

Advaxis, Inc.
Form 10-Q
September 11, 2015

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, 2015

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

For the transition period from _____ to _____

Commission file number 000-28489

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware **02-0563870**
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification No.)

305 College Road East, Princeton, NJ 08540

(Address of principal executive offices)

(609) 452-9813

(Registrant's telephone number)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 (Section 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

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

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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of September 9, 2015 was 33,365,829.

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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.

Cautionary Note Regarding Forward Looking Statements

The Company has included in this Quarterly Report certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 concerning the Company’s business, operations and financial condition. “Forward-looking statements” consist of all non-historical information, and the analysis of historical information, including the references in this Quarterly Report to future revenues, collaborative agreements, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Company’s plans for future periods. In addition, the words “could”, “expects”, “anticipates”, “objective”, “plan”, “may affect”, “may depend”, “believes”, “estimates”, “projects” and similar words and phrases are also intended to identify such forward-looking statements. Such factors include the risk factors included in other filings by the Company with the SEC and other factors discussed in connection with any forward-looking statements.

Actual results could differ materially from those projected in the Company’s forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, the Company’s ability to raise capital, unanticipated technological difficulties, the length, scope and outcome of our clinical trial, costs related to intellectual property, cost of manufacturing and higher consulting costs, product demand, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, and other considerations described as “Risk Factors” in other filings by the Company with the SEC. Such factors may also cause substantial volatility in the market price of the Company’s Common Stock. All such forward-looking statements are current only as of the date on which such statements were made. The Company does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

PART I - FINANCIAL INFORMATION**Item 1. Financial Statements****ADVAXIS, INC.****CONDENSED BALANCE SHEETS**

	July 31, 2015 (unaudited)	October 31, 2014
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$97,142,340	\$17,606,860
Prepaid Expenses	366,702	182,978
Income Tax Receivable	-	1,731,317
Other Current Assets	8,182	8,182
Deferred Expenses - current	1,150,443	964,724
Total Current Assets	98,667,667	20,494,061
Property and Equipment, net	375,688	77,369
Intangible Assets, net	3,142,490	2,767,945
Other Assets	120,863	38,438
TOTAL ASSETS	\$102,306,708	\$23,377,813
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$2,153,604	\$1,411,058
Accrued Expenses	2,293,688	1,241,796
Short Term Convertible Notes and Fair Value of Embedded Derivative	29,549	62,882
Total Current Liabilities	4,476,841	2,715,736
Common Stock Warrant Liability	295,183	32,091
Total Liabilities	4,772,024	2,747,827
Commitments and Contingencies		
Shareholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at July 31, 2015 and October 31, 2014. Liquidation preference of \$0 at July 31, 2015 and October 31, 2014.	-	-
	31,496	19,630

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Common Stock - \$0.001 par value; authorized 45,000,000 shares, issued and outstanding 31,496,398 at July 31, 2015 and 19,630,139 at October 31, 2014.

Additional Paid-In Capital	218,945,481	107,601,493
Accumulated Deficit	(121,442,293)	(86,991,137)
Total Shareholders' Equity	97,534,684	20,629,986
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 102,306,708	\$ 23,377,813

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

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ADVAXIS, INC.**CONDENSED STATEMENTS OF OPERATIONS****(unaudited)**

	Three Months Ended		Nine Months Ended	
	July 31,		July 31,	
	2015	2014	2015	2014
Revenue	\$-	\$-	\$-	\$1,000,000
Operating Expenses				
Research and Development Expenses	7,289,944	3,005,306	17,004,939	6,110,095
General and Administrative Expenses	6,339,335	2,993,739	17,240,302	9,442,630
Total Operating Expenses	13,629,279	5,999,045	34,245,241	15,552,725
Loss from Operations	(13,629,279)	(5,999,045)	(34,245,241)	(14,552,725)
Other Income (expense):				
Interest Expense	-	-	-	(5,253)
Gain on Note retirement	-	-	-	6,243
Debt conversion expense	-	-	(6,599)	-
Net changes in fair value of derivative liabilities	32,384	210,298	(254,923)	616,095
Other Income	34,869	9,553	55,608	28,874
Net Loss before benefit for income taxes	(13,562,026)	(5,779,194)	(34,451,155)	(13,906,766)
Income Tax Benefit	-	-	-	625,563
Net Loss	(13,562,026)	(5,779,194)	(34,451,155)	(13,281,203)
Net Loss per share, basic and diluted	\$(0.44)	\$(0.30)	\$(1.30)	\$(0.82)
Weighted Average Number of Shares Outstanding, Basic and Diluted	30,955,708	19,273,062	26,400,596	16,294,134

