

Edgar Filing: Advaxis, Inc. - Form 10-Q

Advaxis, Inc.
Form 10-Q
September 24, 2009

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended July 31, 2009

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from to _____ to _____

Commission file number 000 28489

ADVAXIS, INC.

(Exact name of small business issuer as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

02-0563870
(IRS Employer Identification No.)

The Technology Centre of New Jersey, 675 Route 1, Suite 119, North Brunswick, NJ 08902
(Address of principal executive offices)

(732) 545-1590
(Issuer's telephone number)

(Former name, former address and former fiscal year, if changed since last report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No (not required)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

Edgar Filing: Advaxis, Inc. - Form 10-Q

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes
" No x

The number of shares of the Registrant's common stock, \$0.001 par value, outstanding as of August 31, 2009 was 115,638,243.

ADVAXIS, INC.
 (A Development Stage Company)
 July 31, 2009

INDEX

	Page No.
PART I	FINANCIAL INFORMATION
Item 1.	Financial Statements 3
	Balance Sheets at July 31, 2009 (unaudited) and October 31, 2008 3
	Statements of Operations for the three and nine month periods ended July 31, 2009 and 2008 and the period March 1, 2002 (inception) to July 31, 2009 (unaudited) 4
	Statements of Cash Flow for the nine month periods ended July 31, 2009 and 2008 and the period March 1, 2002 (inception) to July 31, 2009 (unaudited) 5
	Notes to Financial Statements 7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations 14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk 23
Item 4.	Controls and Procedures 23
PART II	OTHER INFORMATION
Item 1.	Legal Proceedings 23
Item 1A.	Risk Factors 23
Item 6.	Exhibits 25
SIGNATURES	26

All other items called for by the instructions to Form 10-Q have been omitted because the items are not applicable or the relevant information is not material.

PART I-FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ADVAXIS, INC.
(A Development Stage Company)
BALANCE SHEETS

	July 31, 2009 (unaudited)	October 31, 2008
ASSETS		
Current Assets:		
Cash	\$ 49,126	\$ 59,738
Prepaid expenses	40,105	38,862
Total Current Assets	89,231	98,600
Deferred expenses	366,938	-
Property and Equipment, net	63,661	91,147
Intangible Assets, net	1,310,078	1,137,397
Other Assets	3,876	3,876
Total Assets	\$ 1,833,784	\$ 1,331,020
LIABILITIES & SHAREHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable	\$ 1,362,832	\$ 998,856
Accrued expenses	965,886	603,345
Convertible Bridge Notes and fair value of embedded derivative	796,154	-
Notes payable - current portion including interest payable	1,094,450	563,317
Total Current Liabilities	4,219,322	2,165,518
Common Stock Warrants	11,253,594	-
Notes payable - net of current portion	-	4,813
Total Liabilities	\$ 15,472,916	\$ 2,170,331
Commitments and Contingencies		
Shareholders' Deficiency:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	-	-
Common Stock - \$0.001 par value; authorized 500,000,000 shares, issued and outstanding 115,638,243 as of July 31, 2009; and 109,319,520 as of October 31, 2008	115,637	109,319
Additional Paid-In Capital	4,217,074	16,584,414
Deficit accumulated during the development stage	(17,971,843)	(17,533,044)
Total Shareholders' Deficiency	\$ (13,639,132)	\$ (839,311)
Total Liabilities & Shareholders' Deficiency	\$ 1,833,784	\$ 1,331,020

The accompanying notes are an integral part of these financial statements.

