

Advaxis, Inc.  
Form 10-Q  
March 13, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended January 31, 2015

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-28489

**ADVAXIS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

**02-0563870**

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

(State or other jurisdiction of (IRS Employer  
incorporation or organization) Identification No.)

305 College Road East, Princeton, NJ 08540

(Address of principal executive offices)

(609) 452-9813

(Registrant's telephone number)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of March 9, 2015 was 27,208,826.



**INDEX**

	Page No.
<b>PART I <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Financial Statements</u>	F-1
<u>Balance Sheets at January 31, 2015 (unaudited) and October 31, 2014</u>	F-1
<u>Statements of Operations for the three month periods ended January 31, 2015 and 2014 (unaudited)</u>	F-2
<u>Statements of Cash Flow for the three month periods ended January 31, 2015 and 2014 (unaudited)</u>	F-3
<u>Notes to Financial Statements</u>	F-4
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>	11
Item 4. <u>Controls and Procedures</u>	11
<b>PART II <u>OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	12
Item 1A. <u>Risk Factors</u>	12
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	12
Item 5. <u>Other Information</u>	12
Item 6. <u>Exhibits</u>	13
<u>SIGNATURES</u>	14

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.****BALANCE SHEETS**

	January 31, 2015 (unaudited)	October 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 30,577,964	\$ 17,606,860
Prepaid Expenses	51,037	182,978
Income Tax Receivable	-	1,731,317
Other Current Assets	8,182	8,182
Deferred Expenses - current	882,467	964,724
Total Current Assets	31,519,650	20,494,061
Property and Equipment (net of accumulated depreciation)	70,467	77,369
Intangible Assets (net of accumulated amortization)	2,920,929	2,767,945
Other Assets	38,438	38,438
<b>TOTAL ASSETS</b>	<b>\$ 34,549,484</b>	<b>\$ 23,377,813</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$ 1,524,694	\$ 1,411,058
Accrued Expenses	1,257,260	1,241,796
Short Term Convertible Notes and Fair Value of Embedded Derivative	62,882	62,882
Total Current Liabilities	2,844,836	2,715,736
Common Stock Warrant Liability	304,331	32,091
Total Liabilities	3,149,167	2,747,827
Commitments and Contingencies		
Shareholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at January 31, 2015 and October 31, 2014.	-	-
Liquidation preference of \$0 at January 31, 2015 and October 31, 2014.		

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

Common Stock - \$0.001 par value; authorized 45,000,000 shares, issued and outstanding 24,021,955 at January 31, 2015 and 19,630,139 at October 31, 2014.	24,021	19,630
Additional Paid-In Capital	125,401,303	107,601,493
Accumulated Deficit	(94,025,007 )	(86,991,137 )
Total Shareholders' Equity	31,400,317	20,629,986
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$34,549,484	\$23,377,813

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

F-1

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

	Three Months Ended January 31,	
	2015	2014
Revenue	\$-	\$-
Operating Expenses		
Research and Development Expenses	3,579,936	1,559,867
General and Administrative Expenses	3,196,099	4,397,836
Total Operating Expenses	6,776,035	5,957,703
Loss from Operations	(6,776,035 )	(5,957,703 )
Other Income (Expense):		
Interest Expense	-	(2,015 )
Gain on Note retirement	-	6,243
Net changes in fair value of derivative liabilities	(264,071 )	131,948
Other Income	6,236	8,572
Loss before benefit for income taxes	(7,033,870 )	(5,812,955 )
Income Tax Benefit	-	625,563
Net Loss	\$(7,033,870 )	\$(5,187,392 )
Net Loss per share, basic and diluted	\$(0.33 )	\$(0.37 )
Weighted Average Number of Shares Outstanding, Basic and Diluted	21,551,169	13,842,144

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



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

	Three Months Ended January 31, 2015	2014
<b>OPERATING ACTIVITIES</b>		
Net Loss	\$ (7,033,870 )	\$ (5,187,392 )
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Non-cash charges to consultants and employees for options and stock	2,030,170	1,602,423
Non-cash interest expense	-	51
Loss (Gain) on change in value of warrants and embedded derivative	264,071	(131,948 )
Warrant expense	8,169	1,482
Settlement expense	-	34,125
Employee Stock Purchase Plan	1,700	5,371
Depreciation expense	6,902	6,903
Amortization expense of intangibles	48,303	41,934
(Gain) on note retirement	-	(6,243 )
Change in operating assets and liabilities:		
Prepaid expenses	131,941	17,116
Income tax receivable	1,731,317	-
Other current assets	-	(75,000 )
Deferred expenses	82,257	105,018
	129,100	(1,371,578 )

Accounts payable and accrued expenses				
Interest payable	-		1,964	
Net cash used in operating activities	(2,599,940	)	(4,955,774	)
<b>INVESTING ACTIVITIES</b>				
Purchase of property and equipment	-		(24,595	)
Cost of intangible assets	(201,287	)	(12,427	)
Net cash used in Investing Activities	(201,287	)	(37,022	)
<b>FINANCING ACTIVITIES</b>				
Net proceeds of issuance of Common Stock	15,772,331		400,000	
Net cash provided by Financing Activities	15,772,331		400,000	
Net increase (decrease) in cash	12,971,104		(4,592,796	)
Cash at beginning of period	17,606,860		20,552,062	
Cash at end of period	\$ 30,577,964		\$ 15,959,266	

