

Advaxis, Inc.  
Form 10-Q  
September 11, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended July 31, 2015

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

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

Commission file number 000-28489

**ADVAXIS, INC.**

(Exact name of registrant as specified in its charter)



The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of September 9, 2015 was 33,365,829.

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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**

	July 31, 2015 (unaudited)	October 31, 2014
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$97,142,340	\$17,606,860
Prepaid Expenses	366,702	182,978
Income Tax Receivable	-	1,731,317
Other Current Assets	8,182	8,182
Deferred Expenses - current	1,150,443	964,724
Total Current Assets	98,667,667	20,494,061
Property and Equipment, net	375,688	77,369
Intangible Assets, net	3,142,490	2,767,945
Other Assets	120,863	38,438
<b>TOTAL ASSETS</b>	<b>\$102,306,708</b>	<b>\$23,377,813</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$2,153,604	\$1,411,058
Accrued Expenses	2,293,688	1,241,796
Short Term Convertible Notes and Fair Value of Embedded Derivative	29,549	62,882
Total Current Liabilities	4,476,841	2,715,736
Common Stock Warrant Liability	295,183	32,091
Total Liabilities	4,772,024	2,747,827
Commitments and Contingencies		
Shareholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at July 31, 2015 and October 31, 2014. Liquidation preference of \$0 at July 31, 2015 and October 31, 2014.	-	-
	31,496	19,630

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Common Stock - \$0.001 par value; authorized 45,000,000 shares, issued and outstanding 31,496,398 at July 31, 2015 and 19,630,139 at October 31, 2014.

Additional Paid-In Capital	218,945,481	107,601,493
Accumulated Deficit	(121,442,293)	(86,991,137)
Total Shareholders' Equity	97,534,684	20,629,986
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 102,306,708	\$ 23,377,813

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

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

	Three Months Ended		Nine Months Ended	
	July 31,		July 31,	
	2015	2014	2015	2014
Revenue	\$-	\$-	\$-	\$1,000,000
Operating Expenses				
Research and Development Expenses	7,289,944	3,005,306	17,004,939	6,110,095
General and Administrative Expenses	6,339,335	2,993,739	17,240,302	9,442,630
Total Operating Expenses	13,629,279	5,999,045	34,245,241	15,552,725
Loss from Operations	(13,629,279)	(5,999,045)	(34,245,241)	(14,552,725)
Other Income (expense):				
Interest Expense	-	-	-	(5,253)
Gain on Note retirement	-	-	-	6,243
Debt conversion expense	-	-	(6,599)	-
Net changes in fair value of derivative liabilities	32,384	210,298	(254,923)	616,095
Other Income	34,869	9,553	55,608	28,874
Net Loss before benefit for income taxes	(13,562,026)	(5,779,194)	(34,451,155)	(13,906,766)
Income Tax Benefit	-	-	-	625,563
Net Loss	(13,562,026)	(5,779,194)	(34,451,155)	(13,281,203)
Net Loss per share, basic and diluted	\$(0.44)	\$(0.30)	\$(1.30)	\$(0.82)
Weighted Average Number of Shares Outstanding, Basic and Diluted	30,955,708	19,273,062	26,400,596	16,294,134

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



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

	Nine Months Ended	
	July 31,	2014
	2015	2014
<b>OPERATING ACTIVITIES</b>		
Net Loss	\$(34,451,156)	\$(13,281,203)
Adjustments to reconcile Net Loss to net cash used in operating activities:		
Non-cash charges to consultants and employees for options and stock	15,836,492	4,599,259
Non-cash interest expense	-	51
Loss (Gain) on change in value of warrants and embedded derivative	254,923	(616,095 )
Warrant expense	8,169	4,445
Gain on disposal of property and equipment	(10,000 )	-
Settlement expense	-	34,125
Employee Stock Purchase Plan	18,014	5,371
Depreciation expense	28,352	20,709
Amortization expense of intangibles	151,108	129,434
Debt conversion expense	6,599	-
(Gain) on note retirement	-	(6,243 )
Change in operating assets and liabilities:		
Prepaid expenses	(183,724 )	(170,596 )
Income tax receivable	1,731,317	-
Other current assets	-	(25,000 )
Deferred expenses	(185,719 )	(566,013 )
Security deposit	(82,425 )	-
Accounts payable and accrued expenses	1,794,438	(2,105,153 )
Interest payable	-	(98,192 )
Net cash used in operating activities	(15,083,612)	(12,075,101)
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(316,671 )	(24,595 )
Cost of intangible assets	(525,653 )	(288,115 )
Net cash used in Investing Activities	(842,324 )	(312,710 )
<b>FINANCING ACTIVITIES</b>		
Repayment of Officer Loan	-	(64,926 )
Proceeds from exercise of options	58,400	-
Proceeds from exercise of warrants	2,329,708	250
Net proceeds of issuance of Common Stock	94,788,419	14,820,105
Taxes paid related to net share settlement of equity awards	(1,715,111 )	(771,028 )
Net cash provided by Financing Activities	95,461,416	13,984,401
Net increase in cash and cash equivalents	79,535,480	1,596,590

