

Advaxis, Inc.  
Form 10-Q  
February 26, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended January 31, 2016

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

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

Commission file number 000-28489

**ADVAXIS, INC.**



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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 February 24, 2016 was 34,101,368.

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All other items called for by the instructions to Form 10-Q have been omitted because the items are not applicable or the relevant information is not material.

*Cautionary Note Regarding Forward Looking Statements*

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

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

**PART I - FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****ADVAXIS, INC.****CONDENSED BALANCE SHEETS****(unaudited)**

	January 31, 2016	October 31, 2015
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$58,670,478	\$66,561,683
Investments – Held-to-Maturity	48,130,343	45,594,495
Interest Receivable	152,307	145,299
Prepaid Expenses	206,766	338,841
Income Tax Receivable	-	1,609,349
Deferred Expenses - current	180,506	749,790
Other Current Assets	153,083	15,116
Total Current Assets	107,493,483	115,014,573
Property and Equipment (net of accumulated depreciation)	1,486,407	1,087,244
Intangible Assets (net of accumulated amortization)	3,467,478	3,355,033
Other Assets	301,218	148,843
<b>TOTAL ASSETS</b>	<b>\$112,748,586</b>	<b>\$119,605,693</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$843,534	\$696,117
Accrued Expenses	6,643,934	3,191,941
Short Term Convertible Notes and Fair Value of Embedded Derivative	29,549	29,549
Total Current Liabilities	7,517,017	3,917,607
Deferred Rent	11,182	-
Common Stock Warrant Liability	39,929	89,211
Total Liabilities	7,568,128	4,006,818
Commitments and Contingencies		
Shareholders' Equity:		

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Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at January 31, 2016 and October 31, 2015.	-	-
Liquidation preference of \$0 at January 31, 2016 and October 31, 2015.		
Common Stock - \$0.001 par value; 45,000,000 shares authorized, 34,012,518 shares issued and 33,931,918 shares outstanding at January 31, 2016 and 33,591,882 shares issued and 33,574,963 shares outstanding at October 31, 2015.	34,013	33,592
Additional Paid-In Capital	259,604,332	249,807,303
Treasury Stock, at cost, 80,600 shares at January 31, 2016 and 16,919 shares at October 31, 2015.	(558,693 )	(187,761 )
Accumulated Deficit	(153,899,194)	(134,054,259)
Total Shareholders' Equity	105,180,458	115,598,875
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 112,748,586</b>	<b>\$ 119,605,693</b>

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

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

	Three Months Ended January 31,	
	2016	2015
Revenue	\$250,000	\$-
Operating Expenses		
Research and Development Expenses	13,064,954	3,628,239
General and Administrative Expenses	7,136,823	3,147,796
Total Operating Expenses	20,201,777	6,776,035
Loss from Operations	(19,951,777)	(6,776,035 )
Other Income (Expense):		
Interest Income	71,800	6,236
Net Changes in Fair Value of Derivative Liabilities	49,282	(264,071 )
Other Income (Expense)	(4 )	-
Loss before benefit for income taxes	(19,830,699)	(7,033,870 )
Income Tax Expense	14,236	-
Net Loss	\$(19,844,935)	\$(7,033,870 )
Net Loss per share, basic and diluted	\$(0.59 )	\$(0.33 )
Weighted Average Number of Shares Outstanding, Basic and Diluted	33,684,715	21,551,169

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



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

	Three Months Ended January 31,	
	2016	2015
<b>OPERATING ACTIVITIES</b>		
Net Loss	\$(19,844,935)	\$(7,033,870)
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Stock Compensation	9,529,008	2,185,669
(Gain) Loss on change in fair value of derivative liabilities	(49,282 )	264,071
Warrant expense	-	8,169
Employee Stock Purchase Plan	9,673	1,700
Depreciation expense	46,034	6,902
Amortization expense of intangibles	57,946	48,303
Amortization of premium on held-to-maturity investments	82,491	-
Change in operating assets and liabilities:		
Interest receivable	(7,008 )	-
Prepaid expenses	132,075	131,941
Income tax receivable	1,609,349	1,731,317
Other current assets	(135,823 )	-
Deferred expenses	569,284	82,257
Other assets	(152,375 )	-
Accounts payable and accrued expenses	3,250,088	129,100
Deferred rent	11,182	-
Net cash used in operating activities	(4,892,293 )	(2,444,441 )
<b>INVESTING ACTIVITIES</b>		
Purchases of held-to-maturity investments	(5,068,339 )	-
Proceeds from maturities and redemptions on held-to-maturity investments	2,450,000	-
Purchase of property and equipment	(445,197 )	-
Cost of intangible assets	(170,391 )	(201,287 )
Net cash used in investing activities	(3,233,927 )	(201,287 )
<b>FINANCING ACTIVITIES</b>		
Proceeds from exercise of warrants	614,368	-
Net proceeds on issuance of Common Stock	-	15,772,331
Taxes paid related to net share settlement of equity awards	(17,709 )	(155,499 )
Treasury stock purchased to pay employee withholdings on equity awards	(698,398 )	-
Treasury stock sold to pay for employee tax withholdings on equity awards	336,754	-
Net cash provided by financing activities	235,015	15,616,832
Net (decrease) increase in cash and cash equivalents	(7,891,205 )	12,971,104
Cash and cash equivalents at beginning of period	66,561,683	17,606,860

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Cash and cash equivalents at end of period	\$58,670,478	\$30,577,964
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The accompanying notes are an integral part of these condensed financial statements.

