stage II

4. An animal component free growth media will be recommended following evaluation of the existing media formulations with suitable alternatives. The media evaluated will be from published references for media used in *Listeria* culture.

5. Development of a cryopreservation media suitable for administration to patients.
6. Analytical methods will be developed to meet FDA regulatory requirements for a live attenuated bacterial vaccine. Methods developed will include:
  - o host identity
  - o plasmid identity (restriction mapping or sequencing)
  - o culture purity (monosepsis)
  - o viable count.
7. Host characterization methods will be developed for the following:
  - o phenotype auxotrophies and markers
  - o morphology
  
  - o specific media for identification
  - o gram strain
8. Cobra will supply Dr. Paterson with [ \* ] of log phase culture for a hemolysin assay. Additionally, Cobra will supply Dr. Paterson with three samples of [ \* ] for a mouse tumor challenge to study maintenance of virulence.
9. The following documentation will be provided:

Technical Report
10. Confirmation of price estimates for cGMP manufacture at this point, dependent upon successful technology transfer, feasibility study and process development.

### Stage III

11. Cell banking will only proceed based upon the feasibility study achieving cell densities of at least [ \* ] viable cells per litre of culture. The Master Cell Bank will be manufactured under cGMP in accordance with the latest CPMP guidelines and MCA guidance. A Type II Drug Master File has been lodged with the FDA covering these procedures. Cells will be cryopreserved in mid log growth at a density of between [ \* ] to [ \* ] cfu/ml.

Pricing for the Working Cell Bank is based on production immediately following the Master Cell Bank. Characterization for the Working Cell Bank is free of charge if concurrent with Master Cell Bank testing.
12. A [ \* ]-vial cGMP Master Cell Bank and Working Cell Bank will be released according to the agreed program.



13. The Master Cell Bank and Working Cell Bank will be characterised using the following range of tests:

- Confirmation of species (API Listeria)
- Confirmation of strain by partial genotyping
- Plasmid stability by serial sub-culture
- Counter selection for monosepsis
- Plasmid identity by restriction digest
- DNA sequence of the plasmid (to be invoiced separately).

14. The non-cGMP material for use in toxicology studies, stability testing, and quality control lot release will produced at the [ \* ] scale with a yield of [ \* ] based upon the feasibility study achieving cell densities of at least [ \* ] viable cells per litre of culture.

15. The following documentation will be provided to support a Regulatory filing:

Certificates of Analysis  
Analytical Reports

#### Stage IV

16. cGMP Manufacture: Prices are estimates without knowledge of the results of the Phase I Feasibility Program and may require variances to this proposal. If the productivity of the strain cannot be developed to achieve cell densities of at least [ \* ] viable cells per litre of culture the delivery of [ \* ]% of final bulk material cannot be guaranteed. The expected quantity of bulk and scale required will be advised as soon as it is determined during the Phase I Feasibility and Development Program and prior to initiation of the Phase II cGMP manufacturing program. If cell densities of [ \* ] cells per litre are obtained in the feasibility study then a [ \* ] fermentation should yield the requested [ \* ] clinical material. If the desired cell densities of [ \* ] cells per litre are not achieved, then the cGMP manufacturing program will be renegotiated.

#### Stage V

17. Product Stability Testing will be required, but will be negotiated as a separate contract once the methods have been developed and the protocol agreed by Advaxis after FDA discussions. Stability tests for genetic stability; cell bank stability and bulk drug stability will be developed once a program is agreed upon. The figure provided is for budgetary purposes.

#### Stage VI

18. Documentation.

The following documentation will be provided:

Certificate of Analysis  
Technical Summary to support regulatory filing  
A copy of the completed BMR will be provided.

19. Specifications

Cobra warrants that upon delivery of the Product to Advaxis, Inc. the Product shall:

- Have been manufactured in accordance with cGMP.
- Be in conformity with the provisional draft specifications as attached to this document.
  
- That Cobra will provide Product of sufficient quality for human clinical use.
- In the event the Product fails to meet any of the specification described above, the final determination as to the suitability of the product for human clinical use shall be determined by Advaxis, Inc., who may consult with the appropriate offices of the US FDA or other regulatory agencies.

**Stage VII**

20. Fill/Finish will be subcontracted to BioReliance. A quote cannot be provided until the type of container, number of vials and other variables have been determined. The figure provided is for budgetary purposes.
20. The costs of consumables have not been included in this quotation and will be billed directly to the customer without additional charge.
21. The cost of subcontracted work has not been included in this quotation and will be billed directly to the customer (plus a [ \* ]% handling charge).
22. Cobra will take responsibility for shipment. The price of shipment of bulk, dosage forms and samples and insurance thereof is excluded from this contract. Shipping will be arranged in consultation with the customer and will be billed directly to the customer (plus a [ \* ]% handling charge).
23. Cobra and/or Advaxis, Inc. may wish to issue a press release relating to this contract. However, prior to any information being disclosed written approval must be obtained from the other party.
24. The Customer agrees to pay reasonable travel expenses connected with Cobra staff attending meetings, other than those on Company premises and requested by the Customer.

25. Cobra Bio-Manufacturing plc's O422 Phase I Terms and Conditions and O422 Phase II Terms and Conditions apply to this work and acceptance of this quotation implies acceptance of these Terms and Conditions.

***How to Proceed***

Please return a signed copy of the enclosed contract with your formal Purchase Order to Cobra Biomanufacturing.

Cobra Biomanufacturing Plc  
The Science Park  
Keele, United Kingdom ST5 5SP  
Phone: 011 44 1782 714181  
Fax: 011 44 1782 714168

When timing is critical a faxed version is acceptable, but an original must be signed and returned within fourteen days. Upon receipt Cobra will notify the client of acceptance within 72 hours.

July 7, 2003

**Contract O422**

Determination of Manufacturing Parameters, Process Development and cGMP Manufacture of *L. monocytogenes*

**(a) Phase I: Two-month Feasibility Study and Development Program**

Price

(Line items: a + b + c):

**Total:** \$[ \* ]

**Terms of Payment**

The following payment terms will apply: On receipt of a signed copy of the Contract, Cobra Biomanufacturing Plc. will begin Phase I. Upon commencement of the work program, Advaxis will be invoiced for \$[ \* ] net 30 days and will be invoiced the remaining \$[ \* ] appropriately on a monthly basis for the length of the program. The final invoice will be sent before [ \* ].

This phase of the program is governed by the Terms and Conditions set out in the attached document " O422 Phase I Terms and Conditions".

**Phase II: Pre-Clinical and GMP Manufacture**

Price Estimate is based on [ \* ] cGMP manufacture:

(Line items: d + e + f + g + i + k + l + m + n + o)

**Total:** \$[ \* ] (excluding Fill/Finish)

**Terms of Payment**

The following payment terms will apply: On receipt of a signed copy of the Contract, Cobra Biomanufacturing Plc. will hold a slot for Advaxis without a deposit. Advaxis will be notified of any request for the slot and may reserve the slot with a [ \* ]% deposit. Receipt of this payment will reserve the production slots as per the agreed program. On commencement of the work program, [ \* ]% of the cost will be appropriately invoiced on a monthly basis for the length of the program, with the remaining [ \* ]% due upon the delivery and acceptance of the Certificate of Analysis by the Customer's QA Department (less deposit if required). There is an intention by Advaxis and Cobra to agree on % royalties of final commercial products utilizing the current *Listeria monocytogenes* platform and variations thereof for various indications in exchange for a reduction in price of the Phase II cGMP manufacturing campaign of proposal 0422.

This phase of the program is governed by the Terms and Conditions set out in the attached document “ O422 Phase II Terms and Conditions”.

**Contract O422**

Determination of Manufacturing Parameters, Process Development and cGMP Manufacture of *L. monocytogenes*

For Advaxis, Inc.

For Cobra Biomanufacturing Plc

Accepted by: J. Todd Derbin

David R. Thatcher

Signature: /s/ J. Todd Derbin

/s/ David R. Thatcher

Date: 7/7/03

8<sup>th</sup> July 2003

Confidential Document

July 7, 2003

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<u>Test</u>	<u>Method</u>	<u>Specification</u>
[ * ]		
<b><u>Identity</u></b>		
API Listeria		Profile number conforms, typically >0.95
Growth on selective media		Good growth
Gram stain		Gram positive
Colony morphology		Complies with that for L. monocytogenes

**Quantity**

[ \* ]

**Purity**

[ \* ]

COBRA BIO-MANUFACTURING PLC

O422 PHASE II - TERMS AND CONDITIONS

1. **Definitions**

In these conditions the following words have the following meanings unless the context requires otherwise:

<b>“Agreement”</b>	means these conditions of business;
<b>“Background”</b>	means all Intellectual Property Rights belonging to Cobra existing prior to the date of this Agreement or which, if created subsequent to the date of this Agreement, are created outside of any work with Advaxis under this Agreement or the scope of any Contract;
<b>“Cobra”</b>	means Cobra Biomanufacturing Plc, a corporation located at The Science Park, Keele, United Kingdom ST5 5SP;
<b>“Confidential Information”</b>	means, in relation to a party to the Contract, any and all confidential and/or proprietary information relating its business methods, customers, suppliers, finances, ideas, strategies, concepts, methodologies, protocols, inventions, processes, specifications, materials, marketing plans, formulae, products, software and other matters, including but not limited to its Intellectual Property Rights, and, in the case of Advaxis, including the Results, but excluding all information described in clause 15.8;
<b>“Contract”</b>	means any contract relating to Phase II of Proposal 0422 dated 7th July 2003 by and between Cobra and Advaxis incorporating the conditions of business set forth in this Agreement for the sale of Products and/or the provision of the Services and agreed to in writing by an authorized representative of each of Advaxis and Cobra;

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<b>“Contract Price”</b>	means, with respect to a Contract, the total sums payable to Cobra by Advaxis under the Contract for Phase II of Proposal 0422 dated 7th July 2003;
<b>“Deposit”</b>	means, with respect to a Contract, the sum of 10% of the Contract Price;
<b>“Foreground”</b>	means all Intellectual Property Rights conceived or made by or on behalf of either Cobra or Advaxis, or jointly by Cobra and Advaxis, as a result of work under any letter of intent executed by the parties or under this Agreement or the performance of any Contract, other than general laboratory or manufacturing know-how that is not specifically related to any Materials;
<b>“GMP”</b>	means the current good manufacturing practices (under U.S. 21 CFR Part 211, as amended and supplemented from time to time, or the equivalent EU good manufacturing practices as confirmed at inspection by the UK Medicines Control Agency) for the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing and holding of Products, as applicable under a Contract;
<b>“Intellectual Property Rights”</b>	means any or all intellectual property rights including, without limitation, patents, registered and/or unregistered design rights, registered and/or unregistered trade marks and/or trade names, logos, copyright, know-how and any other similar industrial or intellectual property rights subsisting anywhere in the world together with any application for such rights and/or the right to make any such application;
<b>“Liability”</b>	means liability for damages, claims, proceedings, actions, awards, expenses, costs (including reasonable attorneys’ fees and expenses) and any other losses and/or liabilities in any way related to this Agreement or any Contract;



<b>“Materials”</b>	means any products, DNA, protein, cell lines, biological matter and/or other materials which are supplied by Advaxis and used by Cobra in performing its obligations under a Contract;
<b>“Products”</b>	means any protein, DNA, biological matter, cell lines, materials, products, goods and/or other matter ordered from Cobra by Advaxis or to be supplied by Cobra to Advaxis and/or such items which are to be provided to Advaxis in the performance of the Services;
<b>“Results”</b>	means any results from any Services carried out by Cobra for Advaxis;
<b>“Services”</b>	means the research, evaluation, development, scale up, manufacturing services and/or any other services to be performed by Cobra for Advaxis;
<b>“Specification”</b>	means the manufacturing procedures specified for a Product and/or the acceptance criteria for such Product;
<b>“Advaxis”</b>	Means Advaxis, Inc., located at 212 Carnegie Center, Princeton, NJ 08540;

2. **Basis Of Contract**

- 2.1 This Agreement shall govern each Contract “Phase II” of the Quotation detailed in proposal O422 between Cobra and Advaxis and shall supersede and replace any conflicting terms or conditions included therein.
- 2.2 No order placed by Advaxis shall be accepted by Cobra unless it is a Contract which incorporates these conditions.
- 2.3 This Agreement supersedes all previous terms and conditions relating to Phase II of Proposal O422 and shall replace any terms and conditions previously notified to Advaxis.