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Cash and cash equivalents at beginning of period	17,606,860	20,552,062
Cash and cash equivalents at end of period	\$97,142,340	\$22,148,652

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

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**Supplemental Disclosures of Cash Flow Information**

	Nine months ended July 31, 201 <del>5</del> 2014
Cash Paid for Interest	\$- \$103,445

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

	Nine months ended July 31, 2015      2014	
Accounts Payable from consultants settled with Common Stock	\$-	\$342,309
Conversion of notes payable into common stock	\$39,932	\$-

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

**ADVAXIS, INC.**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**1. ORGANIZATION**

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

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

Axalimogene filolisbac (ADXS-HPV) has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in 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’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer; ii) a Phase 2 multi-center, open-label study alone and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360) in patients with Stage I-IIa HPV-associated cervical cancer; iii) a Phase 1/2 study evaluating higher doses and repeat cycles of axalimogene filolisbac (ADXS-HPV) in patients with recurrent cervical cancer; iv) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer and, v) 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 (ADXS-HPV) in HPV-associated non-small cell lung cancer. In addition to the Company-sponsored trials, axalimogene filolisbac (ADXS-HPV) 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. The Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer, is currently enrolling patients.

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

Since inception in 2002, the Company has focused its development efforts on understanding its platform technology and establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, currently those targeting HPV-associated cancer (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2 expressing cancers. Although no immunotherapies have been commercialized to date, research and development and investment continues to be placed behind the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting and expanding its clinical development program. In addition to its existing single target vectors targeting tumor associated and stromal targets, 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. Lastly, the Company is developing certain internal capabilities to manufacture clinical trial materials for its Phase 1 and Phase 2 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. On December 19, 2014, the Company priced a registered direct offering of 3,940,801 shares of its Common Stock ("Common Stock"). The transaction closed on December 22, 2014, and the Company received net proceeds of approximately \$15.8 million from the offering. In addition, on February 18, 2015, the Company priced an additional registered direct offering of 3,068,095 shares of its Common Stock. The transaction closed on February 19, 2015, and the Company received net proceeds of approximately \$22.3 million from the offering. The shares in each offering were sold under a Registration Statement (No. 333-194009) on Form S-3, filed by the Company with the United States Securities and Exchange Commission ("SEC"). On May 5, 2015, the Company closed on an underwritten public offering of 2,800,000 shares of Common Stock at a public offering price of \$19.00 per share. On May 20, 2015, the Company closed the Underwriters' overallotment option to purchase 420,000 shares of its Common Stock at a public offering price of \$19.00 per share. The net proceeds from the May 2015 public offerings were approximately \$56.7 million. On August 25, 2015, the Company priced a registered direct offering of 1,797,269 of its Common Stock at a price of \$13.91 per share. The transaction closed on August 28, 2015 and the Company received net proceeds of approximately \$25 million. The sale of the shares in these offerings were registered pursuant to a Registration Statement (No. 333-203497) on Form S-3, filed by the Company with the SEC.

The Company believes its current cash position is sufficient to fund its business plan approximately through fiscal 2018. 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 Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim 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, 2014 and notes thereto contained in the Company’s annual report on Form 10-K for the year ended October 31, 2014, as filed with the SEC on January 6, 2015.

### *Revenue Recognition*

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

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

Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur.

If product development is successful, the Company will recognize revenue from royalties based on licensees’ sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

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

#### *Estimates*

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

#### *Reclassifications*

Certain prior year amounts have been reclassified to conform to the current year presentation.

#### *Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of July 31, 2015 and October 31, 2014, the Company had approximately \$92.2 million and \$- 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 \$97.0 million is subject to credit risk at July 31, 2015. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is



not exposed to any significant credit risk.

### *Fair Value of Financial Instruments*

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

### *Net Loss per Share*

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

	As of July 31,	
	2015	2014
Warrants	3,263,008	4,587,540
Stock Options	1,933,154	490,338
Convertible Debt (using the if-converted method)	1,576	3,354
Total	5,197,738	5,081,232

### *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.

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

### *Recent Accounting Pronouncements*

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

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

### **3. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

	July 31, 2015 (Unaudited)	October 31, 2014
Leasehold Improvements	\$ 25,685	\$-
Laboratory Equipment	320,927	250,456
Furniture and Fixtures	138,415	72,554
Computer Equipment	2,977	10,717
Total Property and Equipment	488,004	333,727
Accumulated Depreciation and Amortization	(112,316 )	(256,358)
Net Property and Equipment	\$ 375,688	\$ 77,369

Depreciation expense for the three and nine months ended July 31, 2015 and 2014 was \$14,204, \$28,352, \$6,903 and \$20,709, respectively.