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**Supplemental Disclosures of Cash Flow Information**

	Three months ended January 31, 2016      2015	
Cash paid for taxes	\$50,000	\$ -

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

	Three months ended January 31, 2016      2015	
Accrued expenses from consultants settled with Common Stock	\$55,000	\$ -
Sale of treasury shares pending settlement	\$2,144	\$ -

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

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**ADVAXIS, INC.**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**1. NATURE OF OPERATIONS**

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

Axalimogene filolisbac (ADX5-HPV) is our lead *Lm*-LLO immunotherapy product candidate for the treatment of Human Papilloma Virus (“HPV”) associated cancers. The Company completed a randomized Phase 2 study in 110 patients with recurrent cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”), now part of NRG Oncology, is conducting a cooperative group sponsored Phase 2 open-label clinical study of axalimogene filolisbac in patients with persistent or recurrent cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed its first stage and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient recruitment. The Company plans to advance this immunotherapy into a registrational clinical trial for the treatment of women with high-risk locally advanced cervical cancer.

Axalimogene filolisbac has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and has received European Medicines Agency (“EMA”) orphan drug designation for anal cancer. It is being evaluated in Company-sponsored trials executed under an Investigational New Drug (“IND”) which include the following: i) a Phase 1/2 clinical trial alone and in combination with MedImmune, LLC’s (“MedImmune”) investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic cervical cancer and HPV-associated head and neck cancer; ii) a Phase 1/2 study evaluating higher doses and repeat cycles of axalimogene filolisbac in patients with recurrent cervical cancer; iii) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer; and iv) a Phase 2 study in collaboration with and funded by Global BioPharma Inc. (“GBP”), under a development and commercialization license agreement applicable to Asia, of axalimogene filolisbac in HPV-associated non-small cell lung cancer. In addition to the Company-sponsored trials, axalimogene filolisbac is also being evaluated in three ongoing investigator-initiated clinical trials as follows: locally advanced cervical cancer (GOG-0265), head and neck cancer (Mount Sinai), and anal cancer (Brown University).

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

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

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

The Company has focused its development efforts on understanding its platform technology and establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, with clinical trials currently targeting HPV-associated cancer (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2-expressing cancers. Although no immunotherapies have been commercialized to date, the Company continues to invest in research and development to advance the technology and make it available to patients with many different types of cancer. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting and expanding its clinical development program. In addition to its existing single antigen vectors that target one tumor associated antigen, the Company is actively engaged in the development of new constructs that will address multiple targets that are common to tumor types, as well as mutation-associated neo-epitopes that are specific to an individual patient's tumor. Lastly, the Company is developing certain internal capabilities to produce supplies for its neoepitope and its other programs.

### *Liquidity and Financial Condition*

The Company's products are being developed and have not generated significant revenues. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. During fiscal 2015, the Company raised an aggregate of \$119.7 million in equity offerings and has approximately \$106.8 million in cash, cash equivalents and investments as of January 31, 2016.

The Company believes its current cash position is sufficient to fund its business plan approximately through year end 2017. The estimate is based on assumptions that may prove to be wrong, and the Company could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of its current product candidates.

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

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION**

### *Basis of Presentation - Unaudited Interim Financial Information*

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information, and in accordance with the rules and regulations of the SEC with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, necessary to represent a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2015 and notes thereto contained in the Company’s annual report on Form 10-K for the year ended October 31, 2015, as filed with the SEC on January 8, 2016.

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

#### *Revenue Recognition*

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

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

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

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

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*Estimates*

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

*Reclassifications*

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

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of January 31, 2016 and October 31, 2015, the Company had approximately \$55.5 million and \$62.8 million in cash equivalents.

*Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$57.5 million is subject to credit risk at January 31, 2016. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

*Fair Value of Financial Instruments*

The carrying amounts of financial instruments, including cash, 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,	
	2016	2015
Warrants	3,110,575	4,082,248
Stock Options	3,357,074	477,968
Convertible Debt (using the if-converted method)	1,576	3,354
Total	6,469,225	4,563,570

*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*

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

### **3. INVESTMENTS**

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

	January 31, 2016			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 12,735,191	\$ -	\$ -	\$ 12,735,191
Domestic Governmental Agency Loans	27,879,192	60	15,637	27,863,615
U.S Treasury Notes	7,515,960	-	4,555	7,511,405
Total short-term investment securities	\$ 48,130,343	\$ 60	\$ 20,192	\$ 48,110,211

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

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

#### 4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	January 31, 2016	October 31, 2015
Leasehold Improvements	\$ 267,726	\$ 237,209
Laboratory Equipment	717,255	532,249
Furniture and Fixtures	351,283	331,500
Computer Equipment	64,007	48,745
Construction Progress	275,167	80,538
Total Property and Equipment	1,675,438	1,230,241
Accumulated Depreciation and Amortization	(189,031 )	(142,997 )
Net Property and Equipment	\$ 1,486,407	\$ 1,087,244

Depreciation expense for the three months ended January 31, 2016 and 2015 was \$46,034 and \$6,902, respectively.

**5. 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, 2016	October 31, 2015
License	\$651,992	\$651,992
Patents	4,068,884	3,898,493
Total intangibles	4,720,876	4,550,485
Accumulated Amortization	(1,253,398)	(1,195,452)
Intangible Assets	\$3,467,478	\$3,355,033

The expirations of the existing patents range from 2016 to 2030 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, 2016 or 2015. Amortization expense for licensed technology and capitalized patent costs is included in research and development expenses and aggregated \$57,946 and \$48,303 for the three months ended January 31, 2016 and 2015, respectively.

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

Year ended October 31,

2016 (Remaining)	\$174,000
2017	232,000
2018	232,000
2019	232,000
2020	232,000

**6. ACCRUED EXPENSES:**

The following table represents the major components of accrued expenses:

	January 31, 2016	October 31, 2015
Salaries and Other Compensation	\$2,762,631	\$1,698,371
Vendors	2,497,627	1,000,579
Professional Fees	758,585	272,058
Withholding Taxes Payable	625,091	220,933
	\$6,643,934	\$3,191,941

## 7. DERIVATIVE INSTRUMENTS

### *Warrants*

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

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

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

#### *Warrant Liability*

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

At January 31, 2016 and October 31, 2015, the fair value of the warrant liability was \$39,929 and \$89,211, respectively. For the three months ended January 31, 2016 and 2015, the Company reported a gain of approximately \$49,000 and a loss of approximately \$264,000, respectively, due to changes in the fair value of the warrant liability. In determining the fair value of the warrant liability, at January 31, 2016 and October 31, 2015, the Company used the following inputs in its BSM:

	January 31, 2016	October 31, 2015
Exercise Price	\$10.63-18.75	\$10.63-18.75
Stock Price	\$6.82	\$11.09
Expected term	1.30-1.50 years	1.52-1.76 years
Expected Volatility	102.59%-106.19%	93.87%-95.00 %
Risk Free Interest Rate	.047%-.076 %	.075 %

#### *Exercise of Warrants*

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

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

As of January 31, 2016, the aggregate intrinsic value of outstanding warrants was approximately \$5,631,000.

## 8. SHARE BASED COMPENSATION

### *Employment Agreements*

Management voluntarily purchases restricted stock directly from the Company at market price. The respective stock purchases occur on the last trading day of each month. This voluntary election is outlined in each of Daniel J. O'Connor, Chief Executive Officer and President, Gregory T. Mayes, Executive Vice President, Chief Operating Officer 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 Annual Amount to be Purchased	For the Three Months Ended January 31, 2016	
		Gross Purchase \$ # of shares	Net Purchase \$ # of shares
Daniel J. O'Connor	\$ 116,410	\$26,653 2,950	\$17,360 1,832
Gregory T. Mayes	\$ 27,794	\$7,033 767	\$5,294 573
Robert G. Petit	\$ 28,704	\$7,100 777	\$5,326 557
Sara M. Bonstein	\$ 25,420	\$6,051 666	\$4,585 500

For the three months ended January 31, 2016, the Company recorded stock compensation expense of \$64,332 in the statement of operations for the portion of management salaries voluntarily paid in stock representing 7,060 shares of its Common Stock (4,947 shares on a net basis after employee payroll taxes). For the three months ended January 31, 2015, the Company recorded a similar stock compensation expense of \$46,153 in 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 164,909 shares of Common Stock out of his personal funds at the then market price for an aggregate consideration of \$689,004. These purchases consisted of the conversion of amounts due to Mr. O'Connor under a promissory note given by Mr. O'Connor to the Company in 2012 of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$186,555 for 34,752 shares (21,489 on a net basis after employee payroll taxes), 2013 and 2014 cash bonuses voluntarily requested to receive in equity of \$214,359 for 62,064 shares (57,990 on a net basis after employee payroll taxes), fiscal 2014 voluntary request to purchase stock directly from the Company at market price purchases of \$68,750 for 21,687 shares (15,950 on a net basis after employee payroll taxes), fiscal 2015 voluntary request to purchase stock directly from the Company at market price purchases of \$88,840 for 8,482 shares (7,556 on a net basis after employee payroll taxes), and purchases of the Company's Common Stock in the October 2013 and March 2014 public offerings of 13,500 shares for \$54,000 and 3,333 shares for \$10,000.