- 2.4 No variation to this Agreement shall be binding on Cobra or Advaxis unless agreed to in writing between an authorised representative of each of Advaxis and Cobra.
- 2.5 Cobra's employees, sub-contractors and/or agents are not authorised to make any representations or warranties concerning the Products and/or Services unless confirmed by Cobra in writing.
- 2.6 Advaxis acknowledges that Advaxis does not rely on any representation and/or warranty which has not been made in this Agreement or a Contract or other writing signed by an authorized representative of Cobra.

### 3. **Orders And Contract**

- 3.1 Quotations (unless stated otherwise) are not binding or capable of acceptance and are estimates only. A binding quotation issued by Cobra shall be binding for 10 business days unless withdrawn by Cobra by oral or written notice given to Advaxis at any time before the expiry of the 10-business-day period. Advaxis may place an order based on a binding quotation issued to Advaxis at any time before the expiry of the 10-business-day period or earlier withdrawal of the quotation by Cobra (whichever is the first to occur).
- 3.2 A Contract between Cobra and Advaxis shall come into effect when it has been executed and delivered (whether in one or more counterparts) by an authorized representative of each party.

### 4. **Samples and Additional Work**

- 4.1 The production of any additional samples or test work not detailed in a Contract shall, unless otherwise agreed to in writing, be delayed until such production is covered by a Contract or Contract amendment entered into in accordance with this Agreement.
- 4.2 If Advaxis approves in writing any sample Product produced or test Services performed by Cobra under a Contract, then, unless and until Advaxis withdraws such approval in writing, Advaxis shall have no claim in respect of, nor any right to reject, Products or Services provided under the Contract if the Products and/or the Services in question are of the same description, Specification, quality and fitness for purpose as the approved sample and/or test work as appropriate. If Advaxis withdraws its approval of any sample Product or test Services, then from and after receipt by Cobra of such written withdrawal by Advaxis, Advaxis shall not be required to accept any additional Products or Services of the same description, and the parties shall promptly amend the terms of the applicable Contract reflect mutually agreed upon changes resulting from such withdrawal (e.g., designation of such withdrawal as a production variation under Section 8, a cancellation under Section 9 or otherwise, provision of alternate supply and pricing terms).

5. **Materials**

- 5.1 Any Materials supplied by or on behalf of Advaxis to Cobra in respect of any Contract shall at all times remain Advaxis's property.
- 5.2 Risk in the Materials shall pass to Cobra whilst such Materials are in the power, possession and/or control of Cobra.
- 5.3 Cobra shall not transfer, or permit the transfer of any Materials to a third party except to a sub-contractor of Cobra. Cobra shall limit access to the Materials to employees or sub-contractors of Cobra who have a need to access the Materials in connection with the production of Products and/or the provision of Services for Advaxis, and shall take all other reasonable measures to protect the Materials from destruction, theft or loss whilst in the possession and/or control of Cobra.
- 5.4 Cobra shall use the Materials only for the production of Products and/or the provision of Services for Advaxis under a Contract, and for no other purpose, except with the specific written consent of Advaxis.
- 5.5 Advaxis shall ensure that Cobra has the right to use in the performance of the Services and/or production of the Products any Materials provided by Advaxis
- 5.6 Advaxis shall provide to Cobra storage, handling, health and safety and/or utilisation information regarding any Materials, to the extent known to Advaxis, at the time of delivery of the Materials to Cobra, or upon request by Cobra in writing, in advance of such delivery.
- 5.7 If any Materials are lost, damaged and/or destroyed, Cobra shall promptly inform Advaxis and shall re-imburse Advaxis for (or Advaxis, at its option, may credit against any amounts due to Cobra) the cost of replacing any Materials lost, damaged and/or destroyed. This shall not apply to any Materials which are properly utilised in and/or natural wastage arising from the performance of the Services and/or production of the Products.

6. **Sub-Contracting**

- 6.1 Cobra may not sub-contract all or any part of a Contract to a third party without the prior written approval of Advaxis (such consent not to be unreasonably refused or delayed). In the event that Advaxis allows any such sub-contracting, Cobra shall remain liable for any non-performance of the Contract due to the acts and/or omissions of a third party sub-contractor.

6.2 If Cobra sub-contracts work to a sub-contractor, Cobra shall ensure that, prior to entering into the sub-contract, the sub-contractor enters into a separate agreement with Cobra obligating the sub-contractor to protect Advaxis's Confidential Information and Materials at least to the same degree as they are protected by the obligations of Cobra under this Agreement, and Cobra shall not disclose to the sub-contractor any Advaxis Confidential Information and shall not provide to the sub-contractor any Materials except as required to permit the sub-contractor to perform the sub-contract approved by Advaxis.

7. **Production Slot Timetable and Deposit**

7.1 In any quotation for the provision of Products and/or Services submitted by Cobra to Advaxis, Cobra shall provisionally allocate to Advaxis a production slot.

7.2 No order for Products and/or Services placed by Advaxis shall become binding until a Contract has been entered into by the parties therefor.

7.3 Upon the execution and delivery of a Contract for Products and/or Services and the receipt of the Deposit by Cobra from Advaxis, Cobra shall firmly allocate the production slot(s) for the Products and/or Services specified in the Contract.

8. **Production Variations and Deposit**

8.1 Cobra has agreed to hold a production slot without requiring pre-payment of a deposit from Advaxis providing no other customers compete for that slot. If another customer requests the same production slot agreed upon with Advaxis, then Advaxis will be required to secure the slot with a deposit of 10% (\$51,100) of the Phase II portion of Proposal 0422. If Advaxis has secured the production slot and requests any change to a production slot for Products to be manufactured under this Contract less than 30 calendar days prior to the commencement of such production slot, Advaxis shall pay Cobra an amount of \$50,000.

8.2 If Advaxis requests a change to a secured production slot for Products to be manufactured under this Contract and the change is requested 30 to 60 days prior to the commencement of such production slot, then Advaxis shall forfeit an amount of \$20,000,

8.3 If Advaxis requests a change of more than one month to a secured production slot for Products to be manufactured under this Contract and the change is requested more than 90 days prior to the commencement of such production slot, then Advaxis shall forfeit 25% of the Deposit allocable to the production slot (calculated as provided in clause 8.1) with the remaining 75% being carried forward and allocated to the alternative production slot. Cobra shall firmly allocate to Advaxis the requested rescheduled production slot, unless that slot has been filled prior to receipt of 25% of the Deposit allocable to the production slot from Advaxis under this clause 8.3, in which case Cobra will secure for Advaxis the next available production slot.

- 8.4 Cobra shall use its reasonable endeavours to accept any request to change to a production slot for Products provided that the requested new production slot is available. All such requests will be considered in good faith.
- 8.5 Cobra shall consider in good faith any request by Advaxis for Cobra to waive Cobra's right to treat all or any portion of the Deposit allocated to the production slot as forfeited under this Section 8.

9. **Cancellation**

- 9.1 If Advaxis cancels or terminates a Contract without cause, or refuses to accept delivery of conforming Products and/or performance of Services rendered in accordance with a Contract:

9.1.1 The Deposit paid by Advaxis under the Contract shall be forfeited and shall not be refundable to Advaxis. Under circumstances where cancellation occurs after commencement of the programme and the Deposit has been waived, Advaxis will pay an equivalent sum to the value of the Deposit; and

9.1.2 Advaxis will pay Cobra for all Services rendered in accordance with the Contract and conforming Products attempted to be delivered in accordance with the Contract through the date of cancellation, on a percentage of completion basis, if and to the extent that their value exceeds the Deposit and the Deposit paid by Advaxis shall be creditable against any payment due for such Services.

10. **Delivery and Performance**

- 10.1 Cobra will use its reasonable commercial efforts to ensure delivery and/or performance on the dates specified in each Contract and shall keep Advaxis promptly informed of any delivery and/or performance that may be delayed. The delivery and/or performance dates specified in a Contract are Cobra's best estimates only and are not guaranteed. Time is not of the essence in relation to such dates. They are also subject to clause 24.4.

- 10.2 Advaxis shall have no right to rescind or terminate a Contract for late delivery and/or performance, or to reject Products and/or Services as non-conforming unless the due date for delivery and/or performance has passed and Advaxis shall have provided notice to Cobra requiring the delivery to be made, the Services to be performed and/or delivery of conforming Products and giving Cobra not less than 14 days in which to do so and the notice shall not have been complied with.

- 10.3 Cobra shall arrange for the delivery of the Products to Advaxis's premises or to an agreed delivery address provided that Advaxis confirms that such a location is appropriately equipped to store and handle the Products, otherwise Cobra shall keep and store the Products at its own expense for 45 days. Cobra shall consult with Advaxis as to any and all delivery arrangements. Delivery generally will be made between 9.00am and 5.00pm on days when Advaxis is open for business.
- 10.4 Advaxis shall procure during normal working hours that Cobra and/or its appointed representatives have free right of access to the address for delivery for the purpose of delivering the Products between 9.00am and 5.00pm on any working day for Advaxis.
- 10.5 If the parties agree that the Products are to be collected from Cobra's premises, then Advaxis shall collect the Products within 30 working days of being notified that the Products are ready for collection. If the Products are not collected by Advaxis or its agent within the specified period, Cobra shall provide notice thereof to Advaxis and at any time commencing three business days after Advaxis receives such notice, the parties will negotiate in good faith as to the appropriate steps to be taken.
- 10.6 If Advaxis refuses to take delivery of any Products and/or to allow performance of the Services without cause, then after providing a notice to Cobra in writing 45 days in advance. Cobra shall be entitled to withhold delivery and/or performance of any other Products and/or Services and to treat this Agreement or any Contract as repudiated by Advaxis and Cobra shall have the right to rescind this Contract.
11. **Price**
- 11.1 The price of the Products and/or the Services shall be as set forth in the applicable Contract.
- 11.2 Unless expressly stated in a Contract, Cobra's prices are exclusive of costs of importation, transport, insurance, packaging and/or freight of Products and/or Materials which shall be payable by Advaxis in addition.
- 11.3 The parties will negotiate in good faith an increase a Contract Price to take into account of any changes in methodology and/or additional work that are requested by Advaxis or are reasonably deemed necessary by Cobra in light of any Results or are required to comply with changes in GMP.
- 11.4 Advaxis will be informed in writing by Cobra of any increases in a Contract Price to be made pursuant to clause 11.3 or 11.4, not less than 30 days before such increase takes effect.

- 11.5 If the increase in Contract Price cannot be agreed between Cobra and Advaxis, Cobra may cease working on the Contract, and Advaxis may cease making payments on the Contract (except as required under clause 11.7), until any increase is agreed.
- 11.6 Advaxis may cancel without Liability any Contract in relation to which the price is to be increased and such increase cannot be agreed provided that Cobra receives notice of cancellation from Advaxis within 30 days after receipt by Advaxis of Cobra's notice of the price increase. In such cases, Advaxis will pay Cobra for all Services rendered and conforming Products produced in accordance with the Contract up to the date of cancellation, on a percentage of completion basis, if and to the extent that their value exceeds the Deposit.
- 11.7 If the Contract Price is to be increased as provided in clause 11.3 or 11.4 and Advaxis does not cancel the Contract within the 30-day period specified in clause 11.6, then the price increase shall take effect for the Products and/or Services provided by Cobra under the Contract after the end of the 30-day period unless Advaxis has notified Cobra that it does not agree with such increase.
- 11.8 Advaxis shall reimburse Cobra for its out-of-pocket costs in connection with reasonable travel and accommodation expenses involved in the provision of the Services, provided that such travel is specified in the Contract or otherwise approved in advance by Advaxis in writing.
12. **Payment**
- 12.1 The balance of the Contract Price shall be payable:
- 12.1.1 85% paid as equal monthly payments over the length of the Contract as detailed in the Contract; and
- 12.1.2 15% on receipt of the certificate of analysis and/or acceptance/deemed acceptance by Advaxis of the Products and/or Services under the Contract.
- 12.2 Cobra's terms of payment are net cash within 30 days after Advaxis receives Cobra's duly issued invoice, except as otherwise provided in clauses 12.1 and 12.8. Cobra shall have no right to terminate a Contract for failure by Advaxis to make timely payment of any amount due thereunder unless Cobra provides Advaxis a written notice specifying the unpaid amount and requiring such payment and giving Advaxis not less than three business days in which to make such payment and the notice shall not have been complied with.
- 12.3 If Advaxis fails to make any undisputed payment in full on the due date, Advaxis will be extended 90 days free of interest, after 90 days Cobra may charge Advaxis interest (both before and after judgment) on the amount unpaid at the annual rate of 2% above the prime, compounded monthly.