### Supplemental Schedule of Non-cash Investing and Financing Activities

	Three months ended January 31, 2015
Accounts Payable from consultants settled with Common Stock	\$- 2014 \$ 3,000

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

## ADVAXIS, INC.

### NOTES TO THE FINANCIAL STATEMENTS

(unaudited)

#### 1. ORGANIZATION

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

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

ADXS-HPV has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in three ongoing investigator-initiated clinical trials as follows: locally advanced cervical cancer (cooperative group sponsor), head and neck cancer, and anal cancer. In addition to the investigator-initiated clinical trials, Company-sponsored trials executed under an Investigational New Drug (“IND”) include the following: i) a Phase 1/2 clinical trial alone and in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in patients with previously treated metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer; ii) a Phase 2 multi-center, open-label study alone and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360) in patients with Stage I-IIa HPV-associated cervical cancer; iii) a Phase 1/2 study evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical 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 ADXS-HPV in HPV-associated non-small cell lung cancer.

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

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

Since inception in 2002, the Company has focused its development efforts on understanding its platform technology and establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, currently those targeting HPV-associated cancer (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2 expressing cancers. Although no immunotherapies have been commercialized to date, research and development and investment continues to be placed behind the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting and expanding its clinical development program. Further, over twenty distinct additional constructs leveraging certain antigens highly expressed in multiple tumor types, developed directly by the Company and through strategic collaborations with recognized centers of excellence, are in various stages of development. Impending priority research advances include, but are not limited to, constructs targeting pan tumor antigens and tumor stromal targets.

### *Liquidity and Financial Condition*

The Company's products are being developed and have not generated significant revenues. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. On December 19, 2014, the Company priced a registered direct offering of 3,940,801 shares of its Common Stock ("Common Stock"). The transaction closed on December 22, 2014, and the Company received net proceeds of approximately \$15.8 million from the offering. In addition, on February 18, 2015, the Company priced an additional registered direct offering of 3,068,095 shares of its Common Stock. The transaction closed on February 19, 2015, and the Company received net proceeds of approximately \$22.3 million from the offering. The shares in each offering were sold under a Registration Statement (No. 333-194009) on Form S-3, filed by the Company with the SEC. The Company believes its current cash position is sufficient to fund its business plan approximately until first calendar quarter 2017. 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 its 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 over and above the amount raised during December 2014 and February 2015 in order to continue to execute its business plan. Subsequent to January 31, 2015, the Company intends to continue to raise additional funds through sales of equity securities. 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 United States Securities and Exchange Commission (the "SEC") with respect to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim 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 financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2014 and notes thereto contained in the Company's annual report on Form 10-K for the year ended October 31, 2014, as filed with the SEC on January 6, 2015.

*Revenue Recognition*

The Company is expected to derive the majority of its revenue from patent licensing in the near term. 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 such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

### *Estimates*

The preparation of financial statements in accordance with 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 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.

### *Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$30.3 million is subject to credit risk at January 31, 2015. 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, 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 January 31,	
	2015	2014
Warrants	4,082,248	4,360,441
Stock Options	477,968	467,923
Convertible Debt (using the if-converted method)	3,354	3,354
Total	4,563,570	4,831,718

### *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 their 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, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers*. Amendments in this ASU create Topic 606, Revenue from Contracts with Customers, and supersede the revenue recognition requirements in Topic 605, Revenue Recognition, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts, and create new Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is the final version of Proposed ASU 2011-230—Revenue Recognition (Topic 605) and Proposed ASU 2011-250—Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in this ASU are effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014-09 on the consolidated 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.

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. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

January 31,	October 31,
2015	2014
(Unaudited)	

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

Laboratory Equipment	\$333,727	\$ 333,727
Accumulated Depreciation	(263,260 )	(256,358 )
Net Property and Equipment	\$70,467	\$ 77,369

Depreciation expense for the three months ended January 31, 2015 and 2014 was \$6,902 and \$6,903, respectively.

#### 4. INTANGIBLE ASSETS

Pursuant to our license agreement with the University of Pennsylvania, 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:

	January 31, 2015 (Unaudited)	October 31, 2014
License	\$651,992	\$651,992
Patents	3,312,911	3,111,624
Total intangibles	3,964,903	3,763,616
Accumulated Amortization	(1,043,974 )	(995,671 )
Intangible Assets	\$2,920,929	\$2,767,945

The expirations of the existing patents range from 2015 to 2028 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 three months ended January 31, 2015 or 2014. Amortization expense for licensed technology and capitalized patent costs are included in general and administrative expenses and aggregated \$48,303 and \$41,934 for the three months ended January 31, 2015 and 2014, respectively.

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

Year ended October 31,

2015 (Remaining)	148,500
2016	198,000
2017	198,000
2018	198,000
2019	198,000

## 5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	January 31, 2015 (Unaudited)	October 31, 2014
Salaries and Other Compensation	\$ 583,895	\$ 890,069
Vendors	420,002	121,200
Professional Fees	205,401	208,000
Withholding Taxes Payable	47,962	22,527
	\$ 1,257,260	\$ 1,241,796

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

As of January 31, 2015 and October 31, 2014, the Company had approximately \$63,000 in principal outstanding on its junior subordinated convertible promissory notes that are currently overdue and are recorded as current liabilities on our balance sheet at January 31, 2015 and October 31, 2014.

