

Advaxis, Inc.
Form SB-2/A
April 28, 2005

As filed with the Securities and Exchange Commission on April 28, 2005.

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

AMENDMENT NO. 2 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) 497-7555**

(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) 497-7555**

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

Copies to:

Gary A. Schonwald, Esq.
Reitler Brown & Rosenblatt LLC
800 Third Avenue
21st Floor
New York, New York 10022
(212) 209-3050 / (212) 371-5500 (Telecopy)

Approximate date of commencement of proposed sale to the public. From time to time after this Registration Statement becomes effective.

If 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> ⁽¹⁾	<u>Proposed maximum offering price per unit</u> ⁽²⁾	<u>Proposed maximum aggregate offering price</u> ⁽²⁾	<u>Amount of registration fee</u>
common stock par value \$0.001 per share ⁽³⁾	36,690,056	\$1.00	\$4,318.42	\$4,318.42
common stock par value \$0.001 per share ⁽⁴⁾	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 April 28, 2005

PRELIMINARY PROSPECTUS

56,320,644 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. 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.

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

The date of this prospectus is _____, 2005.

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

TABLE OF CONTENTS

Item Description	Page No.
PROSPECTUS SUMMARY	iii
THE OFFERING	ix
RISK FACTORS	x
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	xxv
USE OF PROCEEDS	xxvi
MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS	xxvi
DIVIDEND POLICY	xxvi
DILUTION	xxvi
CAPITALIZATION	xxvii
MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS AND PLAN OF OPERATIONS	xxix
BUSINESS	39
MANAGEMENT	55
PRINCIPAL AND MANAGEMENT STOCKHOLDERS	64
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	67
SELLING STOCKHOLDERS	69
DESCRIPTION OF CAPITAL STOCK OF THE COMPANY	81
SHARES OF THE COMPANY ELIGIBLE FOR FUTURE SALE	83
PLAN OF DISTRIBUTION	85
LEGAL MATTERS	87
EXPERTS	87
ADDITIONAL INFORMATION	87
FINANCIAL STATEMENTS	F-1

INFORMATION NOT REQUIRED IN PROSPECTUS	II-1
INDEMNIFICATION OF DIRECTORS AND OFFICERS	II-1
OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION	II-1
RECENT SALES OF UNREGISTERED SECURITIES	II-1
EXHIBITS	II-2
UNDERTAKINGS	II-5

2

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, or incorporated by reference into, 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:

<u>Product</u>	<u>Indication</u>	<u>Stage</u>
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) 844-7755.

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.

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 which contains descriptions of our technology, our drugs and the trial status of each drug.

SUMMARY CONSOLIDATED FINANCIAL DATA OF ADVAXIS

On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation through the Share Exchange. The transaction was accounted for as a recapitalization. The historical financial statements of Advaxis will be our financial statements for reporting purposes. Advaxis, Inc has changed its fiscal year to October 31st and as a result is providing herein its audited financial statements for the 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)	
Statement of Operations Data:	2002	2003	Unaudited 2003	2004	2004	2005
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	4,521	4,106	116,462	(430)	(2,739)
Provision for income taxes	--	--	--	--	--	--
Net loss	\$ (166,936)	\$ (909,745)	(825,907)	(538,076)	\$ (142,466)	\$ (245,355)
Loss per Share Information:						
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)	

Edgar Filing: Advaxis, Inc. - Form SB-2/A

	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

7

THE OFFERING

Common stock offered by selling stockholders	56,320,644 ⁽¹⁾
Common stock outstanding	36,690,056 ⁽²⁾
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.

(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;

9

- 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 or to view its publicly filed documents, 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,