- 12.4 Any monies received by Cobra from Advaxis may be applied by Cobra at its option against any interest charged prior to application against any principal sums due from Advaxis against which it may be applied in any order.
- 12.5 Payment shall not be deemed to be made until Cobra has received either cash or cleared funds in respect of the full amount outstanding.
- 12.6 If any undisputed payment is not made in full to Cobra when due, then Cobra may withhold or suspend future or current deliveries of the Products and/or performance of the Services and delivery and/or performance under any other Contract.
- 12.7 If any Contract is cancelled or terminated under clause 9.1, Cobra shall invoice Advaxis for all amounts due in accordance with clause 9.1, and Advaxis shall pay the amount of such invoice within 15 days after receipt.
13. **Specification**
- 13.1 Any Specification for Products supplied by Cobra to Advaxis shall only be approximate unless the Specification applies to the production of Products under GMP, the Specification is marked "Final" and signed by authorized representatives of Cobra and Advaxis, or the Contract provides otherwise.
- 13.2 The quantity, quality, description and/or Specification for the Products and/or the Services shall be that set out in the Contract unless otherwise agreed in writing by the parties.
- 13.3 It is the responsibility of Advaxis to verify and check any Specification for the Products.
- 13.4 Cobra shall have no Liability for errors in any Specification unless Cobra has been negligent and/or in breach in relation to the Specification.
- 13.5 Advaxis shall indemnify and keep indemnified Cobra against any and all liability, loss, costs and expenses arising out of or in any way connected with any third party claim relating to Cobra's use of Materials and/or information supplied by Advaxis under a Contract or any Specification approved in writing by Advaxis, subject to the limitations set forth in clause 21.6.
- 13.6 Subject to Advaxis' written approval Cobra reserves the right to make changes to the Specification of any Products and/or Services as required from time to time by good laboratory practice, GMP, law, and/or applicable safety requirements, provided that they do not have a material adverse effect on the quality and/or performance of the Products and/or the Services and that they shall not be put into effect until 5 business days after receipt by Advaxis of a description and explanation of any such changes.



13.7 If Cobra does make changes to the Specification of any Products and/or Services in violation of clause 13.6, then Advaxis shall have the right to cancel the Contract without Liability.

#### 14. **Intellectual Property Rights**

14.1 The Background shall remain the absolute and unencumbered property of Cobra. Advaxis shall not obtain any license in respect of Cobra's Background. Advaxis shall not be obligated to pay any royalties in respect of the use of the Background in connection with the performance of any Contract by Cobra or for any use of Background to the extent it is embedded in the Advaxis products. It is understood that any consideration for the use of the Background in connection with the performance of any Contract by Cobra is already included in Contract O422.

14.2 All Foreground relating to process and manufacturing technology shall belong to Advaxis. Cobra will promptly make full written disclosure to Advaxis in the form of summary reports, will hold in trust for the sole right and benefit of Advaxis, and hereby assigns, transfers and conveys to Advaxis, or its designee, all use Foreground covered by this clause.

14.3 All Foreground not covered by clause 14.2 shall belong to Advaxis. Cobra shall provide regular reports to Advaxis describing the Foreground and shall promptly reply to Advaxis's reasonable requests for information regarding the Foreground. Cobra hereby assigns and agrees to assign to Advaxis all of its rights, title and interest in and to the Foreground not covered by clause 14.2, and upon request by Advaxis, Cobra shall promptly execute such documents and perform such other acts as may be reasonably requested by Advaxis, at Advaxis's expense, to obtain, perfect and enforce the rights of Advaxis under this clause 14.3 and the assignment thereof.

14.4 Advaxis grants to Cobra a licence to use such of Advaxis's Intellectual Property Rights (including, without limitation, any Foreground) as are necessary to enable Cobra to carry out its obligations under a Contract, and Cobra may sub-licence such Intellectual Property Rights to any sub-contractors approved by Advaxis in accordance with Section 6, solely for the purpose of performing the Contract.

14.5 Advaxis agrees to indemnify and keep Cobra indemnified against any and all Liability suffered by Cobra arising from and/or due to any claim that the use by Cobra of any or all of Advaxis's Intellectual Property Rights in performing a Contract infringes any third party's Intellectual Property Rights.

- 14.6 Cobra warrants that Cobra has the right to use the Background to perform its obligations in accordance with this Agreement and any Contract.
- 14.7 Cobra agrees to indemnify and keep Advaxis indemnified against any and all Liability suffered by Advaxis arising from or due to any claim that the use of any or all of the Background in performing a Contract infringes any third party's Intellectual Property Rights.
- 14.8 Advaxis warrants that Advaxis has the right to grant the license and any permitted sub-license of the Intellectual Property Rights required under clause 14.4 above.
15. **Confidentiality**
- 15.1 Each party shall use the other party's Confidential Information disclosed to and/or acquired by it only for the purposes of this Agreement, any Contract, and any other purpose for which the other party gives its prior written consent.
- 15.2 Each party shall maintain as confidential all of the other party's Confidential Information which has come into and/or may come into its possession under this Agreement or any Contract.
- 15.3 Each party shall not directly and/or indirectly use and/or disclose any of the other party's Confidential Information in whole or in part except in accordance with this Agreement.
- 15.4 Each party shall at the other party's request made at any time deliver up to the other party all documents, material and/or other media which may be in its possession, power or control which comprises or contains any part of the other party's Confidential Information except that it may retain one complete copy solely for archive purposes.
- 15.5 Each party shall allow access to the other party's Confidential Information only to those employees who need to see and use such Confidential Information in order to perform their obligations under this Agreement.
- 15.6 Each party shall be responsible for the acts and/or omissions of its employees and/or representatives (whether or not they remain its employees and/or representatives) as if they were its own acts and/or omissions under this Agreement.
- 15.7 The obligations of confidentiality and non-use in relation to the other party's Confidential Information and/or Materials shall have retrospective force and effect and apply to any of the other party's Confidential Information disclosed prior to the date of this Agreement and shall continue indefinitely.

- 15.8 A party's Confidential Information shall not include any information which:
- 15.8.1 the receiving party can prove by documentary evidence was information already in its possession and at its free disposal when received by it under this Agreement or any Contract;
  - 15.8.2 is after the date of this Agreement disclosed to the receiving party in writing without any obligations of confidentiality by a third party who is not in breach of any duty of confidentiality in doing so;
  - 15.8.3 is or becomes generally available to the public in printed publications in general circulation through no act or default on the part of the receiving party; or
  - 15.8.4 is required to be disclosed by law, provided that the party required to make such disclosure gives the other party prompt notice of such requirement so that the other party may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Agreement, and provided, further, that the party required to make such disclosure cooperates with all reasonable efforts of the other party to obtain confidential treatment of, or to otherwise limit, the required disclosure.

15.9 The exceptions in clause 15.8 above shall not apply to:

- 15.9.1 Confidential Information merely because it is embraced by more general information which falls within any one or more of such exceptions; and/or
- 15.9.2 any combination of features merely because individual features (but not the combination itself) fall within any one or more of such exceptions.

## 16. **Property And Risk**

16.1 Risk in and title to the Products shall pass to Advaxis at the time of delivery to Advaxis. Delivery shall be deemed to occur:-

- 16.1.1 at the time when the Products arrive at the place of delivery if Cobra delivers the Products by its own transport and/or it arranges transport for Advaxis; or
- 16.1.2 after the expiration of 10 working days after Advaxis has been notified of that the Products are available for collection from Cobra in accordance with clause 10.6.

16.2 If any Products are to be utilised in the Services, risk of damage to or loss of such Products shall pass to Advaxis once utilised in the performance of the Services. Cobra will replace free of charge any Products in which risk has passed to Advaxis if it can be shown that they were damaged or lost due to the neglect or default of Cobra, its employees or other representatives.

17. **Default**

17.1 If Advaxis:-

17.1.1 fails to make any payment to Cobra 30 days after due date;

17.1.2 breaches the terms of this Agreement or any Contract and, if the breach is capable of remedy, has not remedied the breach within 14 days of receiving notice requiring the breach to be remedied;

17.1.3 persistently breach any one or more terms of this Agreement; or

17.1.4 pledges any Products which remain the property of Cobra, or ceases or threatens to cease to carry on business, applies for an interim order under Section 252 Insolvency Act 1986 or has a Bankruptcy Petition presented against Advaxis, enters into voluntary or compulsory liquidation, has a receiver, administrator or administrative receiver appointed over all or any of its assets, or takes or suffers any similar action in any jurisdiction;

then Cobra shall have the right, without prejudice to any other remedies, to exercise any or all of the rights set out in clause 17.2 below.

17.2 If any of the events set out in clause 17.1 above occurs in relation to Advaxis then:-

17.2.1 Cobra may withhold delivery of any undelivered Products and stop any Products in transit;

17.2.2 Cobra may withhold the performance of any Services and cease any Services in progress;

17.2.3 Cobra may cancel, terminate and/or suspend any Contract with Advaxis without Liability to Advaxis for such cancellation, termination or suspension; and/or

17.2.4 All monies owed by Advaxis to Cobra shall immediately become due and payable.

18. **Archiving**

18.1 On termination or completion of a Contract, Cobra shall, within 30 days of Advaxis's written request, either return and/or destroy any and all Materials in Cobra's possession supplied by or on behalf of Advaxis under this Agreement together with any Results provided that Advaxis has paid to Cobra all monies due and payable to Cobra under the Contract, except that Cobra shall be entitled to retain in its archive one copy of such Materials, Results and/or other information to enable it to comply with GMP and/or Good Laboratory Practice and any and all other applicable legislation, regulations and/or best practice from time to time in force. No charge is made for such archive storage.

18.2 If Cobra does not receive a request from Advaxis in accordance with clause 18.1 above, Cobra shall retain in its archives for a period of 10 years (or such other period as Cobra determines based on the quality of the matters to be archived) following either the date of termination of the Contract or from the date of completion of the Contract all of the Materials, Results and other information arising out of that Contract whether or not Cobra is obliged to archive such matters under clause 18.1. At the end of the ten-year period Cobra shall contact Advaxis for further instructions as to the disposal and/or storage of the archived information held by Cobra. If Advaxis does not respond within 30 days of such notification, Cobra may either return the archived matter to Advaxis at Advaxis's own expense or destroy the archived matter.

19. **Warranties**

19.1 Cobra warrants that the Products and/or Services:-

19.1.1 will be free from substantial defects in materials and/or workmanship;

19.1.2 are manufactured and/or performed with all proper and reasonable skill, competence, care and attention;

19.1.3 are produced and/or performed in accordance with GMP and Medicines Control Agency and/or FDA guidelines where specified or appropriate;

19.1.4 will at the time of delivery and/or performance conform with any final Specification (for the avoidance of doubt this warranty does not extend to draft or provisional Specification);

19.1.5 comply with all applicable legal and regulatory standards from time to time; and

19.1.6 are manufactured, packaged, handled and stored in accordance with the terms of the applicable Contract and all appropriate legislation rules and other requirements of the appropriate regulatory authorities in force at the time of the Contract.