## 7. DERIVATIVE INSTRUMENTS

*Warrants*

A summary of changes in warrants for the three months ended January 31, 2015 is as follows:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding Warrants at October 31, 2014:	4,158,092	\$ 5.42
Issued	2,361	\$ 7.20
Exercised	-	-
Expired	(78,205 )	\$ 9.79
Outstanding Warrants at January 31, 2015	4,082,248	\$ 5.21

At January 31, 2015, the Company had approximately 4.0 million of its total 4.1 million outstanding warrants classified as equity (equity warrants). At October 31, 2014, the Company had approximately 4.1 million of its total 4.2 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/Embedded Derivative Liability**Warrant Liability*

At January 31, 2015, the Company had 61,000 of its total 4.1 million outstanding warrants classified as liability warrants (liability warrants). As of October 31, 2014, the Company had approximately 123,000 of its total approximately 4.2 million total warrants classified as liabilities (liability warrants). All of these liability warrants at January 31, 2015 and October 31, 2014 were outstanding. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At January 31, 2015, approximately 32,000 of the 61,000 liability warrants are subject to weighted-average anti-dilution provisions. At October 31, 2014, approximately 60,000 of the 123,000 liability warrants are subject to weighted-average anti-dilution provisions. A certain number of 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 January 31, 2015 and October 31, 2014, the fair value of the warrant liability was approximately \$304,000 and \$32,000, respectively. For the three months ended January 31, 2015 and January 31, 2014, the Company reported a loss of approximately \$264,000 and a gain of approximately \$132,000, respectively, due to changes in the fair value of the warrant liability. In fair valuing the warrant liability, at January 31, 2015 and October 31, 2014, the Company used the following inputs in its BSM:

	01/31/2015	10/31/2014
Exercise Price:	\$5.63-18.75	\$2.76-21.25
Stock Price	\$9.85	\$3.18
Expected term:	31-914 days	4-1006 days
Volatility %	97.11%-184.64%	55.41%-129.38%
Risk Free Rate:	.01%-.77%	.01%-1.62%

*Expiration of Warrants*

During the three months ended January 31, 2015, the Company had 30,400 warrants with anti-dilution provisions, and 47,805 warrants, with no such anti-dilution provisions, expire unexercised.

*Warrants with anti-dilution provisions*

Some of the Company's warrants (approximately 30,000) contain anti-dilution provisions originally set at \$25.00 with a term of five years. As of January 31, 2015, these warrants had an exercise price of approximately \$7.20. As of October 31, 2014, these warrants had an exercise price of approximately \$7.71. If the Company issues any Common Stock, except for exempt issuances as defined in the warrant agreement, for consideration less than the exercise price then the exercise price and the amount of warrant shares available would be adjusted to a new price and amount of shares per the "weighted average" formula included in the warrant agreement. For the three months ended January 31, 2015, this anti-dilution provision required the Company to issue approximately 2,400 additional warrant shares; and the exercise price to be lowered to \$7.20. Any future financial offering or instrument issuance below the current exercise price of \$7.20 will cause further anti-dilution and re-pricing provisions in approximately 30,000 of its total outstanding warrants.

For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company utilized different exercise prices of \$7.20 and \$6.00, weighting the possibility of warrants being exercised at \$7.20 between 40% and 50% and warrants being exercised at \$6.00 between 60% and 50%.

As of January 31, 2015, there were outstanding warrants to purchase 4,082,248 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$21.25 per share.

**8. STOCK OPTIONS:**

A summary of changes in the stock option plan for three months ended January 31, 2015 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2014:	467,968	\$ 15.51
Granted	20,000	\$ 2.92
Exercised	(4,229 )	\$ 4.08
Expired	(5,771 )	\$ 4.08
Outstanding at January 31, 2015	477,968	\$ 15.22
Vested and Exercisable at January 31, 2015	446,035	\$ 15.69

Total compensation cost related to our outstanding stock options, recognized in the statement of operations for the three months ended January 31, 2015, was \$146,846 of which \$45,229 was included in research and development expenses and \$101,627 was included in general and administrative expenses. Total compensation cost related to our outstanding stock options, recognized in the statement of operations for the three months ended January 31, 2014, was \$257,486 of which \$90,380 was included in research and development expenses and \$167,106 was included in general and administrative expenses.

During the three months ended January 31, 2015, 20,000 options were issued for investor relations services with a grant date fair value of \$57,600.

There were no options granted during the three months ended January 31, 2014.

As of January 31, 2015, there was approximately \$125,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining average vesting period of 0.50 years.

The aggregate intrinsic value of these outstanding options, as of January 31, 2015, was approximately \$282,000.

