

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)

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

**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

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

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		

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

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
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$91,224,718</b>	<b>\$119,605,693</b>

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

F-1

**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 )

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

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™”) 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.

#### *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 gross proceeds of approximately \$125.9 million in equity offerings. On August 1, 2016, the Company entered into a collaboration agreement with Amgen Inc. ("Amgen"). In exchange for receiving an exclusive worldwide license to develop and commercialize ADXS-NEO, Amgen made an upfront payment of \$40 million and purchased directly from the Company 3,047,446 shares of common stock for gross proceeds of \$25 million. On August 19, 2016, the Company sold 2,244,443 shares of common stock in a registered direct offering for gross proceeds of approximately \$30.3 million to certain health care specialist investors. The net proceeds to the Company were approximately \$28.3 million. As of August 31, 2016, the Company had approximately \$162.8 million in cash, cash equivalents and investments on its balance sheet.

The Company believes its current cash position is sufficient to fund its business plan approximately through the second quarter of fiscal 2019. 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 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, 2015 and notes thereto contained in the Company’s annual report on Form 10-K for the year ended October 31, 2015, as filed with the SEC on January 8, 2016.

The information presented in the accompanying unaudited condensed balance sheet as of October 31, 2015 has been derived from the Company’s October 31, 2015 audited financial statements.

### *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 of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur. If product development is successful, the Company will recognize revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event and collection is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All milestone payments are recognized in collaborative licensing and development revenue in the Company's statements of operations.

#### *Estimates*

The preparation of financial statements in accordance with U.S. GAAP involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ substantially from these estimates. Significant estimates include the fair value and recoverability of the carrying value of intangible assets (patents and licenses), the fair value of stock options, the fair value of embedded conversion features, warrants and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results may differ from estimates.

#### *Reclassifications*

Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. These reclassifications had no effect on the previously reported net loss.

#### *Cash and Cash Equivalents*



The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of July 31, 2016 and October 31, 2015, the Company had approximately \$23.9 million and \$62.8 million, respectively, in cash equivalents.

*Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$27.9 million is subject to credit risk at July 31, 2016. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

*Fair Value of Financial Instruments*

The carrying amounts of financial instruments, including cash and cash equivalents, accounts payable and accrued expenses approximated fair value as of the balance sheet date presented, because of the relatively short maturity dates on these instruments. The carrying amounts of the financing arrangements issued approximate fair value as of the balance sheet date presented, because interest rates on these instruments approximate market interest rates after consideration of stated interest rates, anti-dilution protection and associated warrants.

*Net Loss per Share*

Basic net income or loss per common share is computed by dividing net income or loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, convertible debt and other potential Common Stock outstanding during the period. In the case of a net loss the impact of the potential Common Stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential Common Stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of Common Stock that have been excluded from diluted net loss per share.

	As of July 31,	
	2016	2015
Warrants	3,110,575	3,263,008
Stock Options	3,351,794	1,933,154
Convertible Debt (using the if-converted method)	-	1,576
Total	6,462,369	5,197,738



### *Stock Based Compensation*

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally measured based on contractual terms. The fair value amount is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over the requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the Black Scholes Model (“BSM”) for the remaining awards, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its Common Stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records stock-based compensation as a charge to earnings net of the estimated impact of forfeited awards. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that are estimated to ultimately vest over their requisite service period, based on the vesting provisions of the individual grants.

### *Recent Accounting Pronouncements*

In May 2014, as part of its ongoing efforts to assist in the convergence of GAAP and International Financial Reporting Standards, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers*, which is a new standard related to revenue recognition. Under the new standard, recognition of revenue occurs when a customer obtains control of promised services or goods in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. The standard must be adopted using either a full retrospective approach for all periods presented in the period of adoption or a modified retrospective approach. In July 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers - Deferral of the Effective Date*, which defers the implementation of this new standard to be effective for fiscal years beginning after December 15, 2017. Early adoption is permitted effective January 1, 2017. In March 2016, the FASB issued ASU 2016-08, *Principal versus*

*Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations in the new revenue recognition standard pursuant to ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, *Identifying Performance Obligations and Licensing*, and in May 2016, the FASB issued ASU 2016-12, *Narrow-Scope Improvements and Practical Expedients*, which amend certain aspects of the new revenue recognition standard pursuant to ASU 2014-09. We are currently evaluating which transition approach we will utilize and the impact of adopting this accounting standard on our unaudited condensed financial statements.

In January 2015, the FASB issued ASU 2015-01, *Income Statement—Extraordinary and Unusual Items*. The objective of this Update is to simplify the income statement presentation requirements in Subtopic 225-20 by eliminating the concept of extraordinary items. Extraordinary items are events and transactions that are distinguished by their unusual nature and by the infrequency of their occurrence. Eliminating the extraordinary classification simplifies income statement presentation by altogether removing the concept of extraordinary items from consideration. This Accounting Standards Update is the final version of Proposed Accounting Standards Update 2014-220—Income Statement—Extraordinary Items (Subtopic 225-20), which has been deleted. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. This Update is not expected to have a material impact on the Company’s financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* (“ASU 2016-02”). The standard amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective beginning in the first quarter of 2019. Early adoption of ASU 2016-02 is permitted. The new leases standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company’s financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This ASU makes targeted amendments to the accounting for employee share-based payments. This guidance is to be applied using various transition methods such as full retrospective, modified retrospective, and prospective based on the criteria for the specific amendments as outlined in the guidance. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted, as long as all of the amendments are adopted in the same period. The Company has evaluated this standard and has chosen early adoption effective March 30, 2016. This ASU has not had a material impact on the Company’s financial statements.

In June 2016, the FASB issued Accounting Standards Update ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard significantly changes how entities will measure credit losses for most financial assets and certain other instruments that aren’t measured at fair value through net income. The standard will replace today’s “incurred loss” approach with an “expected loss” model for instruments measured at amortized cost. For available-for-sale debt securities, entities will be required to record allowances rather than reduce the carrying amount, as they do today under the other-than-temporary impairment model. It also simplifies the accounting model for purchased credit-impaired debt securities and loans. This ASU is effective for annual periods beginning after December 15, 2019, and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018, and interim periods therein. This ASU is not

expected to have a material impact on the Company's financial statements.

F-8

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

### 3. INVESTMENTS

The following table summarizes the Company's investment securities at amortized cost as of July 31, 2016 and October 31, 2015:

	July 31, 2016			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 14,947,987	\$ -	\$ -	\$ 14,947,987
Domestic Governmental Agency Loans	15,502,584	968	-	15,503,552
U.S Treasury Notes	18,525,154	4,551	(850 )	18,528,855
Total short-term investment securities	\$ 48,975,725	\$ 5,519	\$ (850 )	\$ 48,980,394

	October 31, 2015			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 12,628,880	\$ -	\$ -	\$ 12,628,880
Domestic Governmental Agency Loans	27,951,633	5,827	5,979	27,951,481
U.S Treasury Notes	5,013,982	700	262	5,014,420
Total short-term investment securities	\$ 45,594,495	\$ 6,527	\$ 6,241	\$ 45,594,781

All of the Company's investments mature within the next 12 months.