- 19.2 The warranties in clause 19.1 above are given by Cobra subject to the following conditions:-
- 19.2.1 Cobra shall be under no Liability in respect of any defect in the Products and/or Services arising directly from any information and/or specifications supplied to Cobra by Advaxis;
- 19.2.2 Cobra shall have no Liability in respect of any faults arising after risk in the Products has passed to Advaxis that are caused by any subsequent mechanical, chemical, biological, electrolytic or other damage not due to a defect in the Products and/or Services or the neglect or default of Cobra; and/or
- 19.2.3 Cobra shall be under no Liability in respect of any faults or defects caused by wilful damage, abnormal working or operating conditions, failure to follow Cobra's instructions, misuse or alteration of Products and/or Services without Cobra's approval, improper maintenance, storage or negligence on Advaxis's part and/or by a third party.
- 19.3 Cobra does not guarantee that the Services to be carried out by Cobra under this Agreement or any Contract will be successful and/or will achieve any objectives outlined by Advaxis in Advaxis's order.
- 19.4 If Cobra is in breach of any of the warranties given in clause 19.1 with respect to a Contract, Advaxis may suspend the due date for payment of any unpaid amounts under the Contract until Cobra promptly:
- 19.4.1 replaces the defective Products; and/or
- 19.4.2 re-performs the Services;
- and thereafter all outstanding amounts shall become due and payable.
- 19.5 Cobra shall have no liability under the warranties given in clause 19.1 unless it has received written notification of non-conformance from Advaxis within 21 days of discovery by Advaxis of the non-conformance.
20. **Repairs And Replacements**
- 20.1 Cobra will at its option, promptly, either refund the price or re-perform any defective Services and/or replace any defective Products where the defect is apparent on inspection, provided that the defect is notified to Cobra within 21 working days of delivery of such Products or performance of the Services.
- 20.2 If Advaxis fails to notify Cobra of any defect in the Products and/or Services under clause 20.1 within 21 working days of delivery and/or performance, Advaxis will be deemed to have accepted the Products and/or Services.

- 20.3 A sample of any defective Products must where reasonable be returned to Cobra for inspection if requested by Cobra before Cobra will have any Liability for defective Products. If the sample proves to be defective, then Cobra shall reimburse Advaxis for the cost of returning the sample of the defective Products to Cobra.
- 20.4 Cobra, if it requests and where reasonable, shall have the right to inspect the subject-matter of any allegedly defective Services at a mutually convenient time, and Cobra will not have any Liability for any such defective Services until it has been allowed to make such inspection.
- 20.5 Cobra will replace and/or re-perform defective Products and/or Services which are not notified to Cobra within the time limit specified in clause 20.1 where the defect would not have been ascertainable on inspection and has been notified to Cobra as soon as reasonably practicable after discovery by Advaxis.
- 20.6 Cobra will at its option either refund the price of or replace free of charge any Products missing from a delivery of Products provided that the missing items are notified to Cobra within five working days after receipt of the shipment or, in the event of total non-delivery, this fact is notified to Cobra within five working days after receipt by Advaxis of Cobra's invoice for such Products.
- 20.7 If, on investigation, it is found that any claimed defects in the Products and/or Services are not the responsibility of Cobra under this Agreement or the applicable Contract, Cobra may charge Advaxis for all reasonable costs and expenses it has incurred in the course of and/or in consequence of the investigation.
21. **Limitations On Liability**
- 21.1 Cobra shall have no Liability for defective Products and/or Services where the defect has been caused by Advaxis.
- 21.2 Cobra shall have no Liability to Advaxis for defective Products and/or Services, Products not despatched or Products damaged or lost in transit unless the event is notified to Cobra within the appropriate time limit set out in this Contract.
- 21.3 Cobra shall have no Liability for additional damage, loss, liability, claims, costs or expenses caused by Advaxis's continued use of defective Products and/or Services after a defect has become apparent to Advaxis.
- 21.4 Advaxis shall where reasonable give Cobra a reasonable opportunity to remedy any matter for which Cobra is liable before Advaxis incurs any costs and/or expenses in attempting to remedy the matter independently. If Advaxis does not do so, Cobra shall have no liability to Advaxis for any damages caused by Advaxis, which could have been avoided if Advaxis had permitted Cobra the opportunity to remedy the matter first.

21.5 Neither party shall have any Liability to the other party for any:-

21.5.1 consequential losses;

21.5.2 loss of profits (other than direct loss of profit under a Contract in relation to work to be and/or already performed by Cobra under that Contract) and/or damage to goodwill;

21.5.3 economic and/or other similar losses;

21.5.4 special damages and indirect losses; and/or

21.5.5 business interruption, loss of business, contracts, opportunity and/or production;

suffered by the other party, and this shall apply whether or not it has been informed by the other party of the possibility of such matters.

21.6 Each party shall be under a duty to mitigate any loss, damage, costs or expenses that it may suffer.

21.7 Cobra's total Liability to Advaxis in relation to any Contract shall not exceed the amount paid by Advaxis to Cobra in relation to that Contract.

21.8 Each of the limitations and/or exclusions in this Agreement shall be deemed to be repeated and apply as a separate provision for each of:

21.8.1 Liability for breach under any Contract and/or under this Agreement;

21.8.2 Liability in tort (including negligence);

21.8.3 Liability for breach of statutory duty; and

21.8.4 Liability for breach of Common Law.

except clause 21.8 which shall apply once only as to any Contract in respect of all the said types of Liability under the Contract.

21.9 Nothing in this Agreement or any Contract shall exclude or limit the Liability of Cobra for death or personal injury due to its negligence or any Liability which is due to Cobra's fraud or any other liability which it is not permitted to exclude or limit as a matter of law.

## 22. Reporting

22.1 Cobra shall provide prompt and regular updates to Advaxis as the progression of work under each Contract and shall disclose all Results to Advaxis on a regular basis.



- 22.2 All Results and any and all Intellectual Property Rights in the Results shall belong to Advaxis and shall form part of Advaxis's Confidential Information under the Contract. Cobra may only use the Results with Advaxis's prior written consent.
- 22.3 Cobra shall provide Advaxis with a final report within 30 working days of completion of the Services under any Contract, the contents of which include but will not be limited to the Results. Further copies of the final report shall be made available to Advaxis on Advaxis's request and at Advaxis's own expense.
23. **Restrictions**
- 23.1 Advaxis shall not, during the term of any Contract and for a period of 12 months immediately following the termination of the Contract, whether on Advaxis's own behalf or in conjunction with or on behalf of any person, firm, company, business entity or other organisation and whether as employee, director, principal, agent, consultant, shareholder or in any other capacity whatsoever, directly or indirectly:-
- 23.1.1 solicit or procure any person who is or was an employee, agent and/or representative of Cobra to cease working for Cobra or accept into employment or otherwise engage or use the services of any person where that person:-
- 23.1.1.1 is an employee, agent and/or representative of Cobra at that time; and/or
- 23.1.1.2 has been an employee, agent and/or representative of Cobra at any time during the immediately preceding three months.
- 23.2 Whilst each of the restrictions in clause 23.1 are considered by the parties to be reasonable in all the circumstances as at the date of this Contract, it is agreed and declared that if any one or more of such restrictions shall be judged to be void as going beyond what is reasonable in all the circumstances for the protection of the interests of Cobra but would be valid if the restrictions were reduced in scope, the restrictions shall be deemed to apply with such modification.
- 23.3 Any restriction or part of a restriction found in any event to be void shall not affect the validity of any other restriction contained in this Agreement.
- 23.4 Cobra may by written notice at any time reduce the duration and/or scope of any of the restrictions in clause 23.1 above.

24. **General**

- 24.1 Advaxis agrees to indemnify and keep indemnified Cobra against any and all liability, loss, costs and expenses arising out of (i) any third party claim relating to this Agreement, (ii) any third party claim relating to the use of Products by Advaxis or by any third party, or (iii) the breach by Advaxis of any of its obligation or covenants under any Contract, in each case, subject to the limitations set forth in clause 21.6.
- 24.2 Cobra agrees to indemnify and keep indemnified Advaxis against any and all liability, loss, costs and expenses arising out of (i) any third party claim relating to this Agreement, (ii) any third party claim relating to the use of Products by Cobra or by any third party, or (iii) the breach by Cobra of any of its obligation or covenants under any Contract, in each case, subject to the limitations set forth in clause 21.6.
- 24.3
- 24.4 No waiver by a party of any breach of this Agreement or any Contract shall be considered as a waiver of any subsequent breach of the same provision or any other provision.
- 24.5 If any provision of this Agreement or any Contract is held by any competent authority to be invalid or unenforceable in whole or in part, the validity of the other provisions thereof and the remainder of the affected provision shall be unaffected and shall remain in full force and effect.
- 24.6 Neither party shall have any Liability to the other party for any delay in performance of any Contract to the extent that such delay is due to any events outside its reasonable control including but not limited to acts of God, war, flood, fire, labour disputes, subcontractor delays, strikes, lock-outs, riots, civil commotion, malicious damage, explosion, governmental actions and any other similar events. If a party is affected by any such event, then time for performance shall be extended for a period equal to the period that such event or events delayed such performance, provided that the party uses all reasonable efforts to minimize the duration of such effect. This shall not apply to any decision by the Medicines Control Agency that the Products have, where required, been produced without appropriate GMP and/or Good Laboratory Practice controls and/or documentation.
- 24.7 Neither party may assign this Agreement or any Contract without the written consent of the other party, except to a wholly owned subsidiary or to any successor in interest by merger or purchase of all or substantially all of its assets.

- 24.8 All third party rights are excluded and no third party shall have any right to enforce this Agreement or any Contract.
- 24.9 Any dispute arising out of or in connection with the Contract shall be referred to the arbitration in London of a single arbitrator appointed by agreement between the parties or, in default of agreement, nominated on the application of either party by the President for the time being of The Law Society. The arbitration shall be carried out in accordance with the Rules of Arbitration of the International Chamber of Commerce in force as at the date of the dispute. This Agreement shall be governed by and construed in all respects in accordance with the Laws of England. This shall not prevent either party seeking interim injunctive relief from any court of law.
- 24.10 Ongoing Relationship and Commercial Supply
- 24.10.1 Cobra acknowledges that drug development is a lengthy and risky process and accordingly:
- 24.10.2 Advaxis may wish to amend or terminate the Development Program at any time it reasonably considers the manufacture and/or marketing to the public at large of Formulated Product or *Listeria monocytogenes* ceases to be commercially viable; or
- 24.10.3 Advaxis may require Cobra to be a long-term collaborator in the production of Formulated Product or *Listeria monocytogenes* suitable for toxicological studies, stability studies, human clinical trials and marketing to the public at large.
- 24.10.4 Upon Advaxis's written request, the Parties will negotiate in good faith an agreement on the terms under which Cobra will manufacture and supply to Advaxis quantities of Formulated Product or *Listeria monocytogenes* required by Advaxis on a commercial scale for marketing to the public at large.
- 24.10.5 Notwithstanding clause 24.8.4, Cobra acknowledges that Advaxis has made no representation that Advaxis will, intends to or is likely to, issue a request to Cobra for the manufacture and supply of Formulated Product or *Listeria monocytogenes* in quantities on a commercial scale for marketing to the public at large.

**Redacted Version**  
**Confidential Treatment Sought**  
**with respect to certain portions of the Agreement indicated**  
**by a [ \* ]**

**CLINICAL RESEARCH SERVICES AGREEMENT**

**BETWEEN**

**ADVAXIS, INC**

**AND**

**PHARM-OLAM INTERNATIONAL LTD.**

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Attachment I and IA            Payment Schedule, Budget, pass through and Timelines Schedule

Attachment II                 POI Clinical Research Services and POI deliverables

Attachment III                Protocol and Schedule of Procedures

Advaxis Clinical Research Agreement  
April 6, 2005

This Clinical Research Services Agreement (this Agreement) is made and entered into effective as of April 4, 2005, by and between Advaxis, Inc. (hereafter "THE COMPANY"), a Colorado Company with its principal office at 212 Carnegie Center, Suite 206, Princeton, New Jersey 08540, and PHARM-OLAM INTERNATIONAL LTD. (hereafter "POI"), a Texas limited partnership, with its principal office at 450 N Sam Houston Pkwy, Suite 450, Houston, TX 77060, United States.

