Advaxis, Inc. Form SB-2/A April 08, 2005

As filed with the Securities and Exchange Commission on April 7, 2005.

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

#### AMENDMENT NO. 1 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 21<sup>st</sup> Floor New York, New York 10022 (212) 209-3050 / (212) 371-5500 (Telecopy)

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

If any of the Securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box: x

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: o

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: o

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

# CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be <u>Registered</u> <sup>(1)</sup>	Proposed maximum offering price <u>per unit</u> <sup>(2)</sup>	Proposed maximum aggregate offering price (2)	Amount of <u>registration</u> <u>fee</u>
common stock par value \$0.001 per share <sup>(3)</sup> common stock par value \$0.001 per share <sup>(4)</sup>	36,690,056	\$1.00	\$4,318.42	\$4,318.42
	19,630,588	\$1.00	\$2,310.52	\$2,310.52

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION SATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION8(A) MAY DETERMINE.

- (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 7, 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.

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

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

You should rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell shares of our common stock and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are pemitted. 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> Lovaxin C	Indication Cervical and head and neck cancers	Stage 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

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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-clincial
Lovaxin H	Prophylactic vaccine for HIV (AIDS)	Pre-clincial

\* 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.

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

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#### History of the Company

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were administratively dissolved January 1, 1997 and reinstated June 18, 1998 under the name Great Expectations and Associates, Inc. In 1999, we became a reporting company under the Securities Exchange of 1934 (the "Exchange Act"). Until November 2004, we were a shell company without any business. On November 12, 2004, we acquired Advaxis, Inc., a Delaware corporation ("Advaxis"), through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004 (the "Share Exchange"), by and among Advaxis, the stockholders of Advaxis and us. As a result of such acquisition, Advaxis become our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. Our principal executive offices are located at 212 Carnegie Center, Suite 206, Princeton, NJ 08540 and our telephone number is (609) 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 <u>www.advaxis.com</u> which contains descriptions of our technology, our drugs and the trial status of each drug.

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#### 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.

The following condensed statement of operations data for the period from March 1, 2002 (inception) to December 31, 2002, and the year ended December 31, 2003, and the selected balance sheet data at December 31, 2002 and 2003, 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 are included elsewhere herein. 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.

	(i	Period from March 1, 2002 nception) to December 31,	-	Year ended December 31,		Three Months	s Ended	l January 31,
Statement of Operations Data:	-		2002 2003		(unaudited) <b>2004 200</b>			1) 2005
		2002		2005		2004		2005
Total operating expenses	\$	167,902	\$	897,076	\$	132,241	\$	245,126
Interest expense (income)				17,190		10,655		2,968
Other income		966		4,521		(430)		