**9. COMMITMENTS AND CONTINGENCIES:**

*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, David J. Mauro, Executive Vice President, Chief Medical Officer, Gregory T. Mayes, Executive Vice President, Chief Operating Officer and Secretary, Robert G. Petit, Executive Vice President, Chief Scientific Officer, and Sara M. Bonstein, Senior Vice President, Chief Financial Officer (each an "Executive"), employment agreements. The table below reflects the purchases of each Executive:

Executive	ANNUALIZED	For the Three Months Ended			
	Annual Amount to be Purchased	January 31, 2015			
	\$	Gross Purchase	# of shares	Net Purchase	# of shares
Daniel J. O'Connor	\$ 85,647	\$22,294	3,777	\$22,294	3,777
David J. Mauro	\$ 15,918	\$4,256	726	\$3,290	580
Gregory T. Mayes	\$ 20,951	\$5,453	924	\$4,425	773
Robert G. Petit	\$ 25,145	\$6,610	1,123	\$4,856	882
Sara M. Bonstein	\$ 17,651	\$4,617	783	\$3,632	630

For the three months ended January 31, 2015, the Company recorded stock compensation expense of \$46,153 on the statement of operations representing 7,832 shares of its Common Stock (7,053 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 146,616 shares of Common Stock out of his personal funds at the then market price for an aggregate consideration of approximately \$588,294. 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 \$182,919 for 34,752 shares, 2013 and 2014 cash bonus voluntarily requested to receive in equity of approximately \$206,125 for 57,990 shares, 2014 voluntary request to purchase stock directly from the Company at market price purchases of \$68,750 for 15,950 shares, 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.

The Executive's employment agreements entitle them to a performance-based year-end cash bonus. Mr. O'Connor, Dr. Mauro and Mr. Mayes voluntarily requested to be paid all of their bonus, required to be paid in cash, in the Company's Common Stock instead of cash. Ms. Bonstein voluntarily requested to be paid 75% of her cash bonus in the Company's Common Stock instead of cash. Dr. Petit received 100% of his bonus in cash. The total fair value of these equity purchases were \$457,125, or 137,275 shares of the Company's Common Stock (104,461 on a net basis after employee payroll taxes).

#### *Stock Awards*

During the three months ended January 31, 2015, 34,094 shares of Common Stock (27,566 shares on a net basis after employee taxes) were issued to executives and employees related to incentive retention awards, employment inducements and employee excellence awards. Accordingly, \$133,699 was charged to stock compensation expense.

Furthermore, non-executive employees were entitled to receive a performance-based year-end cash bonus. Several non-executive employees requested to be paid all or a portion of their cash bonus in the Company's Common Stock instead of cash. The total fair value of these equity purchases were \$28,164, or 8,458 shares of the Company's Common Stock (8,442 on a net basis after employee payroll taxes).

The Company recognizes the fair value of those vested shares in the statement of operations in the period earned.

#### *Director Compensation*

During the three months ended January 31, 2015, 191,939 shares of Common Stock (178,513 shares on a net basis after taxes) were issued to the Directors for compensation related to board and committee membership. Accordingly,

\$606,539 was charged to stock compensation expense.

### *Legal Proceedings*

#### *Iliad Research and Trading*

On March 24, 2014, Iliad Research and Trading, L.P. (“Iliad”) filed a complaint (the “Complaint”) against the Company in the Third Judicial District Court of Salt Lake County, Utah, purporting to assert claims for breach of express and implied contract. Specifically, Iliad alleged that the Company granted a participation right to Tonaquint, Inc. (“Tonaquint”) in a securities purchase agreement between Tonaquint and the Company, dated as of December 13, 2012 (the “Purchase Agreement”), pursuant to which Tonaquint was entitled to participate in any transaction that the Company structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleged that the settlement that the Company entered into with Ironridge Global IV, Ltd. (“Ironridge”), pursuant to which the Company issued certain shares of its Common Stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, Iliad alleged that it acquired all of Tonaquint’s rights under the Purchase Agreement in April 2013.

On May 9, 2014, the Company filed papers in support of its motion to dismiss the Complaint in its entirety. On June 2, 2014, Iliad filed an amended complaint (the “Amended Complaint”), which purported to add claims against the Company under the federal and Utah securities laws and for common law fraud. On June 30, 2014, the Company removed the action to the United States District Court for the District of Utah. On August 1, 2014, after the Court issued its Order Granting Stipulated Motion for Leave to File Second Amended Complaint, Iliad filed a Second Amended Complaint (the “SAC”), which purported to add a sixth claim for conversion. On August 22, 2014, the Company filed papers in support of its motion to dismiss the SAC in its entirety. On November 24, 2014, the Court filed an order dismissing the conversion claim but denying the remainder of the motion to dismiss.

Meanwhile, on September 22, 2014, Iliad filed papers in support of its motion for partial summary judgment of liability on the express contract claim. On December 5, 2014, Advaxis filed papers in opposition to the motion for partial summary judgment and in support of its separate motion under Rule 56(d) to deny partial summary judgment and for allowance of discovery. On December 8, 2014, Advaxis filed its answer to the SAC and a counterclaim (the “Counterclaim”), alleging that Iliad – by purporting to have surreptitiously preserved its claim for breach of Tonaquint’s alleged right to participate in the Ironridge transaction – had fraudulently induced Advaxis to enter into the parties’ post-assignment Exchange and Settlement Agreement and, in the alternative, had breached the covenant of good faith and fair dealing implied therein. On January 23, 2015, Iliad filed (i) reply papers in further support of its motion for partial summary judgment, (ii) papers in opposition to Advaxis’s motion under Rule 56(d) and (iii) its Reply to Counterclaim (rather than attempting to move to dismiss Advaxis’s Counterclaim). On March 11, 2015, the Court held argument on the partial motion for summary judgment and Rule 56(d) motion, and took both motions under advisement, but did not address the parties’ proposed Scheduling Order.