#### RECITALS

WHEREAS, THE COMPANY is a biotech company that develops biological vaccines to cure cancer; and

WHEREAS, POI is a contract research organization that plans, implements, and manages clinical trials; and

WHEREAS, THE COMPANY desires to engage POI to assist THE COMPANY in planning, implementing, and managing regulatory and conduct of a phase I clinical trial on an Investigational Biological Product Lovaxin C, as hereafter defined; and

WHEREAS, POI is willing to accept such engagement on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and obligations set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties agree as follows:

#### 1. DEFINITIONS

For purposes of this Agreement and the Protocol Synopsis, each capitalized term shall have the meaning ascribed to it in this Agreement. Each capitalized term not defined in this Agreement shall have the meaning ascribed to that term in the Protocol. In the event of a discrepancy in the meaning ascribed to a term in the body of this Agreement and the meaning ascribed to that term in the Protocol, the definition utilized in the body of this Agreement shall control.

1.1 "Case Report Form" or "CRF" means the record of pertinent information collected on each subject who participates in the Study;

1.2 "Clinical Laboratory Agreement" means the Agreement between THE COMPANY and the clinical laboratory or laboratories that will provide clinical laboratory services for the Study.

1.3 "Clinical Research Associate" or "CRA" means the person assigned by POI to monitor one or more Study Sites.

1.4 “Clinical Trial Agreement” means the agreement between POI and an Investigator that details the respective rights and obligations of both parties in relation to the Study;

1.5 “Clinical Trial Materials” means the Investigational Product, printed Case Report Forms, competitor substances, CRF monitoring conventions, the Protocol, the investigational drug brochure, informed consent form, guidelines for use of the Investigational Product, and all other materials provided by THE COMPANY to conduct the Study.

1.6 “Closeout Services” means those services described in Section 14 to be performed by POI upon termination of this Agreement.

1.7 “Company Obligations” means the obligations of THE COMPANY under this Agreement.

1.8 “Confidential Information” means any information, whether written or oral, including all notes, studies, customer lists, forms, business or management methods, marketing data, fee schedules, or trade secrets of any member of the POI Group or of THE COMPANY, as appropriate, disclosed or otherwise made available to one party by the other party pursuant to this Agreement. Confidential Information shall also include the terms and provisions of this Agreement and any transaction or documents executed by the parties pursuant to this Agreement. In addition, Confidential Information shall include any data or information developed or generated in the course of performance of this Agreement. Publication of the fact that THE COMPANY and POI have entered into a clinical trials agreement, without disclosing the terms and provisions of this Agreement, shall not be construed as unauthorized disclosure of Confidential Information.

Confidential Information does not include any information that (i) is or becomes generally available to and known by the public, other than as a result of an unauthorized disclosure directly or indirectly by the receiving party or its affiliates, advisors, or representatives; (ii) is or becomes available to the receiving party on a non-confidential basis from a source other than the furnishing party or its affiliates, advisors, or representatives, provided that such source is not and was not bound by a confidentiality agreement with or other obligation of secrecy to the furnishing party of which the receiving party has knowledge at the time of such disclosure; or (iii) has already been or is hereafter independently developed by the receiving party by persons not having access to the Confidential Information of the furnishing party.

The parties acknowledge that they have already executed a confidentiality agreement. (“CDA”) In the event of a conflict or a contradiction between this Agreement and the CDA, the terms of the CDA shall control.

1.9 “CRO Compensation” means the compensation to be paid by THE COMPANY to POI as set out in Attachment 1.

1.10 “Effective Date” means the effective date of this Agreement as set forth in the initial paragraph of this Agreement.

1.11 “Food and Drug Administration” means the United States government agency responsible for ensuring compliance with the Food, Drug, and Cosmetics Act of 1938.

1.12 “Force Majeure Event” means an event beyond the reasonable control of the relevant party including, but not limited to, acts of God, a public enemy, or a civil or military authority; fires or other catastrophes; strikes, lockouts, or other industrial action taken by the employees of any party or any third party; delays in transportation; riots; or invasions, wars, or threats of war.

1.13 “Good Clinical Practice” means the clinical standards established by the FDA and counterpart agencies of each country in which the Study will take place, designed to regulate the activities of THE COMPANY’s investigators, monitors, and Institutional Review Boards (“IRBs”) involved in clinical drug testing.

1.14 “Institutional Review Board” means the independent group of professionals designated to ensure that the Study is safe and effective for human participation and that the Study adheres to the regulations issued by the FDA and any other applicable country-specific laws, regulations or guidelines.

1.15 “Investigational New Drug Application” or “IND” means the petition filed by THE COMPANY with the FDA requesting the FDA to allow human testing on the Investigational Product.

1.16 “Investigational Product” means the product (drug, device, or biologic) described in the Protocol that will be evaluated in this Study.

1.17 “Investigator” means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the Investigational Product is administered or dispensed to, or used involving a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

1.18 “POI Group” means the following persons and entities, as constituted at the date of this Agreement or subsequently: (i) POI; and (ii) any person or entity that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with POI.

1.19 “POI’s Obligations” means the obligations of POI under this Agreement.

1.20 “Project Manager” means the manager assigned by POI to be the primary contact person between POI and THE COMPANY during the Study.

1.21 “Protocol” means the plan that describes the objectives, study design, and methodology and any approved amendments thereto, which is attached as **Attachment III**, and which is herein incorporated by reference.



- 1.22 “Regulatory Requirements” means those laws, regulations, and professional and ethical standards and guidelines then in effect in the countries in which the Study is conducted that apply to the Investigational Product or clinical trials in general.
- 1.23 “Related Products” means any product (drug, device, or biologic), other than the Investigational Product, administered or utilized as part of this Study.
- 1.24 “Serious Adverse Event” shall take the meaning given this term in the Protocol.
- 1.25 “Services” means the services to be furnished by POI in connection with the Study as set out in this Agreement and the list of deliverable specified in **Attachment II**.
- 1.26 “Staff” means the staff assigned to the Study by THE COMPANY either directly or indirectly through the Clinical Trial Agreement.
- 1.27 “Standard Operating Procedures” or “SOP’s” means internal procedures for the management of a clinical trial designed to ensure that the trial is carried out in a consistent, controlled, and effective manner.
- 1.28 “Study” means the clinical trial of the Investigational Product, the details of which are set out in the Attachments I, II and III and the Protocol..
- 1.29 “Study Documents” means the documents produced by POI in connection with the Study that are, in the sole discretion of POI, necessary for the production of the Final Study Report.
- 1.30 “Term” means the duration of this Agreement as set out in Section 13.

## 2. INTERPRETATION

- 2.1 Words of any gender used in this Agreement shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, and the plural to include the singular, unless the context requires otherwise.
- 2.2 The headings of the sections of this Agreement are inserted for convenience only and in no way define, limit, or prescribe the intent of this Agreement.
- 2.3 Unless otherwise specified, references in this Agreement to Sections and Attachment I are to the sections of, and Attachment I to, this Agreement. Attachment I is deemed to be incorporated into, and form part of, this Agreement, and the term “Agreement” shall be construed accordingly.
- 2.4 Unless otherwise specified, any reference to a statute, rule, or regulation shall be to that statute, rule, or regulation as amended from time to time.

3. APPOINTMENT AND RELATIONSHIP OF PARTIES

3.1 THE COMPANY hereby engages the services of POI, and POI accepts such engagement, to perform the Study and the Services, under the terms and conditions contained in this Agreement.

3.2 During the Term, POI shall at all times be the independent contractor of THE COMPANY, and nothing in this Agreement is intended, nor shall be construed, to create between THE COMPANY and POI the relationship of principal and agent, employer and employee, partnership, or joint venture, and the parties shall not represent themselves otherwise.

3.3 THE COMPANY shall be liable for its own debts, obligations, acts or omissions, including but not limited to the payment of all required compensation, withholding, social security and other taxes or benefits for THE COMPANY's employees. Likewise, POI shall be liable for its own debts, obligations, acts or omissions, including but not limited to the payment of all required compensation, withholding, social security and other taxes or benefits for POI's employees.

3.4 If the Internal Revenue Service or any other government authority shall, at any time, question or challenge the independent contractor status of POI, upon receipt by either party of notice from the Internal Revenue Service or any other governmental authority, the receiving party shall promptly notify the other party and afford the other party the opportunity to participate in any discussion or negotiation with the Internal Revenue Service or other government authority, regardless as to who initiates such discussions or negotiations.

4. REPRESENTATIONS AND WARRANTIES

4.1 POI warrants to THE COMPANY that it has the authority to enter into this Agreement.

4.2 THE COMPANY warrants to POI that (i) it has the authority to enter into this Agreement; and (ii) all consents and approvals required for the Study (except for the consent of the individuals who will participate in the Study) have been, or will be obtained prior to initiation of the Study.

5. POI'S OBLIGATIONS

In addition to POI's Obligations set forth in Attachment I and II and elsewhere in this Agreement, POI shall have the following obligations:

5.1 Before commencement of the Study, POI shall assign to the Study a Project Manager and sufficient personnel, including CRAs, with suitable experience and training to fulfill POI's obligations under this Agreement. Any change in the Project Manager thereafter must be reasonably acceptable to THE COMPANY.

5.2 POI shall apply to the Study systems of quality control designed to ensure that, as far as is reasonably practicable, THE COMPANY and the Investigators conduct the Study; generate data; and record and report data, all in compliance with the Regulatory Requirements, Good Clinical Practice, the Protocol, and this Agreement, in that order.

5.3 POI shall use its best efforts to perform the Services and deliverables within the time frames specified in **Attachment I**.

5.4 POI shall procure and maintain consents, approvals, licenses, and operating certificates as required.

5.5 POI shall retain all material Study Documents, as determined by POI in its sole discretion, until this Agreement has terminated and all Closeout Services has been performed. All Study Documents and CRF's will be forwarded to THE COMPANY after the Study is completed.

5.6 Company shall have the right to visit and co-monitor a Study Site or inspect and audit any of the Study Documents maintained by POI. All such visits and inspections must be conducted during normal working hours on regular business days, unless otherwise agreed. POI shall arrange access to the Study Site as soon as reasonably practicable following notification by THE COMPANY.

5.7 POI will provide THE COMPANY with written status reports in accordance with either THE COMPANY or POI SOP's.

5.8 POI shall notify THE COMPANY by phone immediately after becoming aware of a Serious Adverse Event and shall submit an initial written report to THE COMPANY regarding that Serious Adverse Event via facsimile within 24 hours after POI becomes aware of any such event.

5.9 POI shall indemnify and save harmless THE COMPANY, its officers, agents, and employees from all suits, actions, losses, damages, claims, or liability of any character, types, or description, including without limiting the generality of the foregoing, all expenses of litigation, court costs, and reasonable attorney's fees for injury or death to any person, or injury to property, received or sustained by any person or persons or property, arising out of, or occasioned by POI (or its agents or employees), in connection with its execution or performance of this Agreement. The Investigators are not and shall not be deemed the agents of POI for purposes of this Section 5.9. THE COMPANY will notify POI of any claim or suit which may be subject to the provisions of this Section 5.9 as soon as reasonably practicable after receiving notice of the claim. POI shall have the sole right to control and settle any such claim or suits, and THE COMPANY shall make all reasonable efforts to cooperate (at POI's expense) as requested by POI in handling any such claim or suit.

5.10 For the removal of any doubt, subject to the Company providing POI with the materials necessary for POI to complete and write the Investigational Product, POI shall be responsible to obtain all approvals, construct all the necessary written materials submit any and all applications as necessary, and cause the Phase I clinical trial to be conducted and completed in accordance with the Protocol (a draft of which is attached hereto as **Attachment III**) and in a form and manner acceptable to the US Food and Drug Administration.

5.11 In the event the Phase I study is conducted out of the US, POI shall follow the Special Protocol Assessment procedure of the US Food and Drug Administration and seek the feedback or approval of the US Food and Drug Administration to the Protocol.

5.12 **Outside regulatory consultant:** POI will work with a third party regulatory consultant pre approved by THE COMPANY.