### 4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	July 31, 2016	October 31, 2015
Leasehold Improvements	\$1,317,719	\$237,209
Laboratory Equipment	1,242,919	532,249
Furniture and Fixtures	532,626	331,500
Computer Equipment	109,460	48,745
Construction in Progress	66,118	80,538
Total Property and Equipment	3,268,842	1,230,241
Accumulated Depreciation and Amortization	(306,578 )	(142,997 )
Net Property and Equipment	\$2,962,264	\$1,087,244

Depreciation expense for the three and nine months ended July 31, 2016 and 2015 was \$68,457, \$163,581, \$14,204 and \$28,352, respectively.

## 5. INTANGIBLE ASSETS

Pursuant to our license agreement with the University of Pennsylvania (“Penn”), the Company is billed actual patent expenses as they are passed through from Penn and are billed directly from our patent attorney. The following is a summary of intangible assets as of the end of the following fiscal periods:

	July 31, 2016	October 31, 2015
License	\$776,992	\$651,992
Patents	4,361,480	3,898,493
Software	14,840	-
Total intangibles	5,153,312	4,550,485
Accumulated Amortization	(1,378,636)	(1,195,452)
Intangible Assets	\$3,774,676	\$3,355,033

The expirations of the existing patents range from 2016 to 2032 but the expirations can 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 are charged to expense when the determination is made not to pursue the application. No patent applications with future value were abandoned or expired and charged to expense in the nine months ended July 31, 2016 or 2015. Amortization expense for licensed technology and capitalized patent costs is included in research and development expenses and aggregated \$64,440, \$183,184, \$52,416 and \$151,108 for the three and nine months ended July 31, 2016 and 2015, respectively.

Estimated amortization expense for the next five years is as follows:

Year ended October 31,

2016 (Remaining)	\$63,000
2017	252,000
2018	252,000
2019	252,000
2020	252,000

## 6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	July 31, 2016	October 31, 2015
Salaries and Other Compensation	\$1,700,179	\$1,698,371
Vendors	1,691,638	1,000,579
Professional Fees	697,343	272,058
Withholding Taxes Payable	175,917	220,933
	\$4,265,077	\$3,191,941

## 7. SHORT-TERM CONVERTIBLE NOTES & FAIR VALUE OF EMBEDDED DERIVATIVE

During April 2016, the last remaining promissory note of \$29,549 was converted into 1,481 shares of common stock at the \$18.75 conversion price per the promissory note agreement.



**8. DERIVATIVE INSTRUMENTS***Warrants*

A summary of changes in warrants for the nine months ended July 31, 2016 is as follows:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding Warrants at October 31, 2015:	3,241,466	\$ 5.07
Issued	-	\$ -
Exercised	(122,661 )	\$ 5.01
Expired	(8,230 )	\$ 18.75
Outstanding Warrants at July 31, 2016	3,110,575	\$ 5.04

At July 31, 2016, the Company had approximately 3.09 million of its total 3.11 million outstanding warrants classified as equity (equity warrants). At October 31, 2015, the Company had approximately 3.22 million of its total 3.24 million outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders' equity section of the balance sheet. The equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions.

## Warrant Liability

At July 31, 2016, the Company had approximately 18,000 of its total approximately 3.11 million outstanding warrants classified as liabilities (liability warrants). As of October 31, 2015, the Company had approximately 18,000 of its total approximately 3.24 million total warrants classified as liabilities (liability warrants). The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. The liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

At July 31, 2016 and October 31, 2015, the fair value of the warrant liability was \$32,997 and \$89,211, respectively. For the three months ended July 31, 2016 and 2015, the Company reported a gain of \$6,340 and \$32,384, respectively, due to changes in the fair value of the warrant liability. For the nine months ended July 31, 2016 and 2015, the Company reported a gain of \$56,214 and a loss of \$254,923, respectively, due to changes in the fair value of the warrant liability. In determining the fair value of the warrant liability at July 31, 2016 and October 31, 2015, the Company used the following inputs in its BSM:

	July 31, 2016	October 31, 2015
Exercise Price	\$ 10.63-18.75	\$ 10.63-18.75
Stock Price	\$8.34	\$ 11.09
Expected term	0.80-1.01 years	1.52-1.76 years
Expected Volatility	88.63%-93.35 %	93.87%-95.00 %
Risk Free Interest Rate	0.50 %	.075 %

### *Exercise of Warrants*

During the nine months ended July 31, 2016, warrants to purchase 122,661 shares of common stock were exercised, which resulted in cash proceeds of \$614,368.

As of July 31, 2016, there were outstanding warrants to purchase 3,110,575 shares of the Company's Common Stock with exercise prices ranging from \$3.75 to \$18.75 per share.

As of July 31, 2016, the aggregate intrinsic value of outstanding warrants was approximately \$10,331,000.

**9. SHARE BASED COMPENSATION***Employment Agreements*

Management voluntarily purchases restricted stock directly from the Company at market price. The respective stock purchases occur on the last trading day of each month. This voluntary election is outlined in each of Daniel J. O'Connor, Chief Executive Officer and President, Gregory T. Mayes, Executive Vice President, Chief Operating Officer, Robert G. Petit, Executive Vice President, Chief Scientific Officer, and Sara M. Bonstein, Senior Vice President, Chief Financial Officer and Secretary, (each an "Executive"), employment agreements. The table below reflects the purchases of each Executive:

Executive	ANNUALIZED				
	Annual Amount	For the Nine Months Ended July 31, 2016			
	to be Purchased	Gross Purchase	Net Purchase		
	\$	\$	# of shares	\$	# of shares
Daniel J. O'Connor	\$ 116,410	\$88,066	10,853	\$57,472	7,061
Gregory T. Mayes	\$ 27,794	\$21,238	2,595	\$16,229	1,981
Robert G. Petit	\$ 28,704	\$21,881	2,679	\$15,968	1,944
Sara M. Bonstein	\$ 25,420	\$19,303	2,371	\$14,779	1,812

For the three months ended July 31, 2016, the Company recorded stock compensation expense of \$66,413 in the statement of operations for the portion of management salaries voluntarily paid in stock representing 7,843 shares of its Common Stock (5,620 shares on a net basis after employee payroll taxes). For the three months ended July 31, 2015, the Company recorded a similar stock compensation expense of \$60,795 in the statement of operations representing 3,130 shares of its Common Stock (2,346 shares on a net basis after employee payroll taxes).

For the nine months ended July 31, 2016, the Company recorded stock compensation expense of \$187,670 in the statement of operations for the portion of management salaries voluntarily paid in stock representing 22,931 shares of its Common Stock (16,352 shares on a net basis after employee payroll taxes). For the nine months ended July 31, 2015, the Company recorded a similar stock compensation expense of \$150,883 in the statement of operations representing 14,435 shares of its Common Stock (12,528 shares on a net basis after employee payroll taxes).

From 2013 to present, in addition to the purchases of Common Stock set forth in the above table, Mr. O'Connor has also purchased an additional 164,909 shares of Common Stock out of his personal funds at the then market price for an aggregate consideration of \$689,004. These purchases consisted of the conversion of amounts due to Mr. O'Connor under a promissory note given by Mr. O'Connor to the Company in 2012 of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$186,555 for 34,752 shares (21,489 on a net basis after employee payroll taxes), 2013 and 2014 cash bonuses voluntarily requested to receive in equity of \$214,359 for 62,064 shares (57,990 on a net basis after employee payroll taxes), fiscal 2014 voluntary request to purchase stock directly from the Company at market price purchases of \$68,750 for 21,687 shares (15,950 on a net basis after employee payroll taxes), fiscal 2015 voluntary request to purchase stock directly from the Company at market price purchases of \$88,840 for 8,482 shares (7,556 on a net basis after employee payroll taxes), and purchases of the Company's Common Stock in the October 2013 and March 2014 public offerings of 13,500 shares for \$54,000 and 3,333 shares for \$10,000.