ADVAXIS, INC.
(A Development Stage Company)
Statement of Operations
(Unaudited)

	3 Months Ended July 31, 2009	3 Months Ended July 31, 2008	9 Months Ended July 31, 2009	9 Months Ended July 31, 2008	Period from March 1, 2002 (Inception) to July 31, 2009
Revenue	\$ (5,369)	\$ 28,045	\$ (5,369)	\$ 68,404	\$ 1,319,803
Research & Development Expenses	476,421	657,286	939,407	2,004,324	8,797,391
General & Administrative Expenses	985,726	605,319	2,019,648	2,349,439	12,028,215
Total Operating expenses	1,462,147	1,262,605	2,959,055	4,353,763	20,825,606
Loss from Operations	(1,467,516)	(1,234,560)	(2,964,424)	(4,285,359)	(19,505,803)
Other Income (expense):					
Interest expense	(374,563)	(1,773)	(410,615)	(5,705)	(1,495,098)
Other Income	-	2,599	-	46,427	246,457
Gain on note retirement	-	-	-	-	1,532,477
Net changes in fair value of common stock warrant liability and embedded derivative liability	2,014,220	-	2,014,220	-	371,988
Net income (loss) before benefit for income tax benefit	172,141	(1,233,734)	(1,360,819)	(4,244,637)	(18,849,979)
Income tax benefit	-	-	922,020	-	922,020
Net income (loss)	172,141	(1,233,734)	(438,799)	-	(17,927,959)
Dividends attributable to preferred shares	-	-	-	-	43,884
Net income (loss) applicable to common Stock	\$ 172,141	\$ (1,233,734)	\$ (438,799)	\$ (4,244,637)	\$ (17,971,843)
Net income (loss) per share, basic	\$ 0.00	\$ (0.01)	\$ 0.00	\$ (0.04)	
Net income (loss) per share, diluted	\$ 0.00	\$ (0.01)	\$ 0.00	\$ (0.04)	
Weighted average number of shares outstanding, basic	115,243,678	109,157,170	112,599,706	108,513,191	
Weighted average number of shares outstanding, diluted	115,243,678	109,157,170	112,599,706	108,513,191	

The accompanying notes are in integral part of these financial statements.

ADVAXIS, INC.
(A Development Stage Company)
Statement of Cash Flows
(Unaudited)

	9 Months ended July 31, 2009	9 Months ended July 31, 2008	Period from March 1, 2002 (Inception) to July 31, 2009
OPERATING ACTIVITIES			
Net loss	\$ (438,799)	\$ (4,244,637)	\$ (17,927,959)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash charges to consultants and employees for options and stock	372,695	311,806	2,225,925
Amortization of deferred financing costs	-	-	260,000
Amortization of Discount on bridge Loan	37,231	-	37,321
Amortization of Warrants on Bridge Notes	-	-	53,851
Non-cash interest expense	345,044	3,002	863,229
Change in value of warrants and embedded derivative	(2,014,220)	-	(371,988)
Value of penalty shares issued	-	31,778	149,276
Depreciation expense	27,486	26,975	119,576
Amortization expense of intangibles	54,374	51,795	367,885
Gain on note retirement	-	-	(1,532,477)
(Increase) Decrease in prepaid expenses	(1,243)	94,711	(40,105)
Increase in other assets	-	-	(3,876)
Increase in Deferred expenses	(116,938)	-	(116,938)
Increase in accounts payable	415,954	113,162	1,852,016
Increase in accrued expenses	112,541	101,781	699,699
Accrued interest on notes payable	-	-	18,291
Increase in deferred revenue	-	6,596	-
Net cash used in Operating Activities	(1,205,873)	(3,503,031)	(13,400,213)
INVESTING ACTIVITIES			
Cash paid on acquisition of Great Expectations	-	-	(44,940)
Purchase of property and equipment	-	(10,842)	(137,657)
Cost of intangible assets	(227,054)	(178,542)	(1,752,914)
Net cash used in Investing Activities	(227,054)	(189,384)	(1,935,511)
FINANCING ACTIVITIES			
Proceeds from convertible secured debenture	-	-	960,000
Cash paid for deferred financing costs	-	-	(260,000)
Principal payment on notes payable	(12,320)	(10,960)	(119,239)
Proceeds from notes payable	-	-	1,271,224
Proceeds from notes payable	1,434,635	-	1,909,635
Net proceeds of issuance of Preferred Stock	-	-	235,000
Payment on cancellation of warrants	-	-	(600,000)
Proceeds of issuance of Common Stock; net of issuance costs	-	(78,013)	11,988,230
Net cash provided by (used in) Financing Activities	\$ 1,422,315	\$ (88,973)	\$ 15,384,850
Net (Decrease) Increase in cash	(10,612)	(3,781,388)	49,126

Edgar Filing: Advaxis, Inc. - Form 10-Q

Cash at beginning of period	59,738	4,041,984	-
Cash at end of period	\$ 49,126	\$ 260,596	\$ 49,126

The accompanying notes are an integral part of these financial statements.