5.13 POI shall be responsible for the list of services and deliverables specified in **Attachment II**. POI as the contracted research organization agrees to conduct the proposed phase 1b trial for Advaxis with the highest quality of care and in compliance with accepted standards of Good Research Practice and Good Laboratory Practice. Without derogating from the generality of the foregoing statement, the standards of management mentioned in **Attachment II** shall apply.

## 6. THE COMPANY'S OBLIGATIONS

In addition to THE COMPANY'S Obligations set forth in the Attachment I and elsewhere in this Agreement, THE COMPANY shall have the following obligations:

6.1 THE COMPANY shall provide POI, at no expense to POI (i) with all information and documentation reasonably necessary for POI to perform its duties hereunder, including but not limited to, all Clinical Trial Materials; and (ii) with all advice, guidance, and assistance reasonably requested by POI to fulfill its duties under this Agreement.

6.2 Except for the POI obligations in Paragraph 5.4, or as otherwise specifically provided herein, THE COMPANY shall procure and maintain all consents, approvals, licenses, and operating certificates required to conduct the Study. THE COMPANY shall also develop, comply with, and require Staff to comply with, policies and procedures designed to assure, at all times, that such consents, approvals, licenses, and operating certificates remain in effect throughout the Term.

6.3 THE COMPANY shall indemnify and save harmless POI, its officers, agents, and employees from all suits, actions, losses, damages, claims, or liability of any character, types, or description, including without limiting the generality of the foregoing, all expenses of litigation, court costs, and attorneys' fees for injury or death to any person, or injury to property, received or sustained by any person or persons or property, arising out of, or occasioned by the Investigational Product or the acts or omissions of the Staff or THE COMPANY (or its agents or employees), in connection with the Study or their execution or performance of this Agreement. POI will notify THE COMPANY of any claim or suit which may be subject to the provisions of this Section 6.3 as soon as reasonably practicable after receiving notice of the claim. THE COMPANY shall have the sole right to control and settle any such claims or suits, and POI shall make all reasonable efforts to cooperate (at THE COMPANY'S expense) as requested by THE COMPANY in handling any such claim or suit.

7. CRO COMPENSATION

7.1 THE COMPANY shall pay POI the amounts set forth in Attachment I for all services provided and expenses incurred by POI pursuant to this Agreement, according to the payment schedule set forth in Attachment I. Upon early termination of this Agreement pursuant to Sections 13.2, 13.3, or 13.4, THE COMPANY shall continue to pay POI the amounts set forth in Attachment I for all services provided by POI prior to the termination of this Agreement and for the Closeout Services furnished by POI after the termination of this Agreement, provided that in no event will the amount owed to POI exceed the maximum amounts specified in Attachment I.

7.2 POI shall submit invoices to THE COMPANY upon the completion of each payment milestone event set forth in Attachment I. THE COMPANY shall make full payment of such sums by check or in cleared funds to such bank account in the United States as POI may reasonably specify from time to time, upon receipt of invoice ("Due Date"), without any deduction, set off or withholding except any tax which THE COMPANY is required by law to deduct or withhold. Any amounts which remain unpaid for thirty (30) days or more after the Due Date shall bear interest at the rate equal to 8% per annum. Interest shall be computed on the basis of a 365 or 366-day year, as the case may be, subject to the provisions hereof limiting interest to the maximum rate of interest allowed by applicable law. If any amounts remain unpaid for ninety (90) days or more after the Due Date, POI shall have the right to discontinue all work and services under this Agreement until such amounts are paid in full.

7.3 If THE COMPANY is required by law to make any tax deduction or withholding, THE COMPANY shall provide reasonable assistance as requested by POI to assist POI to claim exemption from, or if that is not possible a credit for, the deduction or withholding under any applicable double taxation or similar agreement. THE COMPANY shall also supply POI from time to time with proper evidence as to the deduction or withholding and payment over of the tax deducted or withheld.

8. INSURANCE

8.1 THE COMPANY and POI shall each maintain, at its sole cost and expense, insurance coverage with a reputable insurer (which shall be either occurrence based or claims made coverage) in an amount usual and customary for companies engaged in activities as contemplated by this Agreement. All such insurance shall be in place before the first patient is enrolled in the Study. Each shall designate the other party as an additional named insured on all such policies, and an endorsement shall be made on each such policy prohibiting the insurer from canceling the policy for any reason or substantially modifying its terms without first giving the other party at least twenty-eight (28) days written notice of its intention to do so.

8.2 Upon request by either party, the other party shall provide evidence of that party's compliance with this Section.

## 9. CONFIDENTIALITY

9.1 Except as specified in the following Section, each of the parties agrees (i) that it shall not disclose any Confidential Information of the other party to other persons without the express written authorization of the other party; (ii) that such Confidential Information shall not be used in any way detrimental to the other party; and (iii) that the parties will keep such Confidential Information confidential and will ensure that its affiliates and advisors who have access to such Confidential Information comply with these non-disclosure obligations.

9.2 Notwithstanding the foregoing, the parties may disclose Confidential Information to (i) those of its representatives, including, but not limited to the other party's legal, financial and accounting advisors, who need to know Confidential Information for the purpose of conducting this Study, it being understood and agreed by the parties that such representatives will be informed of the confidential nature of the Confidential Information, will agree to be bound by this Section, and will be directed by the respective party not to disclose to any other person any Confidential Information; and (ii) the FDA, an IRB, or comparable governmental or professional body with jurisdiction over the Study provided such disclosure is requested by the respective governmental or professional body or is required in order to satisfy Section 6.1.

In the event that either party determines that it is required by law to disclose the other party's Confidential Information, or such disclosure is in response to a subpoena or a similar legal process, such disclosure shall be permitted provided that the other party required to make such disclosure promptly notifies the other party and assists the other party in obtaining a protective order or other appropriate remedy.

## 10. INTELLECTUAL PROPERTY

10.1 POI acknowledges that, as between THE COMPANY and POI, any and all intellectual property rights that may arise in the Study itself shall belong solely to THE COMPANY, including without limitation all data generated in the course of the Study, and all Clinical Trial Materials.

10.2 THE COMPANY acknowledges that, as between POI and THE COMPANY, any and all intellectual property rights in works authored by POI before the Effective Date of this Agreement and works authored by POI independent of the Study shall belong to POI.

## 11. ARBITRATION

11.1 Any controversy or claim between the parties arising out of or relating to this Agreement, shall be finally determined and settled pursuant to arbitration in Princeton, NJ, by three disinterested arbitrators each of whom (i) shall have at least 5 years of experience as an arbitrator and (ii) shall be associated with the American Health Lawyers Association ADR Service or the American Arbitration Association. One arbitrator shall be appointed by THE COMPANY, one arbitrator shall be appointed by POI, and one arbitrator shall be appointed by such party-appointed arbitrators. The third arbitrator shall be an attorney and shall act as chairman. Should either party fail to appoint an arbitrator as contemplated in this Section within 10 days after that party has received such written request, or if the two arbitrators appointed by or on behalf of the parties as contemplated in this Section fail to appoint a third arbitrator, then upon application by either party, the remaining arbitrator(s) shall be appointed pursuant to the Commercial Arbitration Rules of the American Arbitration Association, which arbitrator(s) shall fill such position with the same force and effect as though such arbitrator(s) had been appointed as contemplated in this Section.

11.2 The arbitration proceedings shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association. A determination, award, or other action shall be considered the valid action of the arbitrators if supported by the affirmative vote of two or three of the three arbitrators. The costs of arbitration (exclusive of a party's own costs incurred in attending the arbitration, and of the fees and expenses of legal counsel to such party, all of which shall be borne by such party) shall, in the discretion of the arbitrators, be ordered to be paid by the one or both of the parties either equally or in such proportions as may be decided by the arbitrators. The arbitration award shall be final and binding, and judgment upon such award may be entered in any court having jurisdiction. Notwithstanding any other provision hereof, no party shall be awarded punitive or exemplary damages in any arbitration hereunder.

## 12. NON-SOLICITATION OF STAFF

During the term of this Agreement and for a period of twelve months following its termination or expiration, THE COMPANY shall not directly or indirectly (i) solicit or entice any employee or contractor of POI with whom it comes into contact as a result of participation in the Study, to be employed by it or any other person or entity; or (ii) approach any such employee or contractor for such purpose or authorize or approve the taking of such action by any other person.

## 13. TERM AND TERMINATION

13.1 This Agreement shall commence on the Effective Date and, unless terminated pursuant to this Section 13, shall continue until such time as the Services and Closeout Services have been completed.

13.2 This Agreement may be terminated upon the mutual, written consent of both parties. This Agreement may also be terminated by THE COMPANY without cause upon thirty (30) days prior written notice to the other party.

13.3 Either party may immediately terminate this Agreement for cause, upon written notice to the other party stating the date of termination, pursuant to the following:

13.3.1 *Termination by POI.* POI may terminate this Agreement for cause upon the occurrence of any of the following events:

(i) THE COMPANY fails to maintain the insurance coverage required by Section 8.1;

(ii) The FDA, IRB, or any regulatory authority with jurisdiction over the Study suspends or revokes any consent, approval, license, or operating certificate required to conduct the Study;

(iii) If THE COMPANY enters into a Clinical Trial Agreement with an Investigator relating to the Study, and the Investigator or any member of the Investigator's staff fails to possess all qualifications, training, and licenses necessary to perform the duties and obligations of that individual under that agreement or fails in any material manner to abide by the provisions of the Regulatory Requirements or this Agreement; provided, however, that THE COMPANY may cure any such deficiency by removing the affected individual from providing services under this Agreement;

(iv) THE COMPANY breaches any material provision of this Agreement, other than those specifically referenced in this Section 13.3.1, and fails to remedy that breach within 30 days after receiving notice of such breach; or

(v) THE COMPANY files a petition for the appointment of a receiver in liquidation or a trustee with respect to itself or any of its property; or any person other than THE COMPANY files a petition for the appointment of a receiver in liquidation or a trustee with respect to THE COMPANY in bankruptcy, insolvency, or reorganization, compromise, adjustment or other relief relating to the relief of debtors, and such involuntary petition is not vacated or set aside or stayed within 60 days from THE COMPANY's receiving notice of such petition.

13.3.2 *Termination by THE COMPANY.* THE COMPANY may terminate this Agreement for cause upon the occurrence of any of the following events:

(i) The FDA, IRB, or any regulatory authority with jurisdiction over the Study suspends or revokes any consent, approval, license, or operating certificate required to conduct the Study;

(ii) The occurrence of a Serious Adverse Event which should cause the Study to be terminated due to safety concerns

(iii) POI breaches any material provision of this Agreement, other than those specifically referred to in this Section 13.3.2, and fails to remedy that breach within 30 days after receiving notice of such breach; or

(iv) POI files a petition for the appointment of a receiver in liquidation or a trustee with respect to itself or any of its property; any entity POI controls makes a voluntary assignment for the benefit of creditors or files a petition in bankruptcy or insolvency or for reorganization, compromise, adjustment, or other relief; or if any person other than POI files a petition for the appointment of a receiver in liquidation or a trustee with respect to POI or any entity it controls in bankruptcy, insolvency, or reorganization, compromise, adjustment or other relief relating to the relief of debtors, and such involuntary petition is not vacated or set aside or stayed within 60 days from POI's receiving notice of the petition.



13.4 In the event of any change or reinterpretation of a Regulatory Requirement, the adoption of any new law or regulation, or the initiation of an enforcement action with response to laws, regulations, or guidelines applicable to this Agreement, any of which shall affect the legality of this Agreement, the parties agree to negotiate in good faith to amend this Agreement to comply with the offended law or regulation. If the parties do not agree to such amendment within 30 days prior to the effective date of the offended law or regulation (or such earlier time as may be required to comply), then either party may terminate this Agreement immediately by giving written notice to such effect to the other party.

#### 14. CONSEQUENCES OF TERMINATION

14.1 The termination of this Agreement for any reason shall not affect any right or remedy existing hereunder prior to the effective date of termination.