Iliad seeks “damages in an amount to be determined at trial” (though the common law fraud damages alone are alleged to be “greater than \$300,000”) plus interest, attorneys’ fees and costs. Iliad has also asked for punitive damages in connection with its claims under the Utah Securities Act (equal to three times its actual damages), and common law fraud. The Company intends to continue to defend itself vigorously.

*Numoda*

On June 19, 2009, the Company entered into a master agreement and on July 8, 2009, the Company entered into a Project Agreement with Numoda Corporation (“Numoda”), to oversee Phase 2 clinical activity with ADXS-HPV for the treatment of invasive cervical cancer and CIN.

Numoda and the Company are in a dispute regarding the amounts outstanding under these agreements. Numoda had taken the position that it was owed approximately \$540,000 while the Company believed that the amount due to Numoda should be substantially less than that amount. The Company intends to continue to defend itself 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 us is likely to have, individually or in the aggregate, a material adverse effect on its financial condition or results of operations.

#### *Sale of Net Operating Losses (NOLs)*

The Company may be eligible, from time to time, to receive cash from the sale of its Net Operating Losses under the State of New Jersey NOL Transfer Program. In December 2014, the Company received a net cash amount of \$1,731,317 from the sale of its state NOLs and research and development tax credits for the periods ended October 31, 2012 and 2013.

#### *Description of Property*

The Company's corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. On April 1, 2011, the Company entered into a sublease agreement for such office, which is an approximately 10,000 square foot leased facility in Princeton, NJ. The agreement has a termination date of November 29, 2015. The Company plans to continue to rent necessary offices and laboratories to support its business.

## **10. SHAREHOLDERS' EQUITY**

#### *Registered Direct Offering*

On December 19, 2014, the Company priced a registered direct offering of 3,940,801 shares of its Common Stock at \$4.25 per share. The transaction closed on December 22, 2014, and the Company received gross proceeds of approximately \$16.7 million from the offering. After deducting offering expenses, the net proceeds from the offering were approximately \$15.8 million.

#### *Shares Issued to consultants*

During the three months ended January 31, 2015, 90,000 shares of Common Stock valued at \$698,100 were issued to consultants for investor relations services and 30,000 shares of Common Stock valued at \$93,900 were issued to consultants for research and development services. The common stock share values were based on the grant date fair values.

## 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 January 31, 2015 and October 31, 2014:

January 31, 2015	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$2.76 - \$21.25 from February 2015 through August 2017	\$-	\$	\$304,331	\$304,331
October 31, 2014	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$2.76 - \$21.25 from November 2014 through August 2017	\$-	\$	\$32,091	\$32,091



**Common stock warrant liability:**

	January 31, 2015 (Unaudited)
Beginning balance: October 31, 2014	\$ 32,091
Issuance of additional warrants due to anti-dilution provisions	8,169
Change in fair value	264,071
Balance at January 31, 2015	\$ 304,331

**12. SUBSEQUENT EVENTS**

*Incyte Collaboration Agreement*

On February 10, 2015, the Company entered into a Clinical Study Collaboration Agreement (the “Incyte Agreement”) with Incyte Corporation (“Incyte”) for the development and analysis of a combination therapy for the treatment of cervical cancer (the “Study”). Under the terms of the Incyte Agreement, Incyte will contribute INCB024360, a selective Inhibitor of IDO1, and the Company will contribute ADXS-HPV to be dosed in combination during the course of the Study, with Incyte acting as the sponsor of the Study and taking the lead role in its conduct. Costs for the Study are to be split equally between the parties.

*Registered Direct Offering*

On February 18, 2015, the Company priced a registered direct offering of 3,068,095 shares of its Common Stock at \$7.50 per share. The transaction closed on February 19, 2015, and the Company received gross proceeds of \$23.0 million from the offering. After deducting offering expenses, the net proceeds from the offering were approximately \$22.3 million.

*Recent Sales of Unregistered Securities*

On February 9, 2015, the Company issued 37,916 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On February 13, 2015, the Company issued 13,233 shares of Common Stock to a current Executive which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On February 26, 2015, the Company issued 4,104 shares of Common Stock to accredited investors in consideration for converting notes payable totaling \$33,333.

On February 27, 2015, the Company issued 1,434 shares of Common Stock to management, pursuant to their Employment Agreements.

On March 2, 2015, the Company issued 23,606 shares of Common Stock to accredited investors as payment for consulting services rendered.



## 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, 2014.

### 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.

### *ADXS-HPV Franchise*

ADXS-HPV is a *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV. It is currently under investigation in three HPV-associated cancers: cervical cancer, head and neck cancer, and anal 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. 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 that was 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) 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 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% (3/11) of patients had an 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) was observed. The addition of cisplatin chemotherapy to ADXS-HPV in this study did not significantly improve overall survival or objective tumor response ( $p=0.9981$ ). 109 patients received 254 doses of ADXS-HPV. ADXS-HPV 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 SAE. All observed adverse events either self-resolved or responded readily to symptomatic treatment. Based on the results from the completed randomized Phase 2 clinical study, Biocon Limited (“Biocon”), our co-development and commercialization partner for ADXS-HPV in India and key emerging markets, plans to seek regulatory approval of ADXS-HPV in India for the treatment of recurrent/refractory cervical cancer.