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

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

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

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2015:	1,069,335	\$ 10.89
Granted	214,547	\$ 8.79
Vested	(256,126 )	\$ 8.01
Cancelled	(52,500 )	\$ 22.56
Balance at January 31, 2016	975,256	\$ 10.54

As of January 31, 2016, there was approximately \$8,370,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.23 years.

As of January 31, 2016, the aggregate intrinsic value of non-vested RSUs was approximately \$767,000.

*Employee Stock Awards*

During the three months ended January 31, 2016, 238,129 shares of Common Stock were issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards. Total stock compensation expense associated with these awards was \$1,857,076.

During the three months ended January 31, 2015, 34,095 shares of Common Stock (27,566 shares on a net basis after employee taxes) were issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards. Total stock compensation expense associated with these awards was \$133,699.

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

*Director Stock Awards*

During the three months ended January 31, 2016, 31,767 shares of Common Stock were issued to the Directors for compensation related to board and committee membership. Total stock compensation expense to the Directors was \$311,205.

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. Total stock compensation expense to the Directors was \$606,039.

*Stock Options*

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

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2015:	1,981,939	\$ 13.78
Granted	1,385,000	\$ 12.81
Exercised	-	\$ -
Expired	(9,865 )	\$ 27.21
Outstanding at January 31, 2016	3,357,074	\$ 13.34
Vested and Exercisable at January 31, 2016	703,878	\$ 13.93

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended January 31, 2016, was \$6,671,986. For the three months ended January 31, 2015, compensation cost related to the Company's outstanding stock options was \$121,421.

During the three months ended January 31, 2016, 1,385,000 options were granted with a total grant date fair value of \$14,837,970. During the three months ended January 31, 2015, 20,000 options were granted with a total grant date fair value of \$57,600.

As of January 31, 2016, there was approximately \$27,884,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.31 years.

As of January, 2016, the aggregate intrinsic value of vested and exercisable options was approximately \$44,240.

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

Three Months Ended	
January 31, 2016	January 31, 2015

Expected Term	5.51-6.51 years	10 years
Expected Volatility	109.23%-115.25 %	154.54 %
Expected Dividends	0	0 %
Risk Free Interest Rate	1.65-2.00 %	2.27 %

*Shares Issued to Consultants*

During the three months ended January 31, 2016, 23,124 shares of Common Stock valued at \$275,087 were issued to consultants for services, of which \$55,000 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$302,300 for shares earned pursuant to consulting agreements but not delivered. The common stock share values were based on the dates the shares vested.

During the three months ended January 31, 2015, 120,000 shares of Common Stock valued at \$792,000 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

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

	Three Months Ended	
	January 31,	
	2016	2015
Research and development	\$5,106,640	\$313,919
General and administrative	4,422,368	1,871,750
Total	\$9,529,008	\$2,185,669

## 9. COMMITMENTS AND CONTINGENCIES:

### *Legal Proceedings*

#### *Knoll*

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

#### *Larkin and Bono*

On July 27, 2015, a derivative complaint was filed by a purported Company shareholder in the Court of Chancery of the State of Delaware against certain of the Company’s officers and directors styled Timothy Larkin v. O’Connor, et al., Case No. 11338-VCB (Del. Ch. July 27, 2015). The action was brought derivatively on behalf of the Company, which is also named as a nominal defendant. On August 20, 2015, a related derivative complaint was filed by a purported Company shareholder in the United States District Court for the District of New Jersey against the same defendants styled David Bono v. O’Connor, et al., Case No. 3:15-CV-006326-FLW-DEA (D.N.J. Aug. 20, 2015). Both complaints are based on general allegations related to certain stock options granted to the individual defendants and generally allege counts for breaches of fiduciary duty and unjust enrichment. The Bono complaint alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. Both complaints seek damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief. At this early stage of each proceeding, the Company does not express any opinion as to the likely outcome, but the Company intends to defend each action vigorously.

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

*Operating Leases*

The Company's corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. On February 1, 2016, the Company entered into an amendment to its office lease. The amendment increased the leased space by approximately 25,000 square feet to a total of approximately 44,000 square feet. The additional space will allow the Company to expand manufacturing, testing, and product development capabilities, accelerate execution of pipeline related projects, strengthen the supply chain, and continue to ensure reliable and cost competitive supply of product. The lease term was extended by three years and is now scheduled to expire on November 30, 2025. The Company paid an additional security deposit of \$100,061. The amended lease requires an annual rent of approximately \$893,000 with annual increases in increments between 2% and 11% throughout the remainder of the lease. The lease amendment contains a six month rent abatement period starting in February 2016, and a reduced lease rate for four months starting in August 2016. Rent expense will be recognized on a straight line basis over the term of the lease. The Company plans to continue to rent necessary offices and laboratories to support its business.