Executives were entitled to receive a performance-based year-end cash bonus. For the nine months ended July 31, 2015, the executive officers voluntarily elected to receive a portion of their year-end performance bonus (with a total fair value of approximately \$418,000) in the aggregate amount of 125,411 shares of the Company's Common Stock (98,603 on a net basis after employee payroll taxes).

#### *Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the nine months ended July 31, 2016 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2015:	1,069,335	\$ 10.89
Granted	462,547	\$ 8.31
Vested	(622,052 )	\$ 8.50
Cancelled	(146,921 )	\$ 16.24
Balance at July 31, 2016	762,909	\$ 10.24

As of July 31, 2016, there was approximately \$6,559,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.14 years.

As of July 31, 2016, the aggregate intrinsic value of non-vested RSUs was approximately \$719,000.

*Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards totaled 144,213 and 129,154 shares (100,726 shares on a net basis after employee taxes) for the three months ended July 31, 2016 and 2015, respectively. Total stock compensation expense associated with these awards for the three months ended July 31, 2016 and 2015 was \$1,154,419 and \$2,361,716, respectively.

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards totaled 516,581 shares and 292,832 shares (211,957 shares on a net basis after employee taxes) during the nine months ended July 31, 2016 and 2015, respectively. Total stock compensation expense associated with these awards for the nine months ended July 31, 2016 and 2015 was \$3,887,723 and \$3,633,886, respectively.

Furthermore, non-executive employees were entitled to receive a performance-based year-end cash bonus. Several non-executive employees voluntarily requested to be paid all or a portion of their cash bonus in the Company's Common Stock instead of cash. During the nine months ended July 31, 2016, the total fair value of these equity purchases were \$102,022, or 9,150 shares of the Company's Common Stock. During the nine months ended July 31, 2015, the total fair value of these equity purchases were \$67,671, or 20,322 shares of the Company's Common Stock (14,300 on a net basis after employee payroll taxes).

*Director Stock Awards*

Common stock issued to Directors for compensation related to board and committee membership totaled 31,767 and 23,955 shares for the three months ended July 31, 2016 and 2015, respectively. Total stock compensation expense associated with these awards for the three months ended July 31, 2016 and 2015 was \$311,205 and \$264,552, respectively.

Common stock issued to Directors for compensation related to board and committee membership totaled 125,501 and 239,850 shares (226,423 shares on a net basis after taxes) for the nine months ended July 31, 2016 and 2015, respectively. Total stock compensation expense associated with these awards for the nine months ended July 31, 2016 and 2015 was \$933,615 and \$967,631, respectively.

*Stock Options*

A summary of changes in the stock option plan for the nine months ended July 31, 2016 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2015:	1,981,939	\$ 13.78
Granted	1,385,000	\$ 12.81
Exercised	-	\$ -
Expired	(15,145 )	\$ 29.69
Outstanding at July 31, 2016	3,351,794	\$ 13.31
Vested and Exercisable at July 31, 2016	1,353,109	\$ 13.55

F-12

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended July 31, 2016 and 2015, was approximately \$3,108,000 and \$1,959,000, respectively. For the nine months ended July 31, 2016 and 2015, compensation cost related to the Company's outstanding stock options was approximately \$13,060,000 and \$6,824,000, respectively.

During the nine months ended July 31, 2016, 1,385,000 options were granted with a total grant date fair value of approximately \$14,838,000. During the nine months ended July 31, 2015, 1,618,995 options were granted with a total grant date fair value of approximately \$28,318,000.

As of July 31, 2016, there was approximately \$21,496,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.20 years.

As of July 31, 2016, the aggregate intrinsic value of vested and exercisable options was approximately \$66,000.

In determining the fair value of the stock options granted during the nine months ended July 31, 2016 and 2015, the Company used the following inputs in its BSM:

	Nine Months Ended	
	July 31, 2016	July 31, 2015
Expected Term	5.51-6.51 years	5-10 years
Expected Volatility	109.23%-115.25 %	108.72%-154.54 %
Expected Dividends	0 %	0 %
Risk Free Interest Rate	1.65%-2.00 %	1.41%-2.27 %

#### *Shares Issued to Consultants*

During the three months ended July 31, 2016, 31,030 shares of Common Stock valued at \$252,000 were issued to consultants for services, of which \$40,000 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$156,700 for shares earned pursuant to consulting agreements but not delivered. During the three months ended July 31, 2015, 75,628 shares of Common Stock valued at \$1,390,107 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

During the nine months ended July 31, 2016, 120,047 shares of Common Stock valued at \$1,097,088 were issued to consultants for services, of which \$55,000 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$156,700 for shares earned pursuant to consulting agreements but not delivered. During the nine months ended July 31, 2015, 319,278 shares of Common Stock valued at \$3,768,014 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

The following table summarizes share-based compensation expense included in the Statement of Operations by expense category for the nine months ended July 31, 2016 and 2015, respectively:

	Three Months Ended		Nine Months Ended July	
	July 31, 2016	2015	2016	2015
Research and development	\$1,014,034	\$2,499,097	\$7,088,377	\$4,896,922
General and administrative	3,994,331	3,537,359	12,281,571	10,939,570
Total	\$5,008,365	\$6,036,456	\$19,369,948	\$15,836,492



## 10. COMMITMENTS AND CONTINGENCIES:

### *Legal Proceedings*

#### *Knoll*

On August 21, 2015, Knoll Capital Management L.P. (“KCM”) filed a complaint against the Company in the Delaware Court of Chancery. The complaint alleges the existence of an oral agreement for the purchase by Knoll from the Company of 1,666,666.67 shares of Company stock at a price of \$3.00 per share. KCM alleges that the Company breached this alleged agreement and seeks specific performance or, alternatively, money damages for breach of contract. KCM served the Company with the complaint on August 31, 2015, and then served an amended complaint on October 16, 2015. The Company moved to dismiss the amended complaint on October 26, 2015 and that motion was denied on January 29, 2016. The Company filed an answer to the amended complaint on February 12, 2016. The Company intends to defend itself vigorously.

#### *Larkin and Bono*

On July 27, 2015, a derivative complaint was filed by a purported Company shareholder in the Court of Chancery of the State of Delaware against certain of the Company’s officers and directors styled Timothy Larkin v. O’Connor, et al., Case No. 11338-CB (Del. Ch. July 27, 2015) (the “Larkin Action”). The Larkin Action was brought derivatively on behalf of the Company, which is also named as a nominal defendant. On August 20, 2015, a related derivative complaint was filed by a purported Company shareholder in the United States District Court for the District of New Jersey against the same defendants styled David Bono v. O’Connor, et al., Case No. 3:15-CV-006326-FLW-DEA (D.N.J. Aug. 20, 2015) (the “Bono Action”). Both complaints are based on general allegations related to certain stock options granted to the individual defendants and generally allege counts for breaches of fiduciary duty and unjust enrichment. The Bono complaint alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. Both complaints seek damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief.