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

ADVAXIS, INC.**CONDENSED STATEMENTS OF CASH FLOWS****(unaudited)**

	Nine Months Ended	
	July 31,	
	2015	2014
OPERATING ACTIVITIES		
Net Loss	\$(34,451,156)	\$(13,281,203)
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Non-cash charges to consultants and employees for options and stock	15,836,492	4,599,259
Non-cash interest expense	-	51
Loss (Gain) on change in value of warrants and embedded derivative	254,923	(616,095)
Warrant expense	8,169	4,445
Gain on disposal of property and equipment	(10,000)	-
Settlement expense	-	34,125
Employee Stock Purchase Plan	18,014	5,371
Depreciation expense	28,352	20,709
Amortization expense of intangibles	151,108	129,434
Debt conversion expense	6,599	-
(Gain) on note retirement	-	(6,243)
Change in operating assets and liabilities:		
Prepaid expenses	(183,724)	(170,596)
Income tax receivable	1,731,317	-
Other current assets	-	(25,000)
Deferred expenses	(185,719)	(566,013)
Security deposit	(82,425)	-
Accounts payable and accrued expenses	1,794,438	(2,105,153)
Interest payable	-	(98,192)
Net cash used in operating activities	(15,083,612)	(12,075,101)
INVESTING ACTIVITIES		
Purchase of property and equipment	(316,671)	(24,595)
Cost of intangible assets	(525,653)	(288,115)
Net cash used in Investing Activities	(842,324)	(312,710)
FINANCING ACTIVITIES		
Repayment of Officer Loan	-	(64,926)
Proceeds from exercise of options	58,400	-
Proceeds from exercise of warrants	2,329,708	250
Net proceeds of issuance of Common Stock	94,788,419	14,820,105
Taxes paid related to net share settlement of equity awards	(1,715,111)	(771,028)
Net cash provided by Financing Activities	95,461,416	13,984,401
Net increase in cash and cash equivalents	79,535,480	1,596,590

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Cash and cash equivalents at beginning of period	17,606,860	20,552,062
Cash and cash equivalents at end of period	\$97,142,340	\$22,148,652

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

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Supplemental Disclosures of Cash Flow Information

	Nine months ended July 31, 201 5 2014
Cash Paid for Interest	\$- \$103,445

Supplemental Schedule of Non-cash Investing and Financing Activities

	Nine months ended July 31, 2015 2014	
Accounts Payable from consultants settled with Common Stock	\$-	\$342,309
Conversion of notes payable into common stock	\$39,932	\$-

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

ADVAXIS, INC.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. ORGANIZATION

Advaxis, Inc. (“Advaxis” or the “Company”) is a clinical stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm* -LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*” or “*Listeria*”), bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm* -LLO strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as they access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors.

Axalimogene filolisbac (ADX-HPV) is the Company’s lead *Lm* -LLO immunotherapy product candidate for the treatment of human papilloma virus (“HPV”) associated cancers. The Company completed a randomized Phase 2 study in 110 patients with recurrent cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”), now part of NRG Oncology, is conducting a cooperative group sponsor Phase 2 open-label clinical study of axalimogene filolisbac (ADX-HPV) in patients with persistent or recurrent cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed its first stage and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient recruitment which is now enrolling. The Company plans to advance this immunotherapy into a registrational clinical trial for the treatment of women with high-risk locally advanced cervical cancer.

Axalimogene filolisbac (ADX-HPV) has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in Company-sponsored trials executed under an Investigational New Drug (“IND”) which include the following: i) a Phase 1/2 clinical trial alone and in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer; ii) a Phase 2 multi-center, open-label study alone and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360) in patients with Stage I-IIa HPV-associated cervical cancer; iii) a Phase 1/2 study evaluating higher doses and repeat cycles of axalimogene filolisbac (ADX-HPV) in patients with recurrent cervical cancer; iv) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer and, v) a Phase 2 study in collaboration with and funded by Global BioPharma Inc. (“GBP”), under a development and commercialization license agreement applicable to Asia, of axalimogene filolisbac (ADX-HPV) in HPV-associated non-small cell lung cancer. In addition to the Company-sponsored trials, axalimogene filolisbac (ADX-HPV) is also being evaluated in three ongoing

investigator-initiated clinical trials as follows: locally advanced cervical cancer (GOG-0265), head and neck cancer (Mount Sinai), and anal cancer (Brown University).