#### 4. INTANGIBLE ASSETS

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

	July 31, 2015 (Unaudited)	October 31, 2014
License	\$651,992	\$651,992
Patents	3,637,277	3,111,624
Total intangibles	4,289,269	3,763,616
Accumulated Amortization	(1,146,779)	(995,671 )
Intangible Assets	\$3,142,490	\$2,767,945

The expirations of the existing patents range from 2015 to 2028 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. No patent applications with future value were abandoned or expired and charged to expense in the three and nine months ended July 31, 2015 or 2014. Amortization expense for licensed technology and capitalized patent costs is included in general and administrative expenses and aggregated \$52,416, \$151,108, \$44,818 and \$129,434 for the three and nine months ended July 31, 2015 and 2014, respectively.

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

Year ended October 31,

2015 (Remaining)	\$53,500
2016	214,000
2017	214,000
2018	214,000
2019	214,000

## 5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	July 31, 2015 (Unaudited)	October 31, 2014
Salaries and Other Compensation	\$999,223	\$890,069
Vendors	35,014	121,200
Legal	537,500	-
Professional Fees	115,862	208,000
Withholding Taxes Payable	606,089	22,527
	\$2,293,688	\$1,241,796

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

As of July 31, 2015 and October 31, 2014, the Company had approximately \$30,000 and \$63,000 in principal outstanding on its junior subordinated convertible promissory notes that are currently overdue and are recorded as current liabilities on the Company's balance sheet at July 31, 2015 and October 31, 2014, respectively.

During February 2015, the Company induced certain noteholders to convert their convertible promissory notes into common shares by offering conversion prices at a \$1.61 discount from the market price of the common stock. In total, \$33,333 of promissory notes were converted into 4,104 shares of common stock. In connection with the note conversions, the Company recorded a debt conversion expense of \$6,599 in the accompanying statement of

operations.

## 7. DERIVATIVE INSTRUMENTS

### *Warrants*

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

	Number of Warrants	Weighted-Average Exercise Price
Outstanding Warrants at October 31, 2014:	4,158,092	\$ 5.42
Issued	2,361	\$ 7.20
Exercised *	(758,032 )	\$ 5.10
Expired	(139,413 )	\$ 10.47
Outstanding Warrants at July 31, 2015	3,263,008	\$ 5.05

\* Includes the cashless exercise of 291,322 warrants that resulted in the issuance of 216,261 shares of common stock.

At July 31, 2015, the Company had approximately 3.23 million of its total 3.26 million outstanding warrants classified as equity (equity warrants). At October 31, 2014, the Company had approximately 4.1 million of its total 4.2 million outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders' equity section of the balance sheet. The equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions.

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*Warrant Liability*

At July 31, 2015, the Company had approximately 29,000 of its total approximately 3.26 million outstanding warrants classified as liability warrants (liability warrants). As of October 31, 2014, the Company had approximately 123,000 of its total approximately 4.2 million total warrants classified as liabilities (liability warrants). All of these liability warrants at July 31, 2015 and October 31, 2014 were outstanding. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At July 31, 2015, none of the 29,000 liability warrants are subject to weighted-average anti-dilution provisions. At October 31, 2014, approximately 60,000 of the 123,000 liability warrants are subject to weighted-average anti-dilution provisions. A certain number of liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

At July 31, 2015 and October 31, 2014, the fair value of the warrant liability was approximately \$295,000 and \$32,000, respectively. For the three months ended July 31, 2015 and 2014, the Company reported income of approximately \$32,000 and \$210,000, respectively, due to changes in the fair value of the warrant liability. For the nine months ended July 31, 2015 and 2014, the Company reported a loss of approximately \$255,000 and income of approximately \$616,000, respectively, due to changes in the fair value of the warrant liability. In determining the fair value of the warrant liability, at July 31, 2015 and October 31, 2014, the Company used the following inputs in its BSM:

	July 31, 2015	October 31, 2014
Exercise Price	\$5.63-18.75	\$2.76-21.25
Stock Price	\$16.66	\$3.18
Expected term	92-733 days	4-1006 days
Expected Volatility	84.24%-99.38 %	55.41%-129.38 %
Risk Free Interest Rate	.08%-.67 %	.01%-1.62 %

*Exercise of Warrants*

During the nine months ended July 31, 2015, warrants to purchase 758,032 shares of common stock were exercised, which resulted in cash proceeds of \$2,329,708.

#### *Expiration of Warrants*

During the nine months ended July 31, 2015, the Company had 62,430 warrants with anti-dilution provisions, and 76,983 warrants with no such anti-dilution provisions, expire unexercised.