Defendants filed motions to dismiss in both actions. On March 22, 2016, the Delaware Court of Chancery issued a partial ruling on the motion to dismiss in the Larkin Action. The court denied the motion to dismiss as to the breach of fiduciary duty and unjust enrichment claim against the three members of the Compensation Committee, but expressly reserved ruling on the disclosure claim against all defendants and the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants. On May 23, 2016, the United States District Court for the District of New Jersey issued an opinion and order granting in part and denying in part defendants’ motion to dismiss. The court denied the motion to dismiss as to the breach of fiduciary duty claim and unjust enrichment claim against the

three members of the Compensation Committee, but dismissed without prejudice the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants. The court dismissed without prejudice the Section 14(a) disclosure claim and waste claims against all defendants.

At this stage of each proceeding, the Company does not express any opinion as to the likely outcome, but the Company intends to defend each action vigorously.

The Company is from time to time involved in legal proceedings in the ordinary course of its business. The Company does not believe that any of these claims and proceedings against it is likely to have, individually or in the aggregate, a material adverse effect on its financial condition or results of operations.

#### *Clinical Trial Collaboration Agreement*

On February 3, 2016, the Company entered into a Co-Development and Commercialization Agreement (the “Agreement”) with Especificos Stendhal SA de CV (“Stendhal”), for Advaxis’ lead *Lm* Technology™ immunotherapy, AXAL, in HPV-associated cancers. Under the terms of the Agreement, Stendhal will pay \$10 million towards the expense of AIM2CERV, a planned global Phase 3 clinical trial in women with high-risk, locally advanced cervical cancer. This payment will be made over the duration of the trial and covers a significant portion of the total planned study costs. Stendhal will also work with the Company to complete the clinical trial of AXAL in Mexico, Brazil, Colombia and other investigational sites in Latin American countries. Stendhal will manage and is responsible for the costs associated with the regulatory approval process, promotion, commercialization and market access for AXAL in these markets. Upon approval and commercialization of AXAL, Advaxis and Stendhal will share profits on a pre-determined basis.

#### *Operating Leases*

The Company’s corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. Effective February 1, 2016, the Company entered into an amendment to its office lease. On August 29, 2016, the Company entered into a second amendment to its office lease that will become effective January 1, 2017. The first and second amendments increased the leased space by approximately 25,000 and 4,000 square feet respectively, to a total of approximately 48,500 square feet. The additional space will allow the Company to expand manufacturing, testing, and product development capabilities, accelerate execution of pipeline related projects, strengthen the supply chain, and continue to ensure reliable and cost competitive supply of product. The lease term was extended by three years and is now scheduled to expire on November 30, 2025. The Company paid an additional security deposit of \$100,061. The amended lease requires an annual rent of approximately \$962,000 with annual increases in increments between 2% and 11% throughout the remainder of the lease. The lease amendment contains a six month rent abatement period that ran from February 2016 to July 2016, and a reduced lease rate for four months starting in August 2016. Rent expense will be recognized on a straight line basis over the term of the lease. After the second amendment, the Company is entitled upwards to a \$439,575 tenant improvement allowance for leasehold improvements. As of July 31,

2016, the tenant improvement allowance used was \$378,795 and was recorded both as a leasehold improvement and a lease incentive obligation on the Company's balance sheet. The Company plans to continue to rent necessary offices and laboratories to support its business.

F-14

Future minimum payments of the Company's operating leases are as follows:

Year ended October 31,

2016 (Remaining)	\$ 173,990
2017	961,796
2018	1,041,895
2019	1,107,385
2020	1,232,907
Thereafter	7,064,979
Total	\$ 11,582,952

## 11. FAIR VALUE

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the liabilities carried at fair value measured on a recurring basis as of July 31, 2016 and October 31, 2015:

July 31, 2016	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63 - \$18.75 from August 2016 through August 2017	\$ -	\$ -	\$32,997	\$32,997
October 31, 2015	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63 - \$18.75 from November 2015 through August 2017	\$ -	\$ -	\$89,211	\$89,211

**Common stock warrant liability:**

	July 31, 2016
Beginning balance: October 31, 2015	\$89,211
Change in fair value	(56,214)
Balance at July 31, 2016	\$32,997

**12. SUBSEQUENT EVENTS**

On August 1, 2016, the Company entered into a global agreement (the "Agreement") with Amgen for the development and commercialization of the Company's ADXS-NEO, a novel, preclinical investigational immunotherapy, using the Company's proprietary *Listeria monocytogenes* attenuated bacterial vector which activates a patient's immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient's tumor. Under the terms of the Agreement, Amgen receives an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of \$40 million and purchased \$25 million of Advaxis common stock. Advaxis and Amgen will collaborate through a joint steering committee for the development and commercialization of ADXS-NEO. Under the Agreement, Amgen will fund the clinical development and commercialization of ADXS-NEO and Advaxis will retain manufacturing responsibilities. Advaxis will also receive development, regulatory and sales milestone payments of up to \$475 million and high single digit to mid-double digit royalty payments based on worldwide sales.

In connection with the Agreement, Amgen purchased directly from Advaxis 3,047,446 shares of the Company's Common Stock, at approximately \$8.20 per share (representing a purchase at market using a 20 day VWAP methodology). The gross proceeds to Advaxis from the sale of the shares was \$25 million.

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

On August 19, 2016, the Company sold 2,244,443 shares of common stock in a registered direct offering at a per share price of \$13.50 for gross proceeds of approximately \$30.3 million. The net proceeds to the Company, after deducting the Placement Agents' fees and other estimated offering expenses payable by the Company, were approximately \$28.3 million.

F-15

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors" and incorporated by reference herein. See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our annual report on Form 10-K for the year ended October 31, 2015.

### Overview

We are 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* 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.

### *AXAL Franchise*

AXAL is an *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV. It is currently under investigation or planned investigation in four HPV-associated cancers: cervical cancer, head and neck cancer, anal cancer, and lung cancer, either as a monotherapy or in combination.

### Cervical Cancer

There are 527,624 new cases of cervical cancer caused by HPV worldwide every year, and 14,377 new cases in the U.S. alone, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2014 (“WHO”). Current preventative vaccines cannot protect the 20 million women who are already infected with HPV. Challenges with acceptance, accessibility, and compliance have resulted in approximately a third of young women being vaccinated in the United States and even less in other countries around the world.

We completed a randomized Phase 2 clinical study (*Lm-LLO-E7-15*), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results were presented at the 2014 American Society of Clinical Oncology (“ASCO”) Annual Meeting, and showed that 32% (35/109) of patients were alive at 12 months, 22% (24/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months, and 18% (16/91) evaluable with adequate follow-up) of patients were alive for more than 24 months. Of the 109 patients treated in the study, LTS included not only patients with tumor shrinkage but also patients who had experienced stable disease or increased tumor burden. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/12) of patients had a baseline ECOG performance status of 2, a patient population that is often times excluded from clinical trials. Furthermore, a 10% objective response rate (including 5 complete responses and 6 partial responses) and a disease control rate of 38% (42/109) were observed. The addition of cisplatin chemotherapy to AXAL in this study did not significantly improve overall survival or objective tumor response ( $p=0.9981$ ).

In this study, 109 patients received 254 doses of AXAL. AXAL was found to be well tolerated with 38% (41/109) of patients experiencing mild to moderate Grade 1 or 2 transient adverse events associated with infusion; 1 patient experienced a Grade 3 Serious Adverse Events (“SAE”). All observed treatment related adverse events either self-resolved or responded readily to symptomatic treatment.

