

Advaxis, Inc.  
Form POS AM  
June 12, 2007

As filed with the Securities and Exchange Commission on June 12, 2007 Registration No. 333 - 132298

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

**POST-EFFECTIVE AMENDMENT NO. 2 TO  
FORM SB-2**

**REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**Advaxis, Inc.**

**(Name of small business issuer in our charter)**

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

**Technology Center of New Jersey  
675 Route 1  
Suite 119**

**North Brunswick, NJ 08902**

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

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**Mr. Thomas Moore, Chief Executive Officer  
Technology Center of New Jersey  
675 Route 1, Suite 119  
North Brunswick, NJ 08902  
(732) 545-1590**

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

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*Copies to:*

**Gary A. Schonwald, Esq.**

**Reitler Brown & Rosenblatt LLC**  
**800 Third Avenue**  
**21<sup>st</sup> Floor**  
**New York, New York 10022**  
**(212) 209-3050 / (212) 371-5500 (Telecopy)**

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

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

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, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

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

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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 POST-EFFECTIVE AMENDMENT TO THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE POST-EFFECTIVE AMENDMENT TO THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(A) MAY DETERMINE.

#### **EXPLANATORY NOTE**

Pursuant to Rule 429 promulgated under the Securities Act of 1933 as amended, the Prospectus included herein relates to two Registration Statements on Form SB-2 (Registration Nos. 333-132298 and 333-122504). This Registration Statement as amended constitutes the Post-Effective Amendment No. 2 of the Registration Statement on Form SB-2 (Registration No. 333-12298) and Post-Effective Amendment No. 5 to the Registration Statement on Form SB-2 (Registration No. 333-122504).

#### **WITHDRAWAL**

Registrant hereby withdraws from registration pursuant to Registrant Statement on Form SB-2, as Post-Effective Amendment (Registration No. 333-122504) an aggregate of 25,061,907 shares of Common Stock, par value \$.001 per share, representing those shares of Common Stock outstanding on April 19, 2006, or for which the Registrant's obligation to maintain an effective Registration Statement has terminated as a result of the availability of the exemption from registration afforded by Rule 144(k) under the Securities Act of 1933, as amended.

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Subject to completion  
Dated June 12, 2007

Prospectus

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

### **Advaxis, Inc.**

### **Common Stock**

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

· Up to 12,037,550 shares of outstanding shares as of March 31, 2007.

· Up to 43,341,513 shares underlying our Convertible Secured Debentures due February 1, 2009 (the "Debentures") sold in a February and March 2006 private placement of which 5,052,513 shares have been issued upon conversion of \$775,000 principal amount of the Debentures.

· Up to 24,130,588 shares underlying warrants, including 4,500,000 shares underlying warrants issued in the Debenture private placement

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

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

No underwriter or person has been engaged to facilitate the sale of shares of Common Stock in this offering. None of the proceeds from the sale of the shares by the Selling Stockholders will be placed in escrow, trust or any similar account. There are no underwriting commissions involved in this offering. We have agreed to pay all the costs of this offering. Selling Stockholders will not pay any 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 10.**

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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 June , 2007.



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

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

We have not authorized anyone to give any information or make any representation about the Offering that differs from, or adds to, the information in this prospectus or in its documents that are publicly filed with the SEC. Therefore, if anyone does give you different or additional information, you should not rely on it. The delivery of this prospectus does not mean that there have not been any changes in our condition since the date of this prospectus. If you are in a jurisdiction where it is unlawful to offer the securities offered by this prospectus, or if you are a person to whom it is unlawful to direct such activities, then the offer presented by this prospectus does not extend to you. This prospectus speaks only as of its date except where it indicates that another date applies.

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

## **CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING INFORMATION**

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

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

## PROSPECTUS SUMMARY

This summary highlights some information from this prospectus, and it may not contain all of the information that is important to you. You should read the following summary together with the more detailed information regarding our Company and the common stock being sold in this offering, including “Risk Factors” and our consolidated financial statements and related notes, included elsewhere in this prospectus.

### 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 on 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 publicly-traded “shell” company without any business until November 12, 2004 when 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 became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006 our shareholders approved the reincorporation of the Company from the state of Colorado to the state of Delaware by merging the Company into its wholly-owned subsidiary. As used herein, the words “Company” and “Advaxis” refer to the current Delaware corporation only unless the context references such entity prior to the June 20, 2006 reincorporation into Delaware. Our principal executive offices are located at Technology Centre of NJ, 675 US Highway One, North Brunswick, NJ 08902 and our telephone number is (732) 545-1590.

On July 28, 2005 we began trading on the Over-The-Counter Bulletin Board (OTC:BB) under the ticker symbol ADXS.

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.

