Advaxis, Inc.
Form 10-Q
June 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended April 30, 2016

[ ] 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 incorporation or organization)	(IRS Employer 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 [X] 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 [X] 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 [X] 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 [X]

The number of shares of the registrant's Common Stock, $0.001 par value, outstanding as of June 1, 2016 was 34,346,687.

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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 depe "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

(unaudited)

	April 30, 2016	October 31, 2015
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$44,924,461	$66,561,683
Investments – Held-to-Maturity	49,651,332	45,594,495
Interest Receivable	164,576	145,299
Prepaid Expenses	652,791	338,841
Income Tax Receivable	-	1,609,349
Deferred Expenses – current	3,140,538	749,790
Other Current Assets	7,500	15,116
Total Current Assets	98,541,198	115,014,573
Property and Equipment (net of accumulated depreciation)	1,731,395	1,087,244
Intangible Assets (net of accumulated amortization)	3,692,726	3,355,033
Other Assets	334,862	148,843
TOTAL ASSETS	$104,300,181	$119,605,693
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$5,555,279	$696,117
Accrued Expenses	3,336,505	3,191,941
Short Term Convertible Notes and Fair Value of Embedded Derivative	-	29,549
Total Current Liabilities	8,891,784	3,917,607
Deferred Rent	175,763	-
Common Stock Warrant Liability	39,337	89,211
Total Liabilities	9,106,884	4,006,818
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 April 30, 2016 and October 31, 2015. Liquidation preference of $0 at April 30, 2016 and October 31, 2015.	-	-
Common Stock - $0.001 par value; 65,000,000 shares authorized, 34,293,599 shares issued and 34,274,439 shares outstanding at April 30, 2016 and 33,591,882 shares issued and 33,574,963 shares outstanding at October 31, 2015.	34,293	33,592
Additional Paid-In Capital	264,827,307	249,807,303
Treasury Stock, at cost, 19,160 shares at April 30, 2016 and 16,919 shares at October 31, 2015.	(150,323)	(187,761)
Accumulated Deficit	(169,517,980)	(134,054,259)
Total Shareholders' Equity	95,193,297	115,598,875
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$104,300,181	$119,605,693

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

ADVAXIS, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended April 30,		Six Months Ended April 30,	
	2016	2015	2016	2015
Revenue	$-	$-	$250,000	$-
Operating Expenses				
Research and Development Expenses	8,758,410	6,193,005	21,823,364	9,813,687
General and Administrative Expenses	6,834,824	7,646,922	13,971,647	10,802,275
Total Operating Expenses	15,593,234	13,839,927	35,795,011	20,615,962
Loss from Operations	(15,593,234)	(13,839,927)	(35,545,011)	(20,615,962)
Other Income (expense):				
Interest Income	70,389	14,503	142,189	20,739
Net changes in fair value of derivative liabilities	592	(23,236)	49,874	(287,307)
Other Expense	(197)	(6,599)	(201)	(6,599)
Net Loss before benefit for income taxes	(15,522,450)	(13,855,259)	(35,353,149)	(20,889,129)
Income Tax Expense	-	-	14,236	-
Net Loss	(15,522,450)	(13,855,259)	(35,367,385)	(20,889,129)
Net Loss per share, basic and diluted	$(0.45)	$(0.52)	$(1.04)	$(0.87)
Weighted Average Number of Shares Outstanding, Basic and Diluted	34,131,259	26,655,486	33,906,400	24,085,290