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

Year ended October 31,

2016 (Remaining)	\$360,481
2017	893,452
2018	954,868
2019	1,014,888
2020	1,129,925
Thereafter	6,474,860

**10. 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, 2016 and October 31, 2015:

	Level 1	Level 2	Level 3	Total
January 31, 2016				
Common stock warrant liability, warrants exercisable at \$10.63 - \$18.75 from February 2016 through August 2017	\$ -	\$ -	\$39,929	\$39,929
October 31, 2015				
Common stock warrant liability, warrants exercisable at \$10.63 - \$18.75 from November 2015 through August 2017	\$ -	\$ -	\$89,211	\$89,211

**Common stock warrant liability:**

	January 31, 2016 (Unaudited)
Beginning balance: October 31, 2015	\$ 89,211
Change in fair value	(49,282 )
Balance at January 31, 2016	\$ 39,929

## 11. SUBSEQUENT EVENTS

On February 2, 2016, the Company issued 4,687 shares of Common Stock to the Board of Directors, which represents a portion of their quarterly retainer fees.

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

On February 4, 2016, the Company issued 9,150 shares of Common Stock to employees, which represents 2015 bonus compensation for calendar 2015 that was previously accrued.

On February 16, 2016, the Company issued 12,616 shares of Common Stock to accredited investors as payment for consulting services.

From February 1, 2016 to the date the financial statements were issued, the Company issued 62,397 shares of Common Stock, which represents the initial vesting periods and the anniversary vesting periods of inducement grants to employees.



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

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

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

### Overview

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

#### *Axalimogene filolissbac (ADXS-HPV) Franchise*

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

#### Cervical Cancer

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

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

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

We have completed an End-of-Phase 2 (“EOP2”) meeting with the FDA. The purpose of the EOP2 meeting was to discuss axalimogene filolisbac preclinical data, Chemistry, Manufacturing and Controls (“CMC”), and clinical program, prior to moving axalimogene filolisbac forward into a registrational trial in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We have submitted our Phase 3 protocol for a Special Protocol Assessment (“SPA”) request to the FDA. The SPA request included specific questions from Advaxis to facilitate a meaningful dialogue with the FDA on the proposed study design. We have received back from FDA initial comments and considerations for incorporation into our study design. Additional rounds of review and/or a formal meeting are anticipated, both of which can extend the review period and be beneficial in reaching agreement with the FDA on design elements. Based on the FDA’s feedback, we may reach final agreement with FDA or may decide to incorporate the advice into the design of the Phase 3 clinical study without undergoing additional rounds of review. FDA’s assessment of the SPA request, and all related feedback, will be very valuable in the development of axalimogene filolisbac. Contingent upon the outcome of the forgoing, we plan to initiate, in collaboration with the GOG/NRG 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 2016 to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

The planned registrational clinical trial will be a Phase 3 study of adjuvant axalimogene filolisbac, following primary treatment with chemoradiation, in patients with high-risk locally advanced cervical cancer compared to placebo alone. This population has a high recurrence rate and, once the disease has recurred, there are currently no available treatments. This study will evaluate both the time it takes for the cancer to recur as well as the overall survival. Our goal is to develop a treatment to prevent or reduce the risk of recurrence of cervical cancer after primary treatment interventions.

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

We are conducting a Phase 1/2 trial evaluating higher doses and repeat cycles of axalimogene filolisbac 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 axalimogene filolisbac administered in repeat cycles to patients with cervical cancer whose disease has recurred after receiving one prior systemic dose cytotoxic treatment regimen. At present, a total of 27 cycles of therapy have been delivered at the  $5 \times 10^9$  CFU dose level and 5 cycles at the high dose of  $1 \times 10^{10}$  CFU, which will now constitute the randomized Phase 2 dose. The AEs observed at the high dose are consistent with previous clinical experience with axalimogene filolisbac.

We have entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and immunogenicity of our investigational *Lm*-LLO cancer immunotherapy, axalimogene filolisbac, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated Squamous Cell Carcinoma of the Head and Neck (“SCCHN”). For the axalimogene filolisbac and durvalumab dose escalation portion of the study, Cohort 1 has been completed allowing for advancement to the next dose level. Once the dose escalation has been completed, the recommended combination dose will be advanced further into the study.