We have reached an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for a Phase 3 trial evaluating AXAL in patients with high-risk, locally advanced cervical cancer. We plan to initiate, in collaboration with the GOG/NRG Oncology, an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies, a Phase 3 clinical trial in cervical cancer (“AIM2CERV” or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”) in 2016 to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

AIM2CERV will be a Phase 3 study of adjuvant AXAL, following primary treatment with chemoradiation, in patients with high-risk locally advanced cervical cancer compared to placebo alone. This study will evaluate both the time it takes for the cancer to recur as well as the overall survival. Our goal is to develop a treatment to prevent or reduce the risk of recurrence of cervical cancer after primary treatment interventions.



Biocon Limited (“Biocon”), our co-development and commercialization partner for AXAL in India and key emerging markets, filed a Marketing Authorization Application (“MAA”) for licensure of this immunotherapy in India. The Drug Controller General of India (“DCGI”) accepted this MAA for review. The filing of the MAA was driven by several factors: (i) results from the *Lm*-LLO-E7-15 Phase 2 trial indicated that AXAL was well tolerated and showed significant clinical activity in recurrent/refractory cervical cancer; (ii) cervical cancer is the second most common cancer among Indian women (according to WHO, there are 122,844 new cases per year with 67,544 deaths reported); and (iii) current treatment options for non-operable refractory/recurrent disease are limited in India. As part of the MAA review process, Biocon met with the Scientific Expert Committee (the “Committee”). The Committee indicated that proof of concept for this novel immunotherapy has been established. The Committee advised Biocon to obtain data from a Phase 3 clinical trial in patients with recurrent cervical cancer who have failed prior chemo and radiation therapy. The face-to-face interaction with the Committee provided Biocon and Advaxis with valuable insight for future development and the companies are evaluating next steps.

We are conducting a Phase 1/2 trial evaluating higher doses and repeat cycles of AXAL in patients with recurrent cervical cancer. This study successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The Company believes it has gained a sufficient understanding of the safety profile of higher dose levels based on result from this as well as other ongoing Advaxis studies. As a result, the Company has elected not to enroll any additional patients into this study.

We have entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and immunogenicity of our investigational *Lm*-LLO cancer immunotherapy, AXAL, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated Squamous Cell Carcinoma of the Head and Neck (“SCCHN”). For the AXAL and durvalumab dose escalation portion of the study, the second dose-escalation cohort has been completed and we have commenced enrollment in the Part A and B expansion phases. With respect to the dose-escalation portion of this study, five patients were enrolled to Cohort 1 (AXAL at  $1 \times 10^9$  CFU with 3mg/kg of durvalumab). Three of these five patients received less than three doses of AXAL due to the clinical hold. Following the clinical hold, five patients were enrolled into Cohort 2 (AXAL at  $1 \times 10^9$  CFU with 10mg/kg of durvalumab).

The GOG Foundation, Inc. (now a member of NRG Oncology), under the sponsorship of the Cancer Therapy Evaluation Program (“CTEP”) of the National Cancer Institute (“NCI”), is independently conducting GOG-0265, an open-label, single arm Phase 2 study of AXAL in persistent or recurrent cervical cancer (patients must have received at least 1 prior chemotherapy regimen for the treatment of their recurrent/metastatic disease, not including that administered as a component of primary treatment) at 21 clinical sites in the U.S. The first stage of enrollment in GOG-0265 has successfully been completed with 26 patients treated and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Clinical data from the first stage of GOG-0265 was presented at the American Gynecological & Obstetrical Society (“AGOS”) annual meeting on September 17, 2015. Overall survival at 12 months was 38.5% (10/26) (the predefined criteria for 12-month survival

was  $\geq 20\%$ ), and, among patients who had received the full treatment regimen of 3 doses of AXAL, the 12-month survival rate was 55.6% (10/18). The adverse events observed in the first stage of the study have been consistent with those reported in other clinical studies with AXAL. It was well-tolerated, with Grade 1-2 fatigue, chills, and fever the most commonly reported Adverse Events (“AE”); six patients experienced a treatment-related Grade 3 or Grade 4 AE, which was considered possibly-related to AXAL. The second stage of the study began enrollment in February 2015 and includes a protocol amendment to allow patients to continue to receive repeat cycles of therapy until disease progression. Stage 2 enrollment ceased upon the clinical hold in October 2015. Patients enrolled in Stage 2 are available for evaluation, however, Advaxis and the GOG Foundation/NRG Oncology agreed to re-enroll a new cohort of Stage 2 patients to GOG-0265 in order to obtain a complete cohort of data for Stage 2 and final analysis. Stage 2 enrollment is expected to begin in early calendar Q4 2016. Preliminary findings from patients initially enrolled in Stage 2 of GOG-0265, noting data generally consistent with findings in Stage 1 despite a more heavily bevacizumab pre-treated population, were presented at the American Society of Clinical Oncology (“ASCO”) annual meeting.

AXAL has received FDA orphan drug designation for invasive Stage II-IV cervical cancer, and has received Fast Track designation from the FDA for high-risk locally advanced cervical cancer patients. AXAL 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”).

#### Head and Neck Cancer

SCCHN is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of SCCHNs originate from the mucosal linings of the oral cavity, pharynx, or larynx and 60-80% of these cancers are caused by HPV. According to the American Cancer Society, head and neck cancer accounts for about 3% to 5% of all cancers in the United States with an increasing incidence of HPV-associated head and neck cancers. Approximately 12,000 new cases will be diagnosed in the United States in 2016 according to the Surveillance, Epidemiology, and End Results (“SEER”) database.

The safety and immunogenicity of AXAL is being evaluated in a Phase 2 study under an investigator-sponsored IND at Mount Sinai and Baylor College of Medicine in a pre-surgery “window of opportunity” trial in patients with HPV-positive head and neck cancer. This clinical trial is the first study to evaluate the immunologic and pathologic effects of AXAL in patients when they are initially diagnosed with HPV-associated head and neck cancer. Preliminary clinical data from this trial was presented at the American Association of Cancer Research (“AACR”) annual meeting on April 18, 2016. The data presented showed that, among the eight enrolled AXAL - treated patients, HPV E7- and/or E6-specific T cell responses increased in the peripheral blood in five of the study patients. Increased infiltration of both CD4+ and CD8+ T cells were observed in the Tumor Immune Microenvironment (“TME”) of four patients, with a reduction of FOXP3+ regulatory T cells within the tumors of 3/6 patients. Increased T cell responses to HPV E6 supports enhanced immune activity against additional tumor targets. Changes to the TME included cytotoxic T cell infiltration into the post-resection tumor, increased immune activation, a reduction of regulatory T cells, infiltration of cytotoxic T cells, and increased expression of inflammatory activation markers. In addition, fluctuations of circulating serum cytokine (IL-15, IL-9, TNfa, IL-2 and MIP-1b) levels were observed potentially suggesting consumption by activated T cells and migration of T cells to the TME. This study met its Stage 1 primary objective and is now advancing into the second stage of the clinical study. The study is designed to show that AXAL is highly immunogenic and worth further investigation if the overall rate of vaccine-induced T-cell responses is 75 percent or

more. The assessment based on data from eight of the anticipated nine patients to be enrolled in Stage 1 confirmed that the study met the target for the overall rate of vaccine-induced T-cell response. Stage 2 of the clinical study will enroll up to 13 patients with late-stage HPV-associated oropharyngeal cancer.