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

ADVAXIS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended April 30,	
	2016	2015
OPERATING ACTIVITIES		
Net Loss	$(35,367,385)	$(20,889,129)
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Stock Compensation	14,361,583	9,793,777
(Gain) Loss on change in value of warrants and embedded derivative	(49,874)	287,307
Warrant expense	-	8,169
Employee Stock Purchase Plan	17,257	6,909
Depreciation expense	95,124	14,148
Amortization expense of intangibles	118,744	98,692
Debt conversion expense	-	6,599
Amortization of premium on held-to-maturity investments	164,284	-
Change in operating assets and liabilities:		
Interest receivable	(19,277)	-
Prepaid expenses	(313,950)	(221,982)
Income tax receivable	1,609,349	1,731,317
Other current assets	7,616	-
Deferred expenses	(2,390,748)	(1,252,556)
Security deposit	(186,019)	-
Accounts payable and accrued expenses	5,018,726	1,305,221
Deferred rent	175,763	-
Net cash used in operating activities	(16,758,807)	(9,111,528)
INVESTING ACTIVITIES		
Purchases of held-to-maturity investments	(7,651,121)	-
Proceeds from maturities and redemptions on held-to-maturity investments	3,430,000	-
Purchase of property and equipment	(739,275)	(10,298)
Cost of intangible assets	(456,437)	(333,704)
Net cash used in investing activities	(5,416,833)	(344,002)
FINANCING ACTIVITIES		
Proceeds from exercise of options	-	58,400
Proceeds from exercise of warrants	614,368	239,593
Net proceeds of issuance of Common Stock	-	38,110,072
Tax withholdings paid related to net share settlement of equity awards	(34,025)	(618,677)
Treasury stock purchased to pay employee withholdings on equity awards	(1,393,595)	-
Treasury stock sold to pay for employee tax withholdings on equity awards	1,351,670	-

Net cash provided by Financing Activities	538,418	37,789,388
Net (decrease) increase in cash and cash equivalents	(21,637,222)	28,333,858
Cash and cash equivalents at beginning of period	66,561,683	17,606,860
Cash and cash equivalents at end of period	44,924,461	45,940,718

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

Supplemental Disclosures of Cash Flow Information

	Six months ended April 30,	
	2016	2015
Cash paid for taxes	$50,000	$ -

Supplemental Schedule of Non-Cash Investing and Financing Activities

	Six months ended April 30,	
	2016	2015
Accrued expenses from consultants settled with Common Stock	$55,000	$-
Conversion of notes payable into common stock	$29,549	$39,932

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

ADVAXIS, INC.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. NATURE OF OPERATIONS

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 ("AXAL") is our 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") Foundation, Inc., now part of NRG Oncology, is conducting a cooperative group sponsored Phase 2 open-label clinical study of AXAL 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. The Company plans to advance this immunotherapy into a registrational clinical trial for the treatment of women with high-risk locally advanced cervical cancer.

AXAL 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 has received European Medicines Agency ("EMA") orphan drug designation for anal cancer. It 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, LLC's ("MedImmune") investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic cervical cancer and HPV-associated head and neck cancer; (ii) a Phase 1/2 study evaluating higher doses and repeat cycles of AXAL in patients with recurrent cervical cancer; (iii) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer; and (iv) 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 AXAL in HPV-associated non-small cell lung cancer. In addition to the Company-sponsored trials, AXAL 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 & Baylor College of

Medicine), 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 which is being evaluated in a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck & Co.'s ("Merck") humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer.

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. ADXS-HER2 is being evaluated in a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. We received orphan drug designation from both the FDA and EMA for ADXS-HER2 in osteosarcoma and have received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. Clinical research with ADXS-HER2 in canine osteosarcoma is being developed by our 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 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2016.

In October of 2015, the Company received notification from the FDA that the INDs for AXAL were put on clinical hold in response to its submission of a safety report to the FDA. The clinical hold also included the INDs for ADXS-PSA and ADXS-HER2. Following discussions with the FDA and in accordance with their recommendations, the Company agreed to implement certain risk mitigation measures, including revised study protocol inclusion / exclusion criteria, post-administration antibiotic treatment and patient surveillance and monitoring measures. In December 2015, the FDA notified the Company that the hold had been lifted with respect to its INDs.

The Company has focused its development efforts on establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, with clinical trials currently 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, the Company continues to invest in research and development to advance the technology and make it available to patients with many different types of cancer. 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 antigen vectors that target one tumor associated antigen, 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 that are specific to an individual patient's tumor. Lastly, the Company is developing certain internal capabilities to produce supplies for its neoepitope and its other 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. During fiscal 2015, the Company raised an aggregate of $119.7 million in equity offerings and has approximately $94.6 million in cash, cash equivalents and investments as of April 30, 2016.

The Company believes its current cash position is sufficient to fund its business plan approximately through calendar year end 2017. 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 Rule 10-01 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 o