The GOG, under the sponsorship of the Cancer Therapy Evaluation Program (“CTEP”) of the National Cancer Institute (“NCI”), is independently conducting an open-label, single arm Phase 2 study of ADXS-HPV in persistent or recurrent cervical cancer (patients must have received no more than 1 prior chemotherapy regimen not including that administered as a component of primary treatment) in the U.S., GOG-0265. The first stage of enrollment in GOG-0265 has successfully been completed with 26/29 patients treated and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. As of January 2015, 27% (7/26) of patients were alive at one year (the predefined criteria for 12-month survival was  $\geq 20\%$ ); 6 additional patients were still alive, but with less than 12 months follow-up, i.e., these 6 patients are eligible to exceed 12-month survival. The adverse events observed in the first stage of the study have been consistent with those reported in other clinical studies with ADSX-HPV. The second stage of the study of approximately 37 patients is now enrolling and has been amended to allow patients to continue to receive repeat cycles of therapy until progression.

We have completed an End-of-Phase 2 (“EOP2”) meeting with the FDA. The purpose of the EOP2 meeting was to discuss ADXS-HPV’s preclinical data, Chemistry, Manufacturing and Controls (“CMC”) and clinical program prior to moving ADXS-HPV forward into a registrational trial in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We plan to submit our Phase 3 protocol for a Special Protocol Assessment (“SPA”). We are planning to initiate, in collaboration with the GOG Foundation, Inc., 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 registrational clinical trial in cervical cancer in the first half of 2015 to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

Subject to FDA concurrence under our request for a SPA, the registrational clinical trial that we plan to conduct will be a Phase 3 study of adjuvant ADXS-HPV following chemoradiation as primary treatment for high risk locally advanced cervical cancer compared to chemoradiation alone. This population has a high risk of recurrence and once recurred there is no cure. 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 have ceased.

We have entered into a clinical trial collaboration agreement with MedImmune, LLC (“MedImmune”), the global biologics research and development arm of AstraZeneca, and have received FDA clearance of an IND to conduct a Phase 1/2, open-label, multicenter, two part study to evaluate the safety and immunogenicity of our investigational *Lm-LLO* cancer immunotherapy, ADXS-HPV, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, as a combination treatment for patients with metastatic HPV-associated squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated Squamous Cell Carcinoma Head and Neck (“SCCHN”).

We have entered into a clinical trial collaboration agreement with Incyte where we plan to conduct a Phase 2, open-label, multicenter study to evaluate the safety and immunogenicity of ADXS-HPV as a monotherapy and in combination with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in patients with Stage I-IIa HPV-associated cervical cancer.

We are conducting a Phase 1/2 trial evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical cancer. This Phase 1/2 study is designed to evaluate the safety, efficacy and immunological effect of the highest-tolerated dose of ADXS-HPV administered in repeat cycles of treatment to patients with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen.

ADXS-HPV has received orphan drug designation for invasive Stage II-IVb cervical cancer.

## 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 the incidence of HPV-associated head and neck cancers increasing at an epidemic rate. Approximately 12,000 new cases will be diagnosed in the United States in 2015.

The safety and immunogenicity of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND at Mount Sinai, in patients with HPV-positive head and neck cancer. This clinical trial is the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer. As of February 2015, 10 patients have been enrolled into the study.

As stated above, we recently 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 MEDI4736 in combination with ADXS-HPV as a combination treatment for patients with metastatic HPV-associated squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. The FDA has cleared our IND application to commence this study in 2015.

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

## Anal Cancer

According to the American Cancer Society, most squamous cell anal cancers seem to be linked to infection by HPV, the same virus that causes cervical cancer. In fact, women with a history of cervical cancer (or pre-cancer) have an increased risk of anal cancer. While anal cancer is fairly rare and much less common than cancer of the colon or rectum, the incidence of anal cancer is increasing 2.2% a year according to the Surveillance, Epidemiology, and End Results ("SEER") database mainly attributed to HPV infections. About 7,270 new cases will be diagnosed in the United States in 2015.

The safety and efficacy of ADXS-HPV 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. As of February 2015, preliminary data from this study indicates all 10 patients who have completed the treatment regimen have experienced a six-month complete response rate, with no disease recurrence. Total planned enrollment for this study is 25 patients. In addition, we plan to initiate a Company sponsored single arm Phase 2 monotherapy study in patients with metastatic anal cancer in 2015.

ADXS-HPV has received orphan drug designation for HPV-associated anal cancer.

#### *ADXS-PSA Franchise*

##### Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. 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 220,800 new cases will be diagnosed in the United States in 2015.

ADXS-PSA is a *Lm*-LLO immunotherapy designed to target the PSA antigen associated with prostate cancer.

We have entered into a clinical trial collaboration and supply agreement with Merck & Co. ("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. The FDA has cleared our IND application and we plan to initiate this Phase 1/2 study in the first quarter of 2015.