Supplemental Schedule of Noncash Investing and Financing Activities

	9 Months ended July 31, 2009	9 Months ended July 31, 2008	Period from March 1, 2002 (Inception) to July 31, 2009
Equipment acquired under capital lease	-	-	\$ 45,580
Common Stock issued to Founders	-	-	\$ 40
Notes payable and accrued interest converted to Preferred Stock	-	-	\$ 15,969
Stock dividend on Preferred Stock	-	-	\$ 43,884
Accounts payable from consultants settled with common stock	\$ 51,978		\$ 51,978
Notes payable and accrued interest converted to Common Stock	-	-	\$ 2,513,158
Intangible assets acquired with notes payable	-	-	\$ 360,000
D Debt discount in connection with recording the original value of the embedded derivative liability	\$ 1,023,116	-	\$ 1,535,912
Allocation of the original secured convertible debentures to warrants	-	-	\$ 214,950
Allocation of the Warrant on Bridge Loan as debt discount	\$ 250,392		\$ 250,392
Warrants issued in connection with issuances of common stock	-	-	\$ 1,505,550
Warrants recorded as a liability	\$ 12,785,695		\$ 12,785,695

The accompanying notes are an integral part of these financial statements.

ADVAXIS, INC.
NOTES TO THE FINANCIAL STATEMENTS (unaudited)

1. Nature of Operations and Liquidity

Advaxis, Inc., (the “company”) is a development stage biotechnology company with the intent to develop safe and effective cancer vaccines that utilize multiple mechanisms of immunity. We are developing a live *Listeria* vaccine technology under license from the University of Pennsylvania (“Penn”) which secretes a protein sequence containing a tumor-specific antigen. We believe this vaccine technology is capable of stimulating the body’s immune system to process and recognize the antigen as if it were foreign, generating an immune response able to attack the cancer. We believe that this to be a broadly enabling platform technology that can be applied to the treatment of many types of cancers, infectious diseases and auto-immune disorders.

The discoveries that underlie this innovative technology are based upon the 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 both arms of the adaptive immune system, as well as supporting the immune response by stimulating systems like the vascular system and the development of specific blood cells that underlie a strong therapeutic immune response.

Since our inception in 2002 we have focused our research and development efforts upon understanding our technology and establishing a product development pipeline that incorporates this technology in the therapeutic cancer vaccines area targeting cervical, prostate, breast and Cervical Intraepithelial Neoplasia (CIN), a pre cancerous indication. Although no products have been commercialized to date, research and development and investment continues to be placed behind the pipeline and the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entail risk and expense. It is anticipated that ongoing operational costs for the development stage company will increase significantly as we expect to begin several clinical trials starting this fiscal year.

As of July 31, 2009, we had \$49,126 in cash, a deficit of \$4,130,091 in working capital, \$ 2,252,803 of principal and interest payable on our notes payable, stockholders deficiency of \$ 13,639,132 and an accumulated deficiency of \$17,971,843.

In a letter dated November 13, 2008 from the New Jersey Economic Development Authority we were notified that our application for the New Jersey Technology Tax Certificate Transfer Program was preliminarily approved. Under the State of New Jersey Program for small business we received a net cash amount of \$922,020 on December 12, 2008 from the sale of our State Net Operating Losses (“NOL”) through December 31, 2007 of \$1,084,729.