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part study to evaluate safety and immunogenicity of durvalumab (MEDI4736) in combination with AXAL as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN.

AXAL has received FDA orphan drug designation for HPV-associated head and neck cancer.

### Anal Cancer

According to the American Cancer Society, nearly all squamous cell anal cancers are linked to infection by HPV, the same virus that causes cervical cancer. According to the SEER database, approximately 7,500 new cases will be diagnosed in the United States in 2016.

The safety and efficacy of AXAL is being evaluated in a Phase 2 study under an investigator-sponsored IND by Brown University in patients with high-risk locally advanced anal cancer. Preliminary data indicates all patients who have completed the treatment regimen have experienced a six-month complete response, with no disease recurrence. In consideration of these preliminary data, the investigator at Brown University is evaluating the opportunity to transition this study into a NCI-funded cooperative group trial to evaluate the safety and efficacy of AXAL in a pivotal Phase 2/3 anal cancer trial, to be conducted by NRG Oncology. In advance of the foregoing, we have entered into a clinical trial collaboration agreement with the Radiation Therapy Oncology Group (“RTOG”) Foundation for the conduct of such study.

We are conducting a Phase 2 multi-center, open-label, two-stage study (“FAWCETT” or “Fighting Anal-Cancer with CTL Enhancing Tumor Therapy”), testing AXAL in patients with persistent or recurrent metastatic anal cancer. FAWCETT is designed to evaluate the efficacy and safety of AXAL as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. Stage 1 of the trial will enroll 31 patients with anal cancer whose disease recurred after receiving treatment. Patients will receive AXAL  $1 \times 10^9$  CFU doses every three weeks for up to two years.

AXAL has received FDA and EMA orphan drug designation for anal cancer.

### Lung Cancer

Lung cancer is the leading cause of cancer death in Taiwan, China, and worldwide. Histologically, Non-Small Cell Lung Cancer (“NSCLC”), including squamous cell carcinoma, adenocarcinoma, and large cell carcinoma, comprises more than 80% of lung cancers. Cigarette smoking is the primary risk factor and accounts for approximately 85% of all lung cancer cases. For those who have never smoked, HPV infection is considered to be an important cause of lung cancer in Asia. In a recent international pooled analysis of data on HPV-associated lung cancers, the prevalence in Asia was found to be 5% of all lung cancers.

GBP, our development and commercialization partner in Asia, is planning to conduct a randomized Phase 2, open-label, controlled study in HPV-associated NSCLC in patients following first-line induction chemotherapy. Pending Taiwanese FDA approval, the study is planned to initiate in 2016 and will enroll up to 124 patients. This trial will be fully funded exclusively by GBP.

#### *ADX-PSA Franchise*

#### Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in seven will get prostate cancer during his lifetime, and one man in 36 will die of this disease. About 210,000 new cases will be diagnosed in the United States in 2016 according to the SEER database.

ADX-PSA is an *Lm-LLO* immunotherapy designed to target the PSA antigen commonly overexpressed in prostate cancer.

We have entered into a clinical trial collaboration and supply agreement with Merck & Co. (“Merck”) to evaluate the safety and efficacy of ADX-PSA as monotherapy and in combination with KEYTRUDA<sup>®</sup> (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADX-PSA monotherapy dose escalation portion of the study, we successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The Company believes it has gained a sufficient understanding of the safety profile of higher dose levels based on result from this as well as other ongoing Advaxis studies. Additional patients at the  $1 \times 10^9$  CFU dose level will be enrolled to complete the dose escalation phase of the study. After ensuring adequate safety of this dose in the prostate cancer patient population, the study will proceed into the combination phase.

## *ADX-HER2 Franchise*

### HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors such as breast, gastric, bladder, brain, pancreatic, ovarian and osteosarcoma. According to the SEER database and recent published literature, the percentage of HER2 expression varies by cancer type, with approximately 70,000 new cases of invasive HER2 positive breast cancer diagnosed each year in the US; approximately 5,000 new cases of HER2 positive gastric cancer; approximately 22,000 new cases of HER2 positive bladder cancer; approximately 20,000 new cases of HER2 positive pancreatic cancer; approximately 2,500 new cases of HER2 positive ovarian cancer; and approximately 600 new cases of HER2 positive osteosarcoma.

ADX-HER2 is an *Lm-LLO* immunotherapy designed to target HER2 expressing solid tumors such as human and canine osteosarcoma, breast, gastric and other cancers. The FDA has cleared our IND application and we have initiated a Phase 1b study in patients with metastatic HER2-expressing cancers. Thereafter, we intend to initiate a clinical development program with ADX-HER2 for the treatment of pediatric osteosarcoma.

### Osteosarcoma

Osteosarcoma affects about 400 children and teens in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic improvement in decades. Osteosarcoma is considered a rare disease and may qualify for regulatory incentives including, but not limited to, orphan drug designation, patent term extension, market exclusivity, and development grants. Given the limited availability of new treatment options for osteosarcoma, and that it is an unmet medical need affecting a very small number of patients in the U.S. annually, we believe that, subject to regulatory approval, the potential to be on the market may be accelerated.

Based on encouraging data discussed below from a veterinarian clinical study in which pet dogs with naturally occurring osteosarcoma were treated with ADX-HER2, we intend to initiate a clinical development program with ADX-HER2 for the treatment of human osteosarcoma. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

ADX-HER2 has received FDA and EMA orphan drug designation for osteosarcoma and has received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

## Canine Osteosarcoma

Osteosarcoma is the most common primary bone tumor in dogs, accounting for roughly 85% of tumors on the canine skeleton. Approximately 10,000 dogs a year (predominately middle to older-aged dogs and larger breeds) are diagnosed with osteosarcoma in the United States. This cancer initially presents as lameness and oftentimes visible swelling on the leg. Current standard of care treatment is amputation immediately after diagnosis, followed by chemotherapy. Median survival time with standard of care is ten to twelve months. For dogs that cannot undergo amputation, palliative radiation and analgesics are frequently employed and median survival times range from three to five months.

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary Medicine is conducting studies in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of naturally occurring canine osteosarcoma. In the initial study, the primary endpoint was to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study were progression-free survival and overall survival. The findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3.3 \times 10^9$  CFU with no evidence of significant cardiac, hematological, or other systemic toxicities. The study determined that ADXS-HER2 is able to delay or prevent metastatic disease and significantly prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). This work was recently published in the March 2016 issue of Clinical Cancer Research. Dogs receiving ADXS-HER2 following standard of care (n=18) had a progression free survival of 615 days and a median survival time of 956 days. These results compared favorably to a historical control group where the median survival time was 423 days. A second study conducted by Dr. Mason has evaluated the effects of combination palliative radiation with ADXS-HER2 on dogs with primary osteosarcoma who were unsuitable for amputation (n=15). Preliminary data was presented at the 2015 ACVIM Forum and showed that repeat doses of ADXS-HER2 administered after palliative radiation were well tolerated with no systemic or cardiac toxicity. In long-term follow-up, several dogs have experienced prolonged survival times ranging from 18 to 28 months.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana Therapeutics Inc. (“Aratana”), where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request has been filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the 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. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals. Aratana is further responsible for the conduct of clinical research with ADXS-Survivin in canine/feline lymphoma, as well as pending investigations of two additional Advaxis constructs in animals.