14.2 Without limiting the foregoing, upon termination of this Agreement, THE COMPANY shall, in addition to all CRO Compensation then due, compensate POI, as specified in Attachment I, for all Closeout Services required to terminate and closeout the Study, including but not limited to, any activities necessary to satisfy the requirements of any governmental, regulatory, or professional authority with jurisdiction over the Study

#### 15. GENERAL PROVISIONS

15.1 This Agreement sets forth the entire agreement and understanding among the parties as to the matters contained therein, and merges and supersedes any prior discussions, agreements, and understanding of every kind and nature relating thereto.

15.2 Any amendment of or modification to this Agreement shall become effective only if it is in writing and executed by the parties.

15.3 This Agreement shall be binding upon, and inure to the benefit of, the parties and their respective legal representatives, trustees, receivers, successors and permitted assigns.

15.4 Except as otherwise specified in this Agreement or otherwise agreed to by the parties in writing, all notices, requests, demands, and other communications provided for in this Agreement shall be in writing in English and shall be deemed to have been given at the time when personally delivered, or mailed by registered or certified mail, return receipt requested, to the address of the other party stated below or to such other address as any such party may have fixed by notice, provided, however, that any notice of change of address shall be effective only upon receipt by addressee.

All notices to THE COMPANY shall be addressed to:

Mr. Todd Durbin  
Advaxis, Inc.  
212 Carnegie Center, Suite 206  
Princeton, N.J. 08540

If notices or communications by telephone or facsimile are specifically authorized in this Agreement or otherwise agreed to by the parties in writing, calls to THE COMPANY shall be placed and facsimiles to THE COMPANY shall be sent to the following numbers:

Phone: 609 895 7150 Fax: 801 459 3596.

All notices to POI shall be addressed to:

John Hovre  
Executive Vice President  
Pharm-Olam International Ltd.  
450 N. Sam Houston Pkyw. Ste 250  
Houston, TX 77060

If notices or communications by telephone or facsimile are specifically authorized in this Agreement or otherwise agreed to by the parties in writing, calls to POI shall be placed and facsimiles to POI shall be sent to the following numbers:

Phone: (713) 463-8075

Fax: (713) 463-8281

The parties shall give notice to each other of any change of their address or telephone, facsimile, or similar number at the earliest possible opportunity.

15.5 All agreements of the parties, as well as any rights or benefits accruing to them, pertaining to a period of time following the termination or expiration of this Agreement or any of its provisions, including but not limited to Paragraph 6.3, and Sections 7 through 12, and 14, shall survive such termination or expiration hereof and shall not be merged.

15.6 The waiver by any party of a breach or default by any other party shall not operate as a waiver of a continuing or subsequent breach or default of the same or a different nature or kind.

15.7 If any provision of this Agreement or the application of any such provision to any person or circumstance is held invalid, the remainder of this Agreement and the application of such provision to other persons or circumstances shall not be affected unless the invalid provision substantially impairs the benefits of the remaining provisions of this Agreement.

Advaxis Clinical Research Agreement  
April 6, 2005

15.8 No party may assign this Agreement or its rights and duties hereunder, without the prior written consent of the other party, except that THE COMPANY may assign this Agreement to a purchaser or acquirer of substantially all of the business to which this Agreement relates.

15.9 The provisions of this Agreement shall be self-executing and shall not require further agreement by the parties except as may otherwise be specifically provided in this Agreement; provided, however, that, at the request of a party, the other party shall execute such additional instruments and perform such additional acts as may be reasonably necessary to effectuate this Agreement.

15.10 This Agreement may be executed in counterpart originals, with each counterpart to be deemed an original, but all counterparts together shall constitute a single instrument.

15.11 In the event that performance by a party of any of its obligations under the terms of this Agreement shall be interrupted or delayed by a Force Majeure, that party shall be excused from such performance for the same amount of time as such occurrence shall have lasted or such period of time as is reasonably necessary after such occurrence abates for the effects thereof to have dissipated.

16. APPLICABLE LAW

This Agreement shall be governed by and be construed under the laws of the State of New Jersey, without giving effect to its choice-of-law rules, and exclusive venue of any action or other proceeding that may be brought or arise out of, in connection with, or by reason of this Agreement shall be in NJ, United States.

IN WITNESS WHEREOF, this Agreement is executed by the parties hereto and is effective as of the day and year first above written.

**Advaxis, Inc.**

By: \_\_\_\_\_

**Pharm-Olam, Int'l.**

By: \_\_\_\_\_

John Hovre, its Executive Vice President

Advaxis Clinical Research Agreement  
April 6, 2005

**Attachment I**

**Timelines and Payment Schedule**

**Timelines:**

<b>Event</b>	<b>Date</b>
Protocol Completion and Investigator Brochure Submitting request for Special	Completed and attached
Protocol Assessment meeting with FDA	[ * ]
Special Protocol Assessment meeting with FDA	[ * ]
Submit to Ethics Committee and RA, [ * ]	[ * ]
Submit IND with FDA	[ * ]
Approval [ * ]	[ * ]
Approval [ * ]	[ * ]
First patient in to study [ * ]	[ * ]
Last patient in to study	[ * ]
Interim report	[ * ]
Last patient out of study	[ * ]
Close database	[ * ]
Statistical analysis complete	[ * ]
Study draft Final Report	[ * ]

<b>CRO Total Grant</b>	\$[ * ]
Excluding pass-through costs	

Payment Schedule for Services:

[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]

\* these payments are subject to the closing of an equity financing equal or greater to \$[ \* ]

Pass-throughs:

Invoices will be sent to Advaxis, Inc for all pass-through cost.

The parties agree that the pass-through costs shall not exceed the cost structure detailed in **Attachment IA**:

**Attachment IA**

**Pass-throughs**

<b>Item</b>	<b>Cost (\$)</b>	<b>Notes</b>
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
<b>Total</b>	\$181,080	

[ \* ]

## **Attachment II**

### Clinical Research Services and POI's deliverables

#### **POI Deliverables**

1. Protocol Completion
2. Investigator Brochure completion
3. Submitting request for Special Protocol Assessment meeting with FDA
4. Special Protocol Assessment meeting with FDA
5. Submit to Ethics Committee and RA, [ \* ]
6. Submit IND with FDA
7. Obtain Approval for Phase I in Lovaxin C in [ \* ]
8. Obtain Approval for Phase I in Lovaxin C in [ \* ]
9. Recruit 2 Phase I study sites In [ \* ]
10. Recruit 2 Phase I study sites In [ \* ]
11. Provide an Interim study report after 10 patients have completed the treatment
12. Create and manage a database accessible to Advaxis at all times.
13. Perform and complete statistical analysis
14. Study draft Final Report
15. Study final report

#### **Quality of Study Management**

1. A site screening visit that assures each site has the appropriate facilities and personnel to conduct the proposed study. This includes approved and certified physicians, a dedicated study nurse, and adequate clerical personnel necessary facilities for patient visits, diagnostic devices, and so forth.
2. A study initiation visit for previously screened sites in which the specific details of the protocol are reviewed in detail and instruction is given to the site personnel as to the correct methods for conducting the study. Specific attention is paid to following the study plan and schedule, collecting information, completing case report forms (CRF) and assuring their veracity when compared with the patient charts.
3. A monitoring schedule which assures that CRFs are audited on a timely basis. Weekly calls to the site to track patient enrollment and visits at least once per month to assure adequate patient enrollment, enrolled patients are being treated in compliance with the protocol as written, auditing of CRF against original documents (patient charts, scans, X-rays, lab reports, etc). The retrieval of all CRF, or portions of CRF, which are completed, audited, and ready for data entry.
4. Verification of data entered into the analytic database against the CRF data forms to assure the reliability of the data to be analyzed.

# Attachment III Protocol

Not yet finalized.

Cobra Bio-manufacturing Plc t +44 (0)1782 714181  
Stanherson Building f +44 (0)1782 714180  
The Science Park e info@cobrabio.com  
Kettle ST5 5SP UK www.cobrabio.com



**DATED** *12 November* **2003** making tomorrow's medicines

- (1) **COBRA BIO-MANUFACTURING PLC**
- and
- (2) **ADVAXIS INC**

**ROYALTY AGREEMENT**

Date: 05/11/2003

Gateley Waring  
One Eleven  
Edmund Street  
Birmingham B3 2HJ

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Registered in England No. 0949837

*[Handwritten signature]*  
*14/2/03*



Cobra Bio-manufacturing Plc t +44 (0)1782 714181  
Stephenson Building f +44 (0)1782 714168  
The Science Park e hjo@cobrabio.com  
Keele ST5 5SP UK www.cobrabio.com

making tomorrow's medicines

THIS AGREEMENT is made the day of 2003

**BETWEEN:**

- (1) **COBRA BIO-MANUFACTURING PLC**, whose principal place of business is at Stephenson Building, Keele University Science Park, Keele, Staffordshire, ST5 5SP, England ("Cobra"); and
- (2) **ADVAXIS INC**, whose principal place of business is at 212 Carnegie Center, Suite 206, Princeton, NJ 08540, USA ("Advaxis").

**BACKGROUND**

Cobra has agreed to carry out a particular programme of work contract number O422 Phase II, for Advaxis at a substantial discount of \$300,000 for that programme of work on condition that Advaxis pays to Cobra the royalties referred to in this Agreement based on the net sales of the product derived from that programme of work.

**IT IS AGREED** as follows:

**1. Definitions**

- 1.1 In this Agreement unless the context otherwise requires:

**"Confidential Information"** means, in relation to each party, any and all financial and business information relating to the other party's business methods, customers, suppliers, licensees, finances, ideas, strategies, marketing plans and other matters which are disclosed by it to the other party under this Agreement;

**"Interest"** means interest (both before and after any judgment) at the rate of 1% above the base rate from time to time of Cobra's bankers calculated on a compound basis with quarterly rests;

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Registered in England No. 4442827

Cobra Biopharmaceuticals Plc t +44 (0)1782 714181  
Stephenson Building f +44 (0)1782 714168  
The Science Park e info@cobrabio.com  
Kemble ST6 5BP UK www.cobrabio.com



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**"Net Sales Value"**

means in relation to any Product anywhere in the world:

(a) where the Product is sold on arm's length terms, the price charged by Advaxis and/or any successor to the Technology and/or any of their sub-licensees less:

- (i) any value added tax or other sales tax,
- (ii) any packaging, packing freight, warehousing, carriage and insurance charges,

to the extent that any of those items are included in the price, and after deducting any allowances for lost or damaged merchandise or returns[, but without deducting (or, to the extent that they have been deducted from the price, after adding back) any discounts or rebates granted by the seller on account of [the quantity purchased or] promptness of payment or otherwise];

(b) where the Product is sold otherwise than on arm's length terms, but are subsequently sold on arm's length terms, the price charged under the first such arm's length sale, calculated in accordance with paragraph (a) above;

(c) where the Product is not sold on arm's length terms but is used or

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Registered in England No. 6442887

*[Handwritten signature]*  
11/12/03

Cobra Bio-manufacturing Plc t +44 (0)1782 714181  
Stephenson Building f +44 (0)1782 714188  
The Science Park e info@cobrabio.com  
Keele ST5 5SP UK www.cobrabio.com



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otherwise disposed of on a commercial basis, the price that would have been charged on the first arm's length sale, calculated in accordance with paragraph (a) above;

- "Product"** means a therapeutic vaccine based on attenuated *L. monocytogenes* for vaccination against HPV E7 expressing tumors produced using and/or incorporating all or any part of the Technology;
- "Quarter"** means each successive period ending on 31 March, 30 June, 30 September and 31 December or the date of termination of this Agreement, and "Quarterly" has a corresponding meaning;
- "Royalties"** means royalties of 1.5% of Net Sales Value payable to Cobra by Advaxis in accordance with section 2 of this Agreement;
- "Royalty Cap"** means \$1,950,000 (US Dollars) (plus any sales taxes) in Royalties;
- "Technology"** means Advaxis' patents, know-how, methodologies, formulae and expertise which is relevant to its therapeutic vaccine based on attenuated *L. monocytogenes* as described in the Schedule and any improvement to, modification, arrangement, re-arrangement, invention and/or adaptation of such matters devised either before or after the date of this Agreement;

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Agreement to Engage 001\_0447827



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**2. Royalties and Accounts**

- 2.1 Advaxis shall forward to Cobra within 30 days of the end of the Quarter a written statement showing for the previous Quarter:
  - 2.1.1 the quantity of each Product sold or otherwise disposed of or exploited on a commercial basis by Advaxis, successors to the Technology and/or any sub-licensees; and
  - 2.1.2 details of the Royalties due for each Product and the total amount of Royalties due for that period.
- 2.2 Advaxis will pay the Royalties to Cobra within 60 days of the end of the Quarter to which the Royalties relate. Time is of the essence in respect of payment of all Royalties under this Agreement.
- 2.3 Payment will not be deemed to have been received until the full amount has been received in cleared funds by Cobra.
- 2.4 Advaxis shall be liable to pay to Cobra interest on any Royalties which are paid late.
- 2.5 All sums due under this Agreement are exclusive of any US sales taxes which will be payable in addition by Advaxis.
- 2.6 All Royalties shall be paid in cleared funds in US Dollars to such bank account or in such other manner as Cobra may specify from time to time, without any set-off, deduction or withholding except any tax which Advaxis is required by law to deduct or withhold.
- 2.7 If Advaxis is required by law to make any deduction or withholding from monies payable under this Agreement, Advaxis shall take all actions and/or execute all documents requested by Cobra to enable or assist Cobra to claim exemption from or (if that is not possible) a credit for the deduction or withholding under any applicable double taxation treaty or similar arrangement from time to time in force and Advaxis shall give Cobra proper evidence of any deduction or withholding and payment over by Advaxis of the tax deducted or withheld.