The GOG (now a member of NRG Oncology), under the sponsorship of the Cancer Therapy Evaluation Program (“CTEP”) of the National Cancer Institute (“NCI”), is independently conducting GOG-0265, an open-label, single arm

Phase 2 study of axalimogene filolisbac in persistent or recurrent cervical cancer (patients must have received at least 1 prior chemotherapy regimen for the treatment of their recurrent/metastatic disease, not including that administered as a component of primary treatment) at 21 clinical sites in the U.S. The first stage of enrollment in GOG-0265 has successfully been completed with 26 patients treated and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Clinical data from the first stage of GOG-0265 was presented at the American Gynecological & Obstetrical Society (“AGOS”) annual meeting on September 17, 2015. Overall survival at 12 months was 38.5% (10/26) (the predefined criteria for 12-month survival was  $\geq 20\%$ ), and, among patients who had received the full treatment regimen of 3 doses of axalimogene filolisbac, the 12-month survival rate was 55.6% (10/18). The adverse events observed in the first stage of the study have been consistent with those reported in other clinical studies with axalimogene filolisbac. It was well-tolerated, with Grade 1-2 fatigue, chills, and fever the most commonly reported Adverse Events (“AE”); six patients experienced a treatment-related Grade 3 or Grade 4 AE, which was considered possibly-related to axalimogene filolisbac. The second stage of the study will include approximately 37 additional patients; it has been amended to permit only one prior chemotherapy regimen for the treatment of recurrent/metastatic disease and allows patients to continue to receive repeat cycles of therapy until disease progression.

In February, 2015, we entered into a clinical trial collaboration agreement with Incyte Corporation (“Incyte”) where we planned to conduct a Phase 2, open-label, multicenter study to evaluate the safety and immunogenicity of axalimogene filolisbac as a monotherapy and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in low risk patients with Stage I-IIa cervical cancer who are expected to be effectively treated by surgery. Prior to starting this study, we reevaluated the relative benefit of the study in this patient population and determined to focus our resources on active malignancies and/or on patients at high risk for recurrence. Consequently, through collaborative discussion with Incyte, we made the decision to terminate the clinical trial before it was initiated and began enrolling patients.

Axalimogene filolisbac has received FDA orphan drug designation for invasive Stage II-IV cervical cancer. (Axalimogene filolisbac was not granted orphan drug designation for cervical cancer in the EMA).

### Head and Neck Cancer

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

The safety and immunogenicity of axalimogene filolisbac is being evaluated in a Phase 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 axalimogene filolisbac in patients when they are initially diagnosed with HPV-associated head and neck cancer.

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

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

#### Anal Cancer

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

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

We plan to enroll patients in a Company sponsored Phase 2 study in patients with persistent/recurrent, loco-regional or metastatic squamous cell carcinoma of the anorectal canal in 2016.

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

## Lung Cancer

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

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

## *ADX-PSA Franchise*

## Prostate Cancer

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

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

We have entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADX-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. For ADX-PSA monotherapy dose escalation portion of the study, Cohort 1 and Cohort 2 have been completed allowing for advancement into Cohort 3, the third and final dose level. Once the dose escalation has been completed, the recommended dose will be advanced into the combination portion of the study.

## *ADX-HER2 Franchise*

### HER2 Expressing Solid Tumors

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

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

ADX-HER2 has received FDA and EMA orphan drug designation for osteosarcoma.

## Canine Osteosarcoma

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

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary Medicine is conducting studies in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of naturally occurring canine osteosarcoma. In the initial study, the primary endpoint was to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study were progression-free survival and overall survival. The findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3 \times 10^9$  CFU with no evidence of significant cardiac, hematological, or other systemic toxicities. The study determined that ADXS-HER2 is able to delay or prevent metastatic disease and significantly prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). Dr. Mason presented data at the 2014 American College of Veterinary Internal Medicine (“ACVIM”) Forum which showed that 80% of the dogs treated (n=15) were still alive and median survival had not yet been reached. A second study is currently being conducted by Dr. Mason and data was presented at the 2015 ACVIM Forum obtained from pet dogs (n=12) with primary osteosarcoma unsuitable for amputation. Repeat doses of ADXS-HER2 administered after palliative radiation were well tolerated with no systemic or cardiac toxicity.

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. Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2016. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals. Aratana is further responsible for the conduct of clinical research with ADXS-Survivin in canine/feline lymphoma, as well as pending investigations of two additional Advaxis constructs in animals



*ADX-NEO Franchise (preclinical)*

In February, 2016, we had a productive pre-IND meeting with the FDA. Following this meeting, we intend to file an IND application for ADXS-NEO and to initiate Company-sponsored studies, as well as external collaborations.

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

*ADX-TNBC Franchise (preclinical)*

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

*Lm-LLO Combination Franchise*

Axalimogene filolisbac and Durvalumab

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune to conduct a Phase 1/2, open-label, multicenter, two part study to evaluate safety and immunogenicity of our investigational *Lm-LLO* cancer immunotherapy, axalimogene filolisbac, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736) for the treatment of patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. Preliminary patient responses have

been observed in Cohort 1. For the axalimogene filolisbac and durvalumab (MEDI4736) dose escalation portion of the study, Cohort 1 has been completed allowing for advancement to the next dose level. Once the dose escalation has been completed, the recommended combination doses will be advanced further into the study.