#### *ADXS-HER2 Franchise*

##### HER2 Expressing Solid Tumors

ADXS-HER2 is a *Lm*-LLO immunotherapy designed to target the HER2 gene which is expressed in some solid tumor cancers such as human and canine osteosarcoma, breast, gastric and other cancers. The FDA has cleared our IND application and we plan to initiate a Phase 1b study in patients with metastatic HER2-expressing cancers in 2015. Thereafter, we intend to initiate a clinical development program with ADXS-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 preliminary data from a veterinarian clinical study in which pet dogs with naturally occurring osteosarcoma were treated with ADXS-HER2, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of osteosarcoma. In this veterinarian clinical study, pet dogs with naturally occurring osteosarcoma treated with ADXS-HER2 after the standard of care showed a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-HER2 (median survival with ADXS-HER2 not reached vs. 316 days in disease-matched control population,  $p < 0.00001$ ). Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

ADXS-HER2 has received orphan drug designation for osteosarcoma.

### Canine Osteosarcoma

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary is conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of canine osteosarcoma. The primary endpoint of the study is to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study are progression-free survival and overall survival. The preliminary findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3 \times 10^9$  CFU with no evidence of 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). Dr. Mason presented data at the 2014 ACVIM Forum which showed that 80% of the dogs treated (n=15) were still alive and median survival had not yet been reached; median survival in control dogs (n=13) was 316 days. Immunological analyses are also being conducted in this study to further evaluate the immune response to ADXS-HER2.



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. For dogs that cannot undergo amputation, palliative radiation and analgesics are frequently employed.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with 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. While the USDA has no specific obligation to respond within a prescribed timeframe, the companies expect a response from the USDA to the request for a product license in 2015. 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 investigation of two additional Advaxis constructs in animals.

#### *Lm-LLO Combination Franchise*

#### ADXS-HPV and MEDI4736

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune, where we plan to collaborate on a Phase 1/2, open-label, multicenter, two part study to evaluate safety and immunogenicity of our investigational *Lm-LLO* cancer immunotherapy, ADXS-HPV, in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736 for the treatment of patients with metastatic HPV-associated squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. The FDA has cleared our IND application and we plan to initiate this Phase 1/2 in 2015.

#### ADXS-HPV and INCB24360

As stated above, we have entered into a clinical trial collaboration agreement with Incyte where we plan to collaborate on a Phase 2, open-label, multicenter, preoperative window-study to evaluate the safety and immunogenicity of ADXS-HPV as a monotherapy and in combination with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in patients with Stage I-IIa HPV-associated cervical cancer. We plan to initiate this Phase 2 in 2015.



ADXS-PSA and MK-3475

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. The FDA has cleared our IND application and we plan to initiate this Phase 1/2 in the first quarter of 2015.

Lm-LLO and GRU

We have a non-clinical research agreement with GRU for a research collaboration to evaluate the *in vitro* effect of our Lm-LLO cancer immunotherapy technology in combination with other immunotherapies, including, but not limited to, anti-PD-1 immune checkpoint inhibitors.

*Corporate*

We continue to invest in the development of our platform technology and utilize our capital most efficiently. To ensure we appropriately support our development efforts, we entered into a master service agreement with inVentiv Clinical Health ("inVentiv"), a leading global CRO, for the clinical development of our immunotherapy products. InVentiv is a suitable partner, providing full CRO services to execute our clinical studies while offering competitive rates and, pending regulatory approval, we have the option to leverage inVentiv's significant commercialization capabilities.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JANUARY 31, 2015 AND 2014

### *Revenue*

We did not record any revenue for the three months ended January 31, 2015 and 2014.

### *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 \$3.6 million for the three months ended January 31, 2015, compared with \$1.6 million for the three months ended January 31, 2014, an increase of \$2.0 million. The increase was primarily a result of higher third-party costs, specifically related to the ADXS-HPV programs and ADXS-PSA Phase 1/2 trial start-up support.

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 \$3.2 million for the three months ended January 31, 2015, compared with \$4.4 million for the three months ended January 31, 2014, a decrease of \$1.2 million. The decrease was mainly due to greater stock based compensation costs in the prior period. The Company also incurred expense, in the prior period, related to the final settlement of an ongoing claim that was not incurred in the current period.

### *Interest Expense*

Interest expense was minimal for both the three months ended January 31, 2015, as well as the comparable three months ended January 31, 2014. The decrease in interest was due to the paydown of a significant amount of debt in the prior year.

*Other Income / (Expense)*

Other income was \$6,236 for the three months ended January 31, 2015, compared to other expense of \$8,572 for the three months ended January 31, 2014. Interest income earned for the three months ended January 31, 2015 and 2014 reflected interest income earned on the Company's savings account balance.

*Gain on Note Retirement*

For the three months ended January 31, 2014, we recorded non-cash income of \$6,243 primarily resulting from the settlement of an outstanding payable, at a discount, with shares of our Common Stock and cash.

*Changes in Fair Values*

For the three months ended January 31, 2015, the Company recorded non-cash expense from changes in the fair value of the warrant liability of \$264,071 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 \$9.85 at January 31, 2015.

For the three months ended January 31, 2014, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$131,948 due to a decrease in the fair value of liability warrants primarily resulting from a smaller range of share prices used in the calculation of the BSM volatility input.