ADXS-PSA is the Company's *Lm*-LLO immunotherapy product candidate designed to target the Prostate Specific Antigen ("PSA") associated with prostate cancer. The Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer, is currently enrolling patients.

ADXS-HER2 is the Company's *Lm*-LLO immunotherapy product candidate designed for the treatment of Human Epidermal Growth Factor Receptor 2 ("HER2") expressing cancers, including human and canine osteosarcoma, breast, gastric and other cancers. The FDA has cleared the Company's IND application and the Company is in the process of initiating a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. The Company received orphan drug designation for ADXS-HER2 in osteosarcoma. Clinical research with ADXS-HER2 in canine osteosarcoma is being developed by the Company's pet therapeutic partner, Aratana Therapeutics Inc. ("Aratana"), who holds exclusive rights to develop and commercialize ADXS-HER2 and three other *Lm*-LLO immunotherapies for pet health applications. Aratana has announced that a product license application for use of ADXS-HER2 in the treatment of canine osteosarcoma has been filed with the United States Department of Agriculture ("USDA"). Aratana received communication from the USDA in March 2015 that the efficacy data previously submitted for product license for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, licensed from the Company was accepted to provide a reasonable expectation of efficacy to support conditional licensure. While Aratana needs to complete additional steps, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2016.

Since inception in 2002, the Company has focused its development efforts on understanding its platform technology and establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, currently those targeting HPV-associated cancer (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2 expressing cancers. Although no immunotherapies have been commercialized to date, research and development and investment continues to be placed behind the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting and expanding its clinical development program. In addition to its existing single target vectors targeting tumor associated and stromal targets, the Company is actively engaged in the development of new constructs that will address multiple targets that are common to tumor types as well as mutation-associated neo-epitopes. Lastly, the Company is developing certain internal capabilities to manufacture clinical trial materials for its Phase 1 and Phase 2 programs.

Liquidity and Financial Condition

The Company's products are being developed and have not generated significant revenues. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. On December 19, 2014, the Company priced a registered direct offering of 3,940,801 shares of its Common Stock ("Common Stock"). The transaction closed on December 22, 2014, and the Company received net proceeds of approximately \$15.8 million from the offering. In addition, on February 18, 2015, the Company priced an additional registered direct offering of 3,068,095 shares of its Common Stock. The transaction closed on February 19, 2015, and the Company received net proceeds of approximately \$22.3 million from the offering. The shares in each offering were sold under a Registration Statement (No. 333-194009) on Form S-3, filed by the Company with the United States Securities and Exchange Commission ("SEC"). On May 5, 2015, the Company closed on an underwritten public offering of 2,800,000 shares of Common Stock at a public offering price of \$19.00 per share. On May 20, 2015, the Company closed the Underwriters' overallotment option to purchase 420,000 shares of its Common Stock at a public offering price of \$19.00 per share. The net proceeds from the May 2015 public offerings were approximately \$56.7 million. On August 25, 2015, the Company priced a registered direct offering of 1,797,269 of its Common Stock at a price of \$13.91 per share. The transaction closed on August 28, 2015 and the Company received net proceeds of approximately \$25 million. The sale of the shares in these offerings were registered pursuant to a Registration Statement (No. 333-203497) on Form S-3, filed by the Company with the SEC.

The Company believes its current cash position is sufficient to fund its business plan approximately through fiscal 2018. The estimate is based on assumptions that may prove to be wrong, and the Company could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of its current product candidates.

The Company recognizes it may need to raise additional capital in order to continue to execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its business plan.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation - Unaudited Interim Financial Information

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information, and in accordance with the rules and regulations of the SEC with respect to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, necessary to represent a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2014 and notes thereto contained in the Company’s annual report on Form 10-K for the year ended October 31, 2014, as filed with the SEC on January 6, 2015.

Revenue Recognition

The Company is expected to derive the majority of its revenue from patent licensing. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

An allowance for doubtful accounts is established based on the Company’s best estimate of the amount of probable credit losses in the Company’s existing license fee receivables, using historical experience. The Company reviews its allowance for doubtful accounts periodically. Past due accounts are reviewed individually for collectability.

Account balances are charged off against the allowance after all means