### 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, PhD., 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 upon cancer vaccines targeting cervical, prostate, breast, ovarian, lung and other cancers. Our lead products in development are as follows:



<b>Product</b>	<b>Indication</b>	<b>Stage</b>
Lovaxin C	Cervical, head and neck cancers	Phase I/II anticipated to be completed during six months ended July 31, 2007, Phase II study in cervical cancer anticipated to commence in 2007*
Lovaxin P	Prostate cancer	Pre-clinical; Phase I study anticipated to commence in late fiscal 2007
Lovaxin B	Breast cancer and melanoma	Pre-clinical; Phase I study anticipated to commence in late fiscal 2008
Lovaxin T	Cancer through control of telomerase	Pre-clinical

\* See "Business - Research and Development Programs".

Since our formation, we have had a history of losses, which as of January 31, 2007 aggregated \$9,699,203, 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.

#### **SUMMARY CONSOLIDATED FINANCIAL DATA OF ADVAXIS**

We were originally incorporated in the state of Colorado on June 5, 1987 under the name Great Expectations, Inc., administratively dissolved on January 1, 1997 and reinstated on June 18, 1998 under the name Great Expectations and Associates, Inc. On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation (“Advaxis”), pursuant to a Share Exchange and Reorganization Agreement, dated as of August 25, 2004 (the “Share Exchange”), by and among Advaxis, the stockholders of Advaxis and us. As a result, Advaxis became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. The transaction was accounted for as a recapitalization. On June 6, 2006, the Company was reincorporated in the state of Delaware by merging the Company into its wholly owned subsidiary. The historical financial statements of Advaxis will be our financial statements for reporting purposes. Advaxis, Inc changed its fiscal year to October 31st and as a result is providing herein its audited financial statements for the years October 31, 2005 and 2006 and the period March 1, 2002 (inception) to October 31, 2006.

The following condensed statement of operations data for the years ended October 31, 2005 and October 31, 2006 and the period March 1, 2002 (inception) to October 31, 2006 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, included elsewhere herein. The condensed unaudited statement of operations data for the year ended October 31, 2004, the three month periods ended January 31, 2006 and January 31, 2007 and the period March 1, 2002 (inception) to January 31, 2007 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.

	Year Ended October 31,			Three Months Ended January 31,		Period from March 1, 2002 (inception) to October 31, 2006		January 31, 2007
	2004 (unaudited)	2005	2006	2006 (unaudited)	2007 (unaudited)	2006	2007 (unaudited)	
<b>Statement of Operations Data:</b>								
Revenue	\$ 116,806	\$ 552,868	\$ 431,961	\$ 329,928	\$ 146,307	\$ 1,105,235	\$ 1,251,542	
Total operating expenses	\$ 715,754	\$ 2,395,328	\$ 3,481,226	\$ 798,990	\$ 1,339,179	\$ 7,591,841	\$ 8,931,020	
Interest expense (income)	\$ 13,132	\$ (7,307)	\$ (437,299)	\$ (1,008)	\$ (153,355)	\$ (466,027)	\$ (619,382)	
Other income	\$ 72	\$ 43,978	\$ 90,899	\$ 11,931	\$ 26,326	\$ 136,422	\$ 162,748	
Net changes in fair value of common stock warrant liability and embedded derivative liability	—	—	—\$ (2,802,078)	—	—\$ 1,282,871	\$ (2,802,078)	\$ (1,519,207)	
Net loss	\$ (655,892)	\$ (1,805,789)	\$ (6,197,744)	\$ (458,139)	\$ (37,030)	\$ (9,618,289)	\$ (9,655,319)	
<b>Loss per Share Information:</b>								
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.05)	\$ (0.16)	\$ (0.01)	\$ (0.00)			
			<b>October 31, 2004 (unaudited)</b>	<b>October 31, 2005</b>	<b>October 31, 2006</b>	<b>October 31, 2006</b>	<b>January 31, 2007 (unaudited)</b>	
<b>Balance Sheet Data:</b>								
Cash and cash equivalents	\$	32,279	\$	2,075,206	\$	2,761,166	\$	1,977,809
Intangible assets	\$	469,803	\$	751,088	\$	956,409	\$	959,842
Total assets	\$	502,083	\$	2,904,039	\$	4,002,704	\$	3,239,714
Total liabilities	\$	1,841,579	\$	1,152,465	\$	7,709,845	\$	6,441,447
Shareholders' (Deficiency) Equity	\$	(1,339,496)	\$	1,751,575	\$	(3,707,141)	\$	(3,201,733)

## THE OFFERING

Common stock offered by Selling Stockholders	48,502,633 shares <sup>(1)</sup>
Common stock outstanding as of March 31, 2007	44,849,283 shares <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” as of March 30, 2007.	\$.23

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(1) Represents 12,037,550 shares issued to Selling Shareholders, 24,130,588 shares which may be acquired upon exercise of warrants issued to Selling Stockholders, and 12,334,495 shares which may be acquired upon conversion of principal and interest on our Debentures issued to a Selling Stockholder in February and March 2006 at a fixed conversion price (“fixed conversion price”) of \$0.287 per share. As of March 31, 2007 to date \$775,000 of the principal was converted into aggregate of 5,052,513 shares acquired leaving a principal of \$2,225,000 to be converted excluding interest. Assuming the “market price” conversion price of \$0.2185 per share (95% of the March 30, 2007 closing price) the number of shares upon conversion will be higher. Such price is to be revised upward to \$0.287 or downward if the “market price” as defined is lower at time of conversion in which event the number of shares issued upon conversion will increase. Up to an additional 31,007,018 shares may be offered for resale by the Selling Stockholders pursuant to this Prospectus in the event the shares were acquired by the Selling Stockholders as a result of conversions or dividend payments at a price less than \$0.287 per share.