Our net income for the three months ended July 31, 2009 was \$172,141 including \$2,014,220 for the net change in fair value of common stock warrant and embedded derivative liabilities. Our net loss for the nine months ended July 31, 2009 was \$438,799 which includes \$922,020 of tax benefit received in this period from the New Jersey Technology Tax Certificate Transfer Program and \$2,014,220 for the net change in fair value of common stock warrant and embedded derivative liabilities

Since our inception until July 31, 2009, the Company has reported accumulated net losses of \$17,927,959 and recurring negative cash flows from operations. In order to maintain sufficient cash and investments to fund future operations, we are seeking to raise additional capital and reduce expenses over the August through September 2009 time period through various financing alternatives. During the fiscal year ended October 31, 2008 the Company received \$475,000 from Notes provided by our CEO, Thomas Moore (the “Moore Notes”). Although the Company repaid Mr. Moore \$50,000 in the three months ended January 31, 2009, as of July 31, 2009 he has loaned an

additional \$522,985 for a total of \$947,985. In addition, the Company sold its Net operating loss (“NOL”) to the New Jersey Economic Development Administration (“NJEDA”) for \$922,020 and has reduced the salaries of all its highly compensated employees effective as of January 4, 2009. On June 18, 2009 we also entered into a Note Purchase Agreement for \$1,131,353 in senior secured bridge notes issued at a 15% discount and received proceeds of \$961,650 (the “Bridge Notes”).

Since inception through July 31, 2009, principally all of the Company’s revenue has been from grants.

2. Basis of Presentation

The accompanying unaudited interim consolidated financial statements include all adjustments (consisting only of those of a normal recurring nature) necessary for a fair statement of the results of the interim period. These interim Financial Statements should be read in conjunction with the Company’s Financial Statements and Notes for the year ended October 31, 2008 filed on Form 10-KSB. We believe these financial statements reflect all adjustments (consisting only of normal, recurring adjustments) that are necessary for a fair presentation of our financial position and results of operations for the periods presented. Results of operations for the interim periods presented are not necessarily indicative of results to be expected for the year.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. There is a working capital deficiency and recurring losses that raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amount and classification of recorded assets and liabilities should we be unable to continue operations.

Management's intends to seek additional funding to assure the Company's viability, through private or public equity offering, and/or debt financing. There can be no assurance that management will be successful in any of those efforts.

Since October 31, 2008 our short term financing plans through July 2009 consisted of the Moore Notes the sale of the NOL provided by the NJEDA, the reduction in salaries of all our highly compensated employees effective as of January 4, 2009 and the 2009 Bridge Notes. We plan on raising an additional \$1,000,000 through additional debt financing. We anticipate that this will be sufficient to finance our currently planned operations to October 2009.

The preparation of financial statements in conformity with generally accepted accounting principles required management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, liabilities, warrant & options valuations, impairment of intangibles and fixed assets.

Recently Issued Accounting Pronouncements

In June 2008, The FASB ratified Emerging Issues Task Force (EITF) Issue No 07-5, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock" (EITF 07-5). EITF 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature indexed to the entities own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which is our first quarter of fiscal 2010. Many of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of EITF 07-5, may result in the instruments no longer being considered indexed to the Company's own stock. Accordingly, adoption of EITF 07-5 may change the current classification (from equity to liability) and the related accounting for many warrants outstanding at that date. Even though the Company now records warrants and the embedded derivative as a liability under the guidance contained in EITF 00-19 "Accounting for Derivative Financial Instrument Indexed to and Potentially Settled In, a Company's Own Common Stock," and SFAS 133 "Accounting for Derivative Instruments and Hedging Activities. In accordance with the guidance provided in EITF 05-2 in order to clarify provisions of EITF 00-19, the Company determined that the conversion feature in the Bridge Notes represented an embedded derivative since the debenture is convertible into a variable number of shares based upon a conversion formula which could require the Company to issue shares in excess of its authorized amount. The convertible debentures are not considered "conventional" convertible debt under EITF 00-19 and the embedded conversion feature was bifurcated from the debt host and accounted for as a derivative liability. The Company is currently evaluating the impact the adoption of EITF 07-5 may have on its financial position, results of operation, or cash flows.

