

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

**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, 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    (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 August 31, 2016 was 39,844,118.

## INDEX

	Page No.
<b>PART I <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Financial Statements (unaudited)</u>	
<u>Condensed Balance Sheets at July 31, 2016 (unaudited) and October 31, 2015</u>	F-1
<u>Condensed Statements of Operations for the three month and nine month periods ended July 31, 2016 and 2015 (unaudited)</u>	F-2
<u>Condensed Statements of Cash Flows for the nine month periods ended July 31, 2016 and 2015 (unaudited)</u>	F-3
<u>Notes to Condensed Financial Statements</u>	F-5
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	4
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	12
Item 4. <u>Controls and Procedures</u>	13
<b>PART II <u>OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	14
Item 1A. <u>Risk Factors</u>	14
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	14
Item 6. <u>Exhibits</u>	15
<u>SIGNATURES</u>	16

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, 2016 (unaudited)	October 31, 2015
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$29,742,196	\$66,561,683
Investments – Held-to-Maturity	48,975,725	45,594,495
Interest Receivable	140,171	145,299
Prepaid Expenses	767,629	338,841
Income Tax Receivable	-	1,609,349
Deferred Expenses	4,364,275	749,790
Other Current Assets	28,830	15,116
Total Current Assets	84,018,826	115,014,573
Property and Equipment (net of accumulated depreciation)	2,962,264	1,087,244
Intangible Assets (net of accumulated amortization)	3,774,676	3,355,033
Other Assets	468,952	148,843
<b>TOTAL ASSETS</b>	<b>\$91,224,718</b>	<b>\$119,605,693</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$2,576,511	\$696,117
Accrued Expenses	4,265,077	3,191,941
Lease Incentive Obligation	40,226	-
Short Term Convertible Notes and Fair Value of Embedded Derivative	-	29,549
Total Current Liabilities	6,881,814	3,917,607
Deferred Rent	374,724	-
Lease Incentive Obligation – net of current portion	335,217	-
Common Stock Warrant Liability	32,997	89,211
Total Liabilities	7,624,752	4,006,818
Commitments and Contingencies		

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Shareholders' Equity:

Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at July 31, 2016 and October 31, 2015. Liquidation preference of \$0 at July 31, 2016 and October 31, 2015.	-	-
Common Stock - \$0.001 par value; 65,000,000 shares authorized, 34,508,715 shares issued and 34,492,899 shares outstanding at July 31, 2016 and 33,591,882 shares issued and 33,574,963 shares outstanding at October 31, 2015.	34,509	33,592
Additional Paid-In Capital	269,701,357	249,807,303
Treasury Stock, at cost, 15,816 shares at July 31, 2016 and 16,919 shares at October 31, 2015.	(131,912 )	(187,761 )
Accumulated Deficit	(186,003,988)	(134,054,259)
Total Shareholders' Equity	83,599,966	115,598,875
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$91,224,718	\$119,605,693

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

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

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2016	2015	2016	2015
Revenue	\$-	\$-	\$250,000	\$-
Operating Expenses				
Research and Development Expenses	10,142,232	7,342,360	31,965,596	17,156,047
General and Administrative Expenses	6,423,988	6,286,919	20,395,635	17,089,194
Total Operating Expenses	16,566,220	13,629,279	52,361,231	34,245,241
Loss from Operations	(16,566,220)	(13,629,279)	(52,111,231)	(34,245,241)
Other Income (expense):				
Interest Income	73,872	34,869	216,061	55,608
Net changes in fair value of derivative liabilities	6,340	32,384	56,214	(254,923 )
Other Expense	-	-	(201 )	(6,599 )
Net Loss before income taxes	(16,486,008)	(13,562,026)	(51,839,157)	(34,451,155)
Income Tax Expense	-	-	14,236	-
Net Loss	(16,486,008)	(13,562,026)	(51,853,393)	(34,451,155)
Net Loss per share, basic and diluted	\$(0.48 )	\$(0.44 )	\$(1.52 )	\$(1.30 )
Weighted Average Number of Shares Outstanding, Basic and Diluted	34,375,814	30,955,708	34,061,127	26,400,596

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,	
	2016	2015
<b>OPERATING ACTIVITIES</b>		
Net Loss	\$(51,853,393)	\$(34,451,156)
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Stock Compensation	19,369,948	15,836,492
(Gain) Loss on change in value of warrants and embedded derivative	(56,214 )	254,923
Warrant expense	-	8,169
Gain on disposal of property and equipment	-	(10,000 )
Employee Stock Purchase Plan	28,189	18,014
Depreciation of property and equipment	163,581	28,352
Amortization of intangible assets	183,184	151,108
Lease incentive obligation	375,443	-
Debt conversion expense	-	6,599
Amortization of premium on held-to-maturity investments	218,733	-
Change in operating assets and liabilities:		
Interest receivable	5,128	-
Prepaid expenses	(428,788 )	(183,724 )
Income tax receivable	1,609,349	1,731,317
Other current assets	(13,714 )	-
Deferred expenses	(3,614,485 )	(185,719 )
Other assets	(320,109 )	(82,425 )
Accounts payable and accrued expenses	2,817,033	1,794,438
Deferred rent	374,724	-
Net cash used in operating activities	(31,141,391)	(15,083,612)
<b>INVESTING ACTIVITIES</b>		
Purchases of held-to-maturity investments	(24,248,963)	-
Proceeds from maturities and redemptions on held-to-maturity investments	20,649,000	-
Purchase of property and equipment	(2,003,804 )	(316,671 )
Cost of intangible assets	(602,827 )	(525,653 )
Net cash used in investing activities	(6,206,594 )	(842,324 )
<b>FINANCING ACTIVITIES</b>		
Proceeds from exercise of options	-	58,400
Proceeds from exercise of warrants	614,368	2,329,708
Net proceeds of issuance of Common Stock	-	94,788,419
Tax withholdings paid related to net share settlement of equity awards	(52,752 )	(1,715,111 )

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Treasury stock purchased to pay employee withholdings on equity awards	(1,926,763 )	-
Treasury stock sold to pay for employee tax withholdings on equity awards	1,893,645	-
Net cash provided by financing activities	528,498	95,461,416
Net (decrease) increase in cash and cash equivalents	(36,819,487)	79,535,480
Cash and cash equivalents at beginning of period	66,561,683	17,606,860
Cash and cash equivalents at end of period	29,742,196	97,142,340

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

F-3

**Supplemental Disclosures of Cash Flow Information**

	Nine months ended July 31,	
	2016	2015
Cash paid for taxes	\$50,000	\$ -

**Supplemental Schedule of Non-Cash Investing and Financing Activities**

	Nine months ended July 31,	
	2016	2015
Accrued expenses from consultants settled with Common Stock	\$55,000	\$-
Conversion of notes payable into common stock	\$29,549	\$39,932
Property and equipment included in accounts payable and accrued expenses	\$34,797	\$-

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*” or “*Lm* Technology<sup>TM</sup>”) 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. AXAL has been designated by the FDA as a Fast Track product for adjuvant therapy for high-risk locally advanced cervical cancer patients. It has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s Committee for Advanced Therapies (“CAT”). AXAL is subject to an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for the Phase 3 AIM2CERV trial in patients with high-risk, locally advanced cervical 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.