#### Axalimogene filolisbac and Epacadostat

As stated above, in February, 2015, we entered into a clinical trial collaboration agreement with Incyte Corporation (“Incyte”) where we planned to conduct a Phase 2, open-label, multicenter study to evaluate the safety and immunogenicity of axalimogene filolisbac as a monotherapy and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in low risk patients with Stage I-IIa cervical cancer who are expected to be effectively treated by surgery. Prior to starting this study, we reevaluated the relative benefit of the study in this patient population and determined to focus our resources on active malignancies and/or on patients at high risk for recurrence. Consequently, through collaborative discussion with Incyte, we made the decision to terminate the clinical trial before it was initiated and began enrolling patients.

#### ADX-PSA and KEYTRUDA® (pembrolizumab)

As stated above, we have entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, Cohort 1 and Cohort 2 have been completed allowing for advancement to next dose level. Once the dose escalation has been completed, the recommended dose will be advanced into the combination portion of the study.

#### Lm-LLO Immunotherapy and Sorrento

In May, 2015, we entered into a non-exclusive research and clinical trial collaboration agreement with Sorrento Therapeutics, Inc. (“Sorrento”) to evaluate our Lm-LLO cancer immunotherapy technology in combination with Sorrento’s fully human antibodies, which may include GITR, OX40, LAG-3 and/or TIM-3, in two clinical trials. Prior to any research activities occurring under this agreement, we have reevaluated our participation and mutually determined to end the collaboration and focus our resources on other opportunities and priorities.

#### Lm-LLO Immunotherapy (preclinical)

We have various preclinical collaborations with academic and other centers of excellence.



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

### *Revenue*

During the quarter ended January 31, 2016, the Company recorded revenue of \$250,000 due to the receipt of an annual exclusive license fee from GBP for the development and commercialization of axalimogene filolisbac.

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

### *Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was approximately \$13.1 million for the three months ended January 31, 2016, compared with approximately \$3.6 million for the three months ended January 31, 2015, an increase of approximately \$9.5 million. The increase was a result of higher third-party costs, specifically related to axalimogene filolisbac support in manufacturing and clinical trial expenses, for the Anal, Head & Neck, High Dose, Prostate and Cervical Cancer programs, as well as ADXS-PSA Phase 1/2 trial support. Stock based compensation for existing and past employees increased by approximately \$4.8 million due to increases in the grant date fair value of stock awards, the number of awards and headcount.

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

### *General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and

administrative expenses were approximately \$7.1 million for the three months ended January 31, 2016, compared with approximately \$3.1 million for the three months ended January 31, 2015, an increase of approximately \$4.0 million. There was an increase of approximately \$3.5 million in compensation related expense, including a non-cash increase in stock based compensation costs of approximately \$2.6 million attributable to increases in the grant date fair value of stock awards, the number of awards and headcount. In addition, legal costs increased by approximately \$0.5 million for consultation on a variety of corporate matters.

#### *Interest Income*

Interest income was \$71,800 for the three months ended January 31, 2016, compared with \$6,236 for the three months ended January 31, 2015. Interest income earned for the three months ended January 31, 2016 reflected interest income earned on the Company's held-to-maturity investments and savings account balance. Interest income earned for the three months ended January 31, 2015 reflected interest income earned on the Company's savings account balance.

#### *Changes in Fair Values*

For the three months ended January 31, 2016, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$49,282 due to a decrease in the fair value of liability warrants primarily resulting from a decrease in our share price from \$11.09 at October 31, 2015 to \$6.82 at January 31, 2016.

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 large range of share prices used in the calculation of 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.

#### *Income Tax Expense*

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

## Liquidity and Capital Resources

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through January 2016, we raised approximately \$166.5 million in gross proceeds from various public and private offerings of our common stock. We have not yet commercialized any drug, and we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approvals for our drug, successfully complete any post-approval regulatory obligations, successfully compete with other available treatment options in the marketplace, overcome any clinical holds that the FDA may impose and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate revenues from our drug candidates. We believe our current cash position is sufficient to fund our business plan approximately through December 2017. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through January 31, 2016, the Company has reported accumulated net losses of approximately \$153.9 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, 2016 was approximately \$4.9 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$1.6 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Cash used in operating activities for the three months ended January 31, 2015 was approximately \$2.4 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.

Cash used in investing activities for the three months ended January 31, 2016 was approximately \$3.2 million resulting from investments in held-to-maturity investments, purchases of property and equipment, 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, 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 provided by financing activities for the three months ended January 31, 2016 was approximately \$235,000, resulting from approximately \$614,000 in proceeds received on option and warrant exercises. This was partially offset by approximately \$379,000 in taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities, for the three months ended January 31, 2015, was approximately \$15.6 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. This was partially offset by approximately \$155,000 in taxes paid related to the net share settlement of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of January 31, 2016 and October 31, 2015, we had an accumulated deficit of \$153,899,194 and \$134,054,259, respectively and shareholders' equity of \$105,180,458 and \$115,598,875, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately through year end 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 our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of our current product candidates.

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

**Tabular Disclosure of Contractual Obligations**

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>
Operating Leases	\$10,828,474	\$579,045	\$1,879,726	\$2,192,125	\$6,177,578
Employment Agreements Subject to Annual Renewal	\$1,009,967	\$1,009,967			

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Estimates**

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements.