*ADX-NEO Franchise (preclinical)*

In August 2016, we entered into a global agreement (the “Agreement”) with Amgen for the development and commercialization of ADXS-NEO, a novel, preclinical investigational cancer immunotherapy treatment, using our proprietary *Lm* Technology attenuated bacterial vector which activates a patient’s immune system to respond against multiple potential unique mutations, or neoepitopes, contained in and identified from an individual patient’s tumor through DNA sequencing.

In February 2016, we had a productive pre-IND meeting with the FDA. Following this meeting, we intend to file an IND application for ADXS-NEO and to initiate Company-sponsored studies, as well as external collaborations, under a program entitled “MINE™” (My Immunotherapy Neo-Epitopes).

The goal of MINE™ is to use our *Lm* Technology cancer immunotherapy technology to develop neo-epitope immunotherapies based on an individual patient’s tumor (“ADX-NEO”). MINE™ will first focus on a preclinical study of our new construct approach to evaluate the immunologic effects and anti-tumor activity of a personalized immunotherapy in a mouse tumor model. We will use learnings from the MINE™ collaboration to identify and target neoepitopes using *Lm*-LLO technology and later develop patient specific immunotherapy constructs that incorporate the neoepitope sequences identified in the patient’s tumor cells. Clinical studies using ADXS-NEO are in development. Further, we have entered into a research collaboration with Memorial Sloan Kettering Cancer Center (“MSK”) to advance the study of neoepitope-based, personalized cancer therapy.

*ADX-TNBC Franchise (preclinical)*

We are developing a construct that targets antigens found in Triple-Negative Breast Cancer (“TNBC”), which accounts for approximately 15-20% of all diagnosed breast cancer cases and has not been amenable to targeted therapies directed toward estrogen, progesterone, or HER2 receptors. A majority of TNBC patients’ still exhibit poor outcomes, with only 30-45% of patients achieving a pathological complete response from conventional chemotherapeutic and radiation therapy. The heterogeneous nature of this cancer type, the presence of mutations in multiple pathways, and the development of resistance to single agents make combination therapy much more attractive and suggest the need for agents that address more than one antigen/target.

*Lm-LLO Combination Franchise*

AXAL and Durvalumab



As stated above, we have entered into a clinical trial collaboration agreement with MedImmune to conduct a Phase 1/2, open-label, multicenter, two part study to evaluate safety and immunogenicity of our investigational *Lm*-LLO cancer immunotherapy, AXAL, in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736) for the treatment of patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. For the AXAL and durvalumab dose escalation portion of the study, the second dose-escalation cohort has been completed and we have commenced enrollment in the Part A and B expansion phases. With respect to the dose-escalation portion of this study, five patients were enrolled to Cohort 1 (AXAL at  $1 \times 10^9$  CFU with 3mg/kg of durvalumab). Three of these five patients received less than three doses of AXAL due to the clinical hold. Following the clinical hold, five patients were enrolled into Cohort 2 (AXAL at  $1 \times 10^9$  CFU with 10mg/kg of durvalumab).

ADXS-PSA and KEYTRUDA® (pembrolizumab )

As stated above, we have entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, we successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The Company believes it has gained a sufficient understanding of the safety profile of higher dose levels based on result from this as well as other ongoing Advaxis studies. Additional patients at the  $1 \times 10^9$  CFU dose level will be enrolled to complete the dose escalation phase of the study. After ensuring adequate safety of this dose in the prostate cancer patient population, the study will proceed into the combination phase.

*Lm-LLO Immunotherapy (preclinical)*

We are developing other ways to exploit the potential of our *Lm* Technology including, but not limited to, the use of *Lm* Technology in Infectious Disease. We have various preclinical collaborations with academic and other centers of excellence.

## **RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JULY 31, 2016 AND 2015**

### *Revenue*

We did not record any revenue for the three months ended July 31, 2016 or 2015.

### *Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was approximately \$10.1 million for the three months ended July 31, 2016, compared with approximately \$7.3 million for the three months ended July 31, 2015, an increase of approximately \$2.8 million. The increase was a result of higher third-party costs, specifically related to AXAL support in manufacturing and clinical trial expenses, for the Anal, Head & Neck, High Dose, Prostate and Cervical Cancer programs, as well as ADXS-PSA Phase 1/2 trial support. Furthermore, the increase was also a result of an increased number of employees to support the research and development initiatives.

We anticipate a significant increase in research and development expenses as a result of our intended expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, we expect to incur expenses in the development of strategic and other relationships required to license, manufacture and distribute our product candidates when they are approved.

### *General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses were approximately \$6.4 million for the three months ended July 31, 2016, compared with approximately \$6.3 million for the three months ended July 31, 2015, an increase of approximately \$0.1 million. Increases in both the number of employees and facilities costs that resulted from an expansion in laboratory and office space were offset by a decrease of approximately \$0.7 million in non-cash investor relations costs.

*Interest Income*

Interest income was \$73,872 for the three months ended July 31, 2016, compared with \$34,869 for the three months ended July 31, 2015. Interest income earned for the three months ended July 31, 2016 reflected interest income earned on the Company's held-to-maturity investments and savings account balance. Interest income earned for the three months ended July 31, 2015 reflected interest income earned on the Company's savings account balance.

*Changes in Fair Values*

For the three months ended July 31, 2016, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$6,340 due to a decrease in the fair value of liability warrants as a smaller range of share prices used in the calculation of the BSM volatility input offset a modest increase in our share price from \$7.74 at April 30, 2016 to \$8.34 at July 31, 2016.

For the three months ended July 31, 2015, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$32,384 due to an decrease in the fair value of liability warrants primarily resulting from a slight decrease in our share price from \$16.81 at April 30, 2015 to \$16.66 at July 31, 2015 in addition to a smaller range of share prices used in the calculation of the BSM volatility input.

## **RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED JULY 31, 2016 AND 2015**

### *Revenue*

During the nine months ended July 31, 2016, the Company recorded revenue of \$250,000 due to the receipt of an annual exclusive license fee from GBP for the development and commercialization of AXAL.

We did not record any revenue for the nine months ended July 31, 2015.

### *Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was \$32.0 million for the nine months ended July 31, 2016, compared with \$17.2 million for the nine months ended July 31, 2015, an increase of \$14.8 million. The increase was a result of higher third-party costs, specifically related to AXAL support in manufacturing and clinical trial expenses, for the Anal, Head & Neck, High Dose, Prostate and Cervical Cancer programs, as well as ADXS-PSA Phase 1/2 trial support. Stock based compensation for existing and past employees increased by approximately \$3.1 million due to increases in the number of awards. Moreover, the increase was also a result of an increased number of employees to support the research and development initiatives.

We anticipate a significant increase in research and development expenses as a result of our intended expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, we expect to incur expenses in the development of strategic and other relationships required to license, manufacture and distribute our product candidates when they are approved.

### *General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expense was \$20.4 million for the nine months ended July 31, 2016, compared with \$17.1 million for

the nine months ended July 31, 2015, an increase of \$3.3 million. There was an increase of approximately \$4.5 million in compensation related expense, including a non-cash increase in stock based compensation costs of approximately \$3.0 million, attributable to increases in our employees, the grant date fair value of stock awards and the number of awards. This was partially offset by a decrease in non-cash investor relations costs of approximately \$1.6 million.