(2) The number of shares of common stock outstanding as of March 31, 2007 listed above excludes, in addition to the shares offered,

· 26,009,220 shares issuable upon exercise of the warrants with exercise prices ranging from \$0.1952 to \$0.40 per share;

· 8,512,841 additional shares of common stock issuable upon exercise of options;

· Commitments to issue stock, options or warrants.

## ADDITIONAL INFORMATION

In this prospectus, the terms “we”, “us”, and “our” refer to Advaxis, Inc., a Delaware 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 an early 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 products. 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 October 31, 2006 and January 31, 2007, we had an accumulated deficit of (\$9,662,173) and (\$9,699,203), respectively and stockholders' deficiency of (\$3,707,141) and (\$3,201,733), respectively. We expect to spend substantial additional sums on the continued research and development of proprietary products and technologies with no certainty that losses will not increase or that we will ever become profitable as a result of these expenditures.

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

Although we believe that the net proceeds received from private placements (i) in November 2004 of the Units of shares of our common stock and of our warrants, and (ii) in February and March 2006 of our \$3,000,000 Debenture (iii) current funding plans will be sufficient to finance our currently planned operations for the near-term (approximately 12 months), such amounts will not be sufficient to meet our longer-term cash requirements or cash requirements for the commercialization of certain products currently in development. We will be required to find additional equity or debt securities placements 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 further clinical trials 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 complete the current clinical trial in Lovaxin C or conduct additional clinical trials.

**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 five to ten or more years. 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;
- Market conditions. For example, when we seek to raise our next round of financing the market conditions may not provide adequate funding.
- 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, expand or change such trials. There is no assurance that we will successfully conclude agreements for the completion of our clinical trials. Delay in concluding such agreements would delay the commencement of future clinical trials and or the completion of the current 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 our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe 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 Biological License Application (“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 BLA for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our product candidates through clinical testing and to market.

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

We received in February 2006 permission from the appropriate governmental agencies in Israel, Mexico and Belgrade to conduct in those countries Phase I clinical testing of Lovaxin C, our Listeria based cancer vaccine which targets cervical cancer in women. However, the testing, marketing and manufacturing of any product for sale or distribution in the United States will require the approval of the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval or further approval, if any, from Israel, Mexico or Belgrade and whether any such approval will ultimately be granted. Pre-clinical and clinical trials may reveal that one or more products is ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from governmental authorities outside of the United States which perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist. See "Business - Governmental Regulation".

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

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the Listeria System, and the proprietary technology of others with which we have entered into licensing agreements. We have licensed eleven patents and fifteen patent applications from Penn in addition to exercising the option to licenses up to eighteen additional inventions from Dr. Paterson's laboratory. 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.

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 an option to license from Penn any new future invention conceived by either Dr. Yvonne Paterson or by Dr. Fred Frankel in the vaccine area until June 17, 2009. We intend to expand our intellectual property base by exercising this option and gaining access to 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. See "Business - Partnerships and agreements - Penn."

Our approach to the 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 earliest known and dominant patent position in the United States 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 in the field of recombinant Listeria monocytogenes.

Cerus has filed an opposition against European Patent Application Number 0790835 (EP 835 Patent) which was granted by the European Patent Office and which is assigned to The Trustees of the University of Pennsylvania and exclusively licensed to us. Cerus' allegations in the Opposition are that the EP 835 Patent, which claims a vaccine for inducing a tumor specific antigen with a recombinant live Listeria, is deficient because of (i) insufficient disclosure in the specifications of the granted claims, (ii) the inclusion of additional subject matter in the granted claims, and (iii) a lack of inventive steps of the granted claims of the EP 835 Patent.

On November 29, 2006, following oral proceedings, the Opposition Division of the European Patent Office determined that the claims of the patent as granted should be revoked due to lack of inventive step under European Patent Office rules based on certain prior art publications.

We will review the formal written decision in order to evaluate whether to file an appeal. In the event of an appeal there is no assurance that it will be successful. If such ruling is upheld on appeal, our patent position in Europe may be eroded. The likely result of this decision will be increased competition for us in the European market for recombinant live *Listeria* based vaccines for tumor specific antigens. Regardless of the outcome, we believe that our freedom to operate in Europe, or any other territory, for recombinant live *Listeria* based vaccine for tumor specific antigen products will not be diminished.

For more information about Cerus Corporation and its claims with respect to *Listeria*-based technology, you should visit their web site at [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 the intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on acceptable terms, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking right. See "Business—Patents and Licenses".

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

The manufacture and sale of any products developed by us will inv