Management considers an accounting estimate to be critical if:

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

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

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, warrant liability valuation and impairment of intangibles.

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



## **New Accounting Pronouncements**

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

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

At January 31, 2016, the Company had approximately \$106.8 million in cash, cash equivalents and investments, which consisted primarily of bank deposits, money market funds and short term investments such as certificates of deposit, domestic governmental agency loans and U.S treasury notes. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

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

## **ITEM 4. CONTROLS AND PROCEDURES**

### *Evaluation of Disclosure Controls and Procedures*

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

*Changes in Internal Control over Financial Reporting*

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

*Limitations on Effectiveness of Controls*

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

## **PART II - OTHER INFORMATION**

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

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

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

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

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

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

During the period covered by this report, we have issued unregistered securities to the persons as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we claim that each transaction was exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 3(a)(9) or Section 4(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 17, 2015, the registrant issued 17,201 shares of Common Stock to accredited investors as payment for consulting services.

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On November 30, 2015, the registrant issued 1,195 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 1, 2015, the registrant issued 1,657 shares of Common Stock to an accredited investor as payment for consulting services.

On December 29, 2015, the Company issued 122,661 shares of Common Stock to accredited investors, pursuant to warrant exercises.

On December 31, 2015, the Company issued 2,044 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On January 7, 2016, the Company issued 5,000 shares of Common Stock to an accredited investor as payment for consulting services.

On January 31, 2016, the Company issued 1,708 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On February 16, 2016, the Company issued 12,616 shares of Common Stock to accredited investors as payment for consulting services.

### Treasury Share Repurchases

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

<b>Period</b>	<b>(a) Total Number of Shares Purchased (1)</b>	<b>(b) Average Price Paid Per Share</b>	<b>(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>(d) Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program</b>
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## Edgar Filing: Advaxis, Inc. - Form 10-Q

November 1, 2015 – November 30, 2015	2,009	\$ 12.49	N/A	N/A
December 1, 2015 – December 31, 2015	3,434	\$ 11.91	N/A	N/A
January 1, 2016 – January 31, 2016	89,008	\$ 7.11	N/A	N/A
Total	94,451	\$ 7.39	N/A	N/A

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

### ITEM 5. OTHER INFORMATION

On February 24, 2016, the Board of Directors of Advaxis, Inc. (the "Company") adopted the Advaxis, Inc. Change in Control Plan (the "Change in Control Plan" or the "Plan").

Under the Change in Control Plan, if an executive officer's employment is terminated by the Company without Cause or by the executive officer for Good Reason (as such terms are defined in the Plan) during the period beginning three months prior to or 18 months following a Change in Control of the Company (as defined in the Plan), then the executive officer will be entitled to a cash severance payment in an amount equal to the sum of (a) a pro rata target annual bonus, plus (b) the product of 1.5, in the case of the Company's Chief Executive Officer, or 1.0, in the case of the Company's other executive officers, multiplied by the sum of the executive's base salary and his or her target annual bonus. In addition, the executive officer will be entitled to continued coverage at no cost to the executive under the Company's group health and welfare plans for period of 18 months, in the case of the Chief Executive Officer, or 12 months, in the case of the other executive officers.

In addition, upon a Change in Control of the Company, unvested equity awards held by an executive officer will be accelerated as follows: (i) outstanding stock options and other awards in the nature of rights that may be exercised shall become fully vested and exercisable, (ii) time-based restrictions on restricted stock, restricted stock units and other equity awards shall lapse and the awards shall become fully vested, and (iii) performance-based equity awards shall become vested and shall be deemed earned based on an assumed achievement of all relevant performance goals at "target" levels, and shall payout pro rata to reflect the portion of the performance period that had elapsed prior to the Change in Control.

To receive any severance benefits under the Plan, a participant must execute a general release of claims against the Company. In addition, participants in the Plan are subject to restrictive covenants, including non-competition, non-solicitation and confidentiality provisions, during their employment and for a period of 12 months following their termination of employment.

The Plan is attached as Exhibit 10.2 to this Quarterly Report and is incorporated herein by reference.



**ITEM 6. EXHIBITS**

- 10.1\*\*\* Co-Development and Commercialization Agreement between Advaxis, Inc. and Especificos Stendhal SA de CV dated February 3, 2016.
- 10.2\* Change of Control Plan dated February 24, 2016.
- 31.1\* Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 31.2\* Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 32.1\* Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS\*\* XBRL INSTANCE DOCUMENT
- 101.SCH\*\* XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
- 101.CAL\*\* XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
- 101.DEF\*\* XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
- 101.LAB\*\* XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
- 101.PRE\*\* XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith

\*\* Furnished herewith

\*\*\* Filed herewith. Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.

**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: February 26, 2016 By: */s/ Daniel J. O'Connor*  
Daniel J. O'Connor  
Chief Executive Officer

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