*Income Tax Benefit*

The Company may be eligible, from time to time, to receive cash from the sale of our Net Operating Losses under the State of New Jersey NOL Transfer Program. In the three months ended January 31, 2014, the Company received a net cash amount of \$625,563 from the sale of our state NOLs and R&D tax credits for the periods ended October 31, 2010 and 2011.



## 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. 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 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. We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate our business plan. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through January 31, 2015, the Company has reported accumulated net losses of approximately \$94.0 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 three months ended January 31, 2015 was approximately \$2.6 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 & administrative spending. Total spending approximated \$7.0 million.

Cash used in operating activities for the three months ended January 31, 2014 was approximately \$5.0 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$0.6 million) primarily from spending associated with our clinical trial programs and general & administrative spending. Total spending approximated \$5.6 million, including one-time non-recurring costs associated with our October 2013 financing, certain compensation costs and the settlement of a legal claim.

Cash used in investing activities for the three months ended January 31, 2015 was approximately \$201,000 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash used in investing activities for the three months ended January 31, 2014 was approximately \$37,000 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities, for the three months ended January 31, 2015, was approximately \$15.8 million resulting from net proceeds of a registered direct offering of 3,940,801 shares of our Common Stock at a price per share of \$4.25.

Cash provided by financing activities for the three months ended January 31, 2014 was \$400,000, resulting from the sale of our Common Stock under a stock purchase agreement with GBP. During February 2014 the Company issued GBP 108,724 shares of our Common Stock under the stock purchase agreement.

Our limited 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 January 31, 2015 and October 31, 2014, we had an accumulated deficit of \$94,025,007 and \$86,991,137, respectively and shareholders' equity of \$31,400,317 and \$20,629,986, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately until first calendar quarter 2017. 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 its 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 over and above the amount raised during December 2014 and February 2015 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.

### **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 valuation, impairment of intangibles, dilution caused by anti-dilution provisions in the warrants and other agreements.

### *Stock Based Compensation*

We account for stock-based compensation using fair value recognition and record stock-based compensation as a charge to earnings net of the estimated impact of forfeited awards. As such, we recognize 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.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-valuation model for the remaining awards, which requires that we make certain assumptions regarding: (i) the expected volatility in the market price of our 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 we revise our assumptions and estimates, our stock-based compensation expense could change materially for future grants.

Stock-based compensation for employees, executives and directors is measured based on the fair value of the shares issued on the date of grant and is to be recognized over the requisite service period in both research and development expenses and general and administrative expenses on the statement of operations.



*Fair Value of Financial Instruments*

The carrying amounts of financial instruments, including cash, receivables, 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. The estimate of fair value of such financial instruments involves the exercise of significant judgment and the use of estimates by management.

*Derivative Financial instruments*

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The determination of fair value requires the use of judgment and estimates by management. For stock-based derivative financial instruments, we used the Black-Scholes valuation model which approximated the binomial lattice options pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date. The variables used in the model are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrant derivative liability.

## **New Accounting Pronouncements**

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. Amendments in this ASU create Topic 606, Revenue from Contracts with Customers, and supersede the revenue recognition requirements in Topic 605, Revenue Recognition, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts, and create new Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is the final version of Proposed ASU 2011-230—Revenue Recognition (Topic 605) and Proposed ASU 2011-250—Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in this ASU are effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014-09 on the consolidated 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.

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 consolidated financial statements.

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

**Not Applicable**

## **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 Rule 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 January 31, 2015, 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 10: 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, 2014.

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

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(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 November 13, 2014, the Company issued 40,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On November 28, 2014 the Company issued 3,868 shares of Common Stock to its Executives, pursuant to their Employment Agreements.

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

On December 5, 2014, the Company issued 30,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On December 31, 2014, the Company issued 1,504 shares of Common Stock to its Executives, pursuant to their Employment Agreements.

On January 15, 2015, the Company issued 50,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On January 30, 2015, the Company issued 1,681 shares of Common Stock to its Executives, pursuant to their Employment Agreements.

On February 9, 2015, the Company issued 37,916 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On February 13, 2015, the Company issued 13,233 shares of Common Stock to a current Executive which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On February 26, 2015, the Company issued 4,104 shares of Common Stock to accredited investors in consideration for converting notes payable totaling \$33,333.

On February 27, 2015, the Company issued 1,434 shares of Common Stock to management, pursuant to their Employment Agreements.

On March 2, 2015, the Company issued 23,606 shares of Common Stock to accredited investors as payment for consulting services rendered.

### **ITEM 5. OTHER INFORMATION**

None



**ITEM 6. EXHIBITS.**

- 3.1 Amended and Restated Certificate of Incorporation. Incorporated by reference to Annex C to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.
- 3.2 Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009.
- 3.3 Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.
- 3.4 Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on August 16, 2012. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on August 17, 2012.
- 3.5 Certificate of Amendment of the Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 11, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
- 3.6 Certificate of Amendment of the Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 12, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
- 3.7 Amended and Restated Bylaws. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed with the SEC on September 13, 2006.
- 10.1 Clinical Study Collaboration Agreement between Advaxis, Inc. and Incyte Corporation, dated February 10, 2015. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on February 12, 2015.
- 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

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

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

\*\* Furnished herewith

13



## 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: March 13, 2015 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