LIQUIDATION OF COBRA BIOSCIENCE/PHARMING AGREEMENTS AS AMENDED BY NEW 03.1 L28.2003  
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- 2.8 Where it is necessary to calculate the exchange rate for the purposes of payment of any sums due under this Agreement, the exchange rate used shall be [the spot rate for US Dollars and the relevant currency] quoted by Cobra's bank at close of business on the business day preceding the due date for payment of each such sum.
- 2.9 Advaxis will (and will procure that any successors to the Technology and/or any sub-licensees will):
- 2.9.1 keep true and accurate accounts and records in sufficient detail to enable the amount of all Royalties payable under this Agreement to be determined; and
- 2.9.2 provide to Cobra, upon reasonable request, copies of the accounts and records and any supporting documentation and/or permit Cobra and/or its agent to inspect at Cobra's expense the same to the extent that they relate to the calculation of Royalties.
- 2.10 If the amount of royalties paid to Cobra in respect of any period falls short of the proper amount of Royalties due in respect of that period, or there is a discrepancy in the written statements which has resulted in an underpayment of the Royalties, Advaxis shall within 45 days of being notified of this discrepancy or shortfall pay the outstanding sum plus interest on that sum to Cobra. If any inspection carried out under clause 2.10.2 above reveals a shortfall of 5% or more in the amount of the Royalties actually paid for any period then Advaxis shall also pay to Cobra the reasonable costs incurred in the inspection.
- 2.11 Advaxis shall pay Royalties up to the level of the Royalty Cap. Advaxis shall have no liability to pay Royalties to the extent that they exceed the Royalty Cap.
3. Confidentiality
- 3.1 The parties shall use all of the Confidential information disclosed to and/or acquired by it during or after the term of this Agreement only for the purposes

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11/12/03

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of this Agreement and any other purpose for which that other party gives its prior written consent.

- 3.2 The parties shall maintain as confidential all of the Confidential Information which may come into its possession in any manner and all other information generated from it.
- 3.3 Neither party shall directly and/or indirectly use and/or disclose any of the Confidential Information in whole or in part except in accordance with this Agreement.
- 3.4 The parties shall at the other's request made at any time, deliver up to the other all documents, material and/or other media which may be in their possession, power or control which comprises or contains any part of the Confidential Information.
- 3.5 The obligations of confidentiality and non-use in relation to the Confidential Information shall continue indefinitely.
- 3.6 The Confidentiality Agreement already in place between Cobra and Advaxis shall prevail and be in full force and effect.
- 3.7 The Confidential Information shall not include any information which:
  - 3.7.1 was information already in either party's possession and at their free disposal;
  - 3.7.2 is after the date of this Agreement disclosed to either party in writing without any obligations of confidentiality by a third party who is not in breach of any duty of confidentiality in doing so;
  - 3.7.3 is or becomes generally available to the public in printed publications in general circulation through no act or default on the part of either party; or
  - 3.7.4 is required to be disclosed by law.

4. Duration and Termination

- 4.1 This Agreement comes into force on the date of this Agreement and shall, unless terminated earlier in accordance with clause 4.2 below, continue in

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force for the commercial life of the Product until such time as the amount of Royalties paid by Advaxis has reached the Royalty Cap.

- 4.2 Either party may terminate this Agreement immediately by giving written notice to the other if the other party:
- 4.2.1 commits any breach of this Agreement (and if the breach is capable of remedy fails to remedy it within 60 days after being given a written notice containing full particulars of the breach and requiring it to be remedied);
  - 4.2.2 persistently breaches any of its obligations under this Agreement; and/or
  - 4.2.3 has a receiver, administrative receiver or manager appointed over all or part of its assets, goes into liquidation, has a winding up petition presented against it, enters into a composition or voluntary arrangement with its creditors, has a bankruptcy petition presented against it, ceases or threatens to cease to carry on business, has any distress or execution levied against it, becomes insolvent or unable to pay its debts or suffers any analogous event in any country in which the other party is constituted or established.
5. **Effects of Termination**
- 5.1 Advaxis shall upon termination promptly provide to Cobra a written statement in accordance with clause 2.1 above in respect of the period from the beginning of the preceding Quarter to the date of termination and at the time of providing such statement Advaxis will pay in full the total Royalties relating to that period.
  - 5.2 Termination of this Agreement shall not affect the accrued rights of either party arising out of this Agreement as at the date of termination.
  - 5.3 Subject to the provisions of this section 5, neither party shall be under any further obligation which may arise after the termination of this Agreement to the other.

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5.4 Upon termination of this Agreement for any reason, the provisions of sections 2, 3, 5, 6 and 7 shall continue in full force and effect.

6. Assignment

6.1 Neither party may assign the benefit and burden of this Agreement to any third party without the other party's prior written consent except that Cobra may assign the debts arising under this Agreement without Advaxis' consent.

6.2 On any assignment of this Agreement, this Agreement shall be binding upon any successor and/or assignee.

6.3 Advaxis shall ensure that, in addition to this Agreement between Cobra and Advaxis, any successor to all and/or any part of the Technology is bound by an agreement with Cobra on the same terms as this Agreement as if such successor were Advaxis under this Agreement provided that Cobra shall not be entitled to receive Royalties more than once in relation to the disposal of the same particular Item.

7. General

7.1 Any notice under this Agreement may be served by first class post, facsimile or e-mail to the addresses given at the start of this Agreement or such other address as may be notified by either party from time to time. A notice shall be deemed served, if sent by facsimile or e-mail, on the working day immediately after the day on which it was sent and if sent by first class post, on the fifth working day after posting.

7.2 This Agreement constitutes the entire agreement and understanding of the parties and supersedes all prior oral or written agreements, understandings or arrangements between them relating to the subject matter of this Agreement. Neither party shall be entitled to rely on any agreement, understanding or arrangement which is not expressly contained in this Agreement and no change may be made to it except in writing signed by duly authorised representatives of the parties.

7.3 All third party rights are excluded and no third party shall have any rights to enforce this Agreement.

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11/12/03



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- 7.4 No waiver by either party of any breach of this Agreement shall be considered as a waiver of any subsequent breach of the same provision or of any other provision.
- 7.5 If any provision of this Agreement is held by any competent authority to be invalid or unenforceable in whole or in part the validity of the other provisions of this Agreement and the remainder of the affected provision shall be unaffected and shall remain in full force and effect.
- 7.6 This Agreement is governed by English law and the parties agree to submit to the non-exclusive jurisdiction of the English courts.

**IN WITNESS OF THE ABOVE** the parties have signed this Agreement on the date written at the head of this Agreement.

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for and on behalf of  
COBRA BIO-MANUFACTURING PLC

Name: DAVID THATCHER  
Title: Chief Executive



for and on behalf of  
ADVAXIS INC

Name: J. Todd Jerbin  
Title: CEO



## GOLDSTEIN GOLUB KESSLER LLP

Certified Public Accountants and Consultants



### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors  
Advaxis, Inc.

We hereby consent to incorporation by reference in Amendment No.4 to the Registration Statement (No. 333-122504) on Form SB-2 of our report dated April 21, 2005 on the balance sheets of Advaxis, Inc. (a development stage company) as of December 31, 2003 and 2002 and October 31, 2004, and the related statements of operations, stockholders' equity (deficiency), and cash flows for the period from March 1, 2002 (inception) to December 31, 2002, the year ended December 31, 2003, the period from January 1, 2004 to October 31, 2004, and the period from March 1, 2002 (inception) to October 31, 2004. We also consent to the reference to our Firm under the caption "Experts".

*Goldstein Golub Kessler LLP*  
GOLDSTEIN GOLUB KESSLER LLP  
New York, New York

June 9, 2005

1185 Avenue of the Americas Suite 500 New York, NY 10036-2602  
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NEXIA INTERNATIONAL IS A WORLDWIDE NETWORK OF INDEPENDENT ACCOUNTING AND CONSULTING FIRMS

June 9, 2005

Securities and Exchange Commission  
460 Fifth Street, N.W.  
Washington, D.C. 20549

Re: **Advaxis, Inc.**  
**Registration Statement on Form SB-2**  
**Application for Confidential Treatment, filed April 7<sup>th</sup> and June 1<sup>st</sup> 2005**  
**File No. 333-122504**

Ladies and Gentlemen:

On behalf of our client, Advaxis, Inc., a Colorado corporation (the "*Company*"), we attach for filing under the Securities Act of 1933, as amended (the "*Act*"), by means of the Electronic Data Gathering, Analysis, and Retrieval system, Amendment No. 4 to Registration Statement on Form SB-2 (File No. 0.50621) (the "*Registration Statement*"), together with certain exhibits thereto.

We are in receipt of the letter, dated June 9, 2005 (the "*Comment Letter*"), from John Krug, Esq., of the Securities and Exchange Commission (the "*Commission*"), addressed to the Company. Set forth below are the responses of the Company to the comments set forth in the Comment Letter, numbered to correspond thereto. All capitalized terms used, but not otherwise defined, herein shall have the respective definitions assigned thereto in the filing transmitted herewith.

**CommentResponse**  
**Number**

1. The Company has revised the application for confidential treatment regarding proper preparation of a confidential treatment request for information required to be included in a filing.
  2. The Company has revised the application for confidential treatment. The Company requests confidential treatment until June 9, 2015 with respect to the redacted portions of the License Agreement with the Trustees of the University of Pennsylvania.
  3. The Company has revised the redactions in Sections 2.6, 2.7, 6.5, 6.6 and 7.6 of the License Agreement with the Trustees of the University of Pennsylvania.
  4. The Company has revised the application for confidential treatment. The Company requests confidential treatment until June 9, 2008 with respect to the redacted portion of the Manufacturing Agreement with Cobra Biomanufacturing PLC.
-

**Comment Response**

**Number**

5. The Company had unintentionally omitted the attached document "0422 Phase II Terms and Conditions". The Company has revised the disclosure to include the attached document.
6. The Company has filed as Exhibit 10.28 the Royalty Agreement, dated as of May 11, 2003, by and between Cobra Bio-Manufacturing PLC and the Company.
7. The Company has revised the application for confidential treatment. The Company requests confidential treatment until June 9, 2008 with respect to the redacted portion of the Clinical Research Services Agreement with Pharm-Olam International Ltd.

Closing Comments The Company takes notice of the Closing Comments.

Please contact the undersigned at (212) 209-3090 if we may be of assistance.

Sincerely,

/s/ Gary A. Schonwald

Gary A. Schonwald