In May 2009, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 165, Subsequent Events ("SFAS 165"), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale as to why the date was selected. SFAS 165 is effective for interim and annual periods ended after June 15, 2009. The Company has adopted the provisions of SFAS 165. The Company has evaluated subsequent events through the date of issuance of these financial statements, September 23, 2009.

In July 2009, the FASB issued SFAS No. 168, FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No. 162 (“SFAS 168”). With the issuance of SFAS 168, the FASB Standards Codification (“Codification”) becomes the single source of authoritative U.S. accounting and reporting standards applicable for all non-governmental entities, with the exception of guidance issued by the Securities and Exchange Commission. The Codification does not change current U.S. GAAP, but changes the referencing of financial standards and is intended to simplify user access to authoritative U.S. GAAP, by providing all the authoritative literature related to a particular topic in one place. The Codification is effective for interim and annual periods ended after September 15, 2009. At that time, all references made to U.S. GAAP will use the new Codification numbering system prescribed by the FASB. The adoption of SFAS No. 168 will result in the change of disclosures to reflect the new codification references, but otherwise the Company does not expect it to have any effect on its financial statements.

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

3. Intangible Assets

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses. The license and patent costs capitalized primarily represent the value assigned to the Company's 20-year exclusive worldwide license agreement with Penn which are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective date of the Penn Agreement dated July 1, 2002. The value of the license and patents is based on management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future uses. This license now includes the exclusive right to strategically exploit 17 patents issued and 18 pending filed in some of the largest markets in the world (excluding the patents issued and applied for that we are no longer pursuing in smaller markets). After careful review and analysis we decided not to pursue 4 patents issued and 6 patent applications filed in smaller countries.

This license agreement has been amended, from time to time, and was amended and restated on February 13, 2007. We have acquired and paid for the First Amended and Restated Patent License Agreement. However, the Second Amendment that we mutually agreed to enter into on March 26, 2007 to exercise our option to license an additional 12 other dockets or approximately 39 or more additional patent applications for Listeria and LLO-based vaccine dockets was not finalized. In order to purchase this Second Amendment as of July 31, 2009 we are contingently liable for \$447,108 including the reimbursement of certain legal and filing costs. We are still in negotiations with Penn over the form of payment, some combination of stock or cash, and expect to reach a conclusion at the close of our next financial raise. These fees are currently unpaid and are not recorded in our financial statements as of the July 31, 2009. While we consider our relationship with Penn good we are in frequent communications over payment of past due invoices and other payables due to our lack of cash. If we fail to reach a mutual understanding Penn may issue a default notice and we will have 60 days to cure the breach or be subject to the termination of the agreement.

As of July 31, 2009, all gross capitalized costs associated with the licenses and patents filed and granted as well as costs associated with patents pending are \$1,569,880 as shown under license and patents on the table below, excluding the Second Amendment costs. Out of the \$1,569,880 capitalized cost the cost of the patents and licenses issued is estimated to be \$797,942 and cost of the patents pending or in the process of filing is estimated to be \$771,938. The expirations of the existing patents range from 2014 to 2020 but the expirations may be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value or patents applications that are not issued are charged to expense when the determination is made not to pursue the application. Based on a review and analysis of its patents we determined that it was no longer cost effective to pursue patents in other countries such as Canada, Israel or Ireland. A review of the capitalized costs for these countries resulted in the write-off of \$26,087 as of July 31, 2009 of capitalized cost since inception of the company and the elimination of a total of eleven patent and patent applications. No other additional patent applications with future value were abandoned and charged to expense in the current or prior year. Amortization expense for licensed technology and capitalized patent cost is included in general and administrative expenses.

Under the amended and restated agreement we are billed actual patent expenses as they are passed through from Penn and or billed directly from our patent attorney. The following is a summary of the intangibles assets as of the following fiscal periods:

	October 31, 2008	July 31, 2009	Increase/(Decrease)
License	\$ 529,915		