#### *Interest Income*

Interest income was \$216,061 for the nine months ended July 31, 2016, compared with \$55,608 for the nine months ended July 31, 2015. Interest income earned for the nine months ended July 31, 2016 reflected interest income earned on the Company's held-to-maturity investments and savings account balance. Interest income earned for the nine months ended July 31, 2015 reflected interest income earned on the Company's savings account balance.

#### *Changes in Fair Values*

For the nine months ended July 31, 2016, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$56,214 due to a decrease in the fair value of liability warrants as a smaller range of share prices were used in the calculation of the BSM volatility input as well as a decrease in our share price from \$11.09 at October 31, 2015 to \$8.34 at July 31, 2016.

For the nine months ended July 31, 2015, the Company recorded non-cash expense from changes in the fair value of the warrant liability of \$254,923 due to an increase in the fair value of liability warrants primarily resulting from a larger range of share prices used in the calculation of the BSM volatility input, as well as a significant increase in our share price from \$3.18 at October 31, 2014 to \$16.66 at July 31, 2015. This was partially offset by the expiration of some warrants.

#### *Other Expense*

During the nine months ended July 31, 2015, we recorded debt conversion expense of \$6,599 as a result of inducing certain noteholders to convert their convertible promissory notes into common shares by offering conversion prices at a discount from the market price of the common stock.

#### *Income Tax Expense*

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

During the nine months ended July 31, 2016, we paid \$50,000 in Taiwanese withholding taxes in connection with the revenue generated from an annual exclusive license fee from GBP. The taxes paid were offset by receipt of a net cash amount of \$35,774 in excess of what was recorded as Income Tax Receivable at October 31, 2015 from the sale of our state NOLs and research and development tax credits for the period ended October 31, 2014.

## Liquidity and Capital Resources

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through August 2016, we raised approximately \$221.8 million in gross proceeds from various public and private offerings of our common stock. We have not yet commercialized any drug, and we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approvals for our drug, successfully complete any post-approval regulatory obligations, successfully compete with other available treatment options in the marketplace, overcome any clinical holds that the FDA may impose and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate revenues from our drug candidates. As of August 31, 2016, the Company had approximately \$162.8 million in cash, cash equivalents and investments on its balance sheet. We believe our current cash position is sufficient to fund our business plan approximately through the second quarter of fiscal 2019. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through July 31, 2016, the Company has reported accumulated net losses of approximately \$186.0 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities for the nine months ended July 31, 2016 was approximately \$31.1 million (including proceeds from the sale of our state NOLs and Research and Development (R&D) tax credits of approximately \$1.6 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Cash used in operating activities for the nine months ended July 31, 2015 was approximately \$15.1 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$1.7 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Cash used in investing activities for the nine months ended July 31, 2016 was approximately \$6.2 million resulting from investments in held-to-maturity investments, purchases of property and equipment, construction of cleanroom and laboratory facilities, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash used in investing activities for the nine months ended July 31, 2015 was approximately \$842,000 resulting from purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities for the nine months ended July 31, 2016 was approximately \$528,000, resulting from approximately \$614,000 in proceeds received on option and warrant exercises. This was partially offset by approximately \$86,000 in taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities for the nine months ended July 31, 2015 was approximately \$95.5 million, resulting primarily from registered direct offerings of 7,008,896 shares of our Common Stock resulting in net proceeds of \$38.1 million and a public offering of 2,800,000 shares of Common Stock resulting in net proceeds of approximately \$56.7 million. In addition, the Company received \$2.4 million from the proceeds received on option and warrant exercises. This was partially offset by approximately \$1.7 million in taxes paid related to the net share settlement of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of July 31, 2016 and October 31, 2015, we had an accumulated deficit of \$186,003,988 and \$134,054,259, respectively and shareholders' equity of \$83,599,966 and \$115,598,875, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately through calendar year end 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of our 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, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.



**Tabular Disclosure of Contractual Obligations**

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>
Operating Leases	\$11,582,952	\$890,321	\$2,116,535	\$2,497,670	\$6,078,426
Employment Agreements Subject to Annual Renewal	\$1,792,993	\$1,792,993			
Consulting and other Services	\$2,201,390	\$1,501,779	\$699,611	\$	

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

**Off-Balance Sheet Arrangements**

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support, or engages in leasing, hedging, or research and development services on our behalf.

**Critical Accounting Estimates**

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

it requires assumptions to be made that were uncertain at the time the estimate was made, and

changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, 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, warrant liability valuation and impairment of intangibles.

See Note 2 to our financial statements that discusses significant accounting policies.

### **New Accounting Pronouncements**

See Note 2 to our financial statements that discusses new accounting pronouncements.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

At July 31, 2016, the Company had approximately \$78.7 million in cash, cash equivalents and investments, which consisted primarily of bank deposits, money market funds and short term investments such as certificates of deposit, domestic governmental agency loans and U.S treasury notes. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

## ITEM 4. CONTROLS AND PROCEDURES

### *Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act). Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is: (1) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure; and (2) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

### *Changes in Internal Control over Financial Reporting*

During the quarter ended July 31, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

### *Limitations on Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. Refer to Footnote 9: Commitments and Contingencies for more information on legal proceedings.

### **ITEM 1A. RISK FACTORS**

There have been no material changes in our risk factors disclosed in our Annual Report on Form 10-K for the year ended October 31, 2015.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

#### **Recent Sales of Unregistered Securities**

During the period covered by this report, we have issued unregistered securities to the persons as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we claim that each transaction was exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 3(a)(9) or Section 4(a)(2) thereof and/or Regulation D promulgated thereunder. All recipients had adequate access to information about us. We have not furnished information under this item to the extent that such information previously has been included under Item 3.02 in a Current Report on Form 8-K.

On May 4, 2016, the Company issued 20,550 shares of Common Stock to accredited investors as payment for consulting services.

On May 31, 2016, the Company issued 1,615 shares of Common Stock to management, pursuant to their Employment Agreements.

On June 30, 2016, the Company issued 2,629 shares of Common Stock to management, pursuant to their Employment Agreements.

On July 29, 2016, the Company issued 1,376 shares of Common Stock to management, pursuant to their Employment Agreements.

On August 5, 2016, the Company issued 28,838 shares of Common Stock to accredited investors as payment for consulting services.

### Treasury Share Repurchases

The following table represents treasury share repurchases during the three months ended July 31, 2016:

	(a) Total Number of Shares Purchased (1)	(b) Average Price Paid Per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program
May 1, 2016 – May 31, 2016	11,726	\$ 7.12	N/A	N/A
June 1, 2016 – June 30, 2016	5,058	\$ 8.49	N/A	N/A
July 1, 2016 – July 31, 2016	48,849	\$ 8.33	N/A	N/A
Total	65,633	\$ 8.12	N/A	N/A

(1) Consists of shares repurchased by the Company for certain employees' restricted stock units that vested to satisfy minimum tax withholding obligations that arose on the vesting of the restricted stock units.

**ITEM 6. EXHIBITS**

31.1\* Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002

31.2\* Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002

32.1\* Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002

32.2\* Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002

101.INS XBRL INSTANCE DOCUMENT

101.SCH XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

101.CAL XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

101.DEF XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

101.LAB XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith

**SIGNATURES**

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ADVAXIS, INC.**

Registrant

Date: September 7, 2016 By: */s/ Daniel J. O'Connor*  
Daniel J. O'Connor  
Chief Executive Officer

By: */s/ Sara M. Bonstein*  
Sara M. Bonstein  
Chief Financial Officer, Senior Vice President & Secretary