#### *Warrants with anti-dilution provisions*

Some of the Company's warrants contained anti-dilution provisions originally set at \$25.00 with a term of five years. As of July 31, 2015, all of these warrants had expired. As of October 31, 2014, these warrants had an exercise price of approximately \$7.71. If the Company had issued any Common Stock, except for exempt issuances as defined in the warrant agreement, for consideration less than the exercise price then the exercise price and the amount of warrant shares available would have been adjusted to a new price and amount of shares per the "weighted average" formula included in the warrant agreement. For the nine months ended July 31, 2015, this anti-dilution provision required the Company to issue approximately 2,400 additional warrant shares; and the exercise price to be lowered to \$7.20.

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

As of July 31, 2015, there were outstanding warrants to purchase 3,263,008 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$18.75 per share.

As of July 31, 2015, the aggregate intrinsic value of outstanding warrants was approximately \$37,643,000.



**8. SHARE BASED COMPENSATION***2015 Incentive Plan*

On March 30, 2015, the Board of Directors adopted, subject to stockholder approval at the Annual Meeting, the Advaxis, Inc. 2015 Incentive Plan (the “2015 Plan”). The 2015 Plan became effective on May 27, 2015 when it was approved by the Company’s stockholders at the 2015 Annual Meeting. The 2015 Plan serves as the successor to the Advaxis, Inc. 2011 Omnibus Incentive Plan (the “Prior Plan”). Effective May 27, 2015, all future equity awards will be made from the 2015 Plan, and no additional awards will be granted under the Prior Plan. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of Common Stock that may be issued under the 2015 Plan is 3,600,000 shares, plus a number of additional shares (not to exceed 650,000) underlying awards outstanding as of the effective date of the 2015 Plan under the Prior Plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

*Employment Agreements*

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

<b>Executive</b>	<b>ANNUALIZED</b>	<b>For the Nine Months Ended July 31, 2015</b>			
	<b>Annual Amount to be Purchased</b>	<b>Gross Purchase</b>		<b>Net Purchase</b>	
	<b>\$</b>	<b>\$</b>	<b># of shares</b>	<b>\$</b>	<b># of shares</b>
Daniel J. O’Connor	\$ 89,064	\$67,494	6,664	\$61,916	6,329
David J. Mauro	\$ 16,531	\$12,568	1,257	\$9,514	980
Gregory T. Mayes	\$ 23,477	\$17,427	1,679	\$14,082	1,387
Robert G. Petit	\$ 25,225	\$19,335	1,942	\$14,499	1,507
Sara M. Bonstein	\$ 19,734	\$14,665	1,417	\$11,695	1,137

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For the three months ended July 31, 2015, the Company recorded stock compensation expense of \$60,795 on the statement of operations representing 3,130 shares of its Common Stock (2,346 shares on a net basis after employee payroll taxes). For the nine months ended July 31, 2015, the Company recorded stock compensation expense of \$150,883 on the statement of operations representing 14,435 shares of its Common Stock (12,528 shares on a net basis after employee payroll taxes).

From 2013 to present, in addition to the purchases of Common Stock set forth in the above table, Mr. O'Connor has also purchased an additional 146,616 shares of Common Stock out of his personal funds at the then market price for an aggregate consideration of \$588,294. These purchases consisted of the conversion of amounts due to Mr. O'Connor under a promissory note given by Mr. O'Connor to the Company in 2012 of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$182,919 for 34,752 shares, 2013 and 2014 cash bonus voluntarily requested to receive in equity of approximately \$206,125 for 57,990 shares, fiscal 2014 voluntary request to purchase stock directly from the Company at market price purchases of \$68,750 for 15,950 shares, and purchases of the Company's Common Stock in the October 2013 and March 2014 public offerings of 13,500 shares for \$54,000 and 3,333 shares for \$10,000.

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

*Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the nine months ended July 31, 2015 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2014:	791,879	\$ 3.81
Granted	641,452	\$ 16.00
Vested	(362,747 )	\$ 8.60
Cancelled	(3,333 )	\$ 11.76
Balance at July 31, 2015	1,067,251	\$ 9.48

As of July 31, 2015, there was approximately \$9,055,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.34 years.

As of July 31, 2015, the aggregate intrinsic value of non-vested RSUs was approximately \$7,661,000.

#### *Employee Stock Awards*

During the three months ended July 31, 2015, 129,154 shares of Common Stock (100,726 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 \$2,361,716.

During the nine months ended July 31, 2015, 292,832 shares of Common Stock (211,957 shares on a net basis after employee taxes) were issued to executives and employees related to incentive retention awards, employment inducements and employee excellence awards. Total stock compensation expense associated with these awards was \$3,633,886.

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

#### *Director Stock Awards*

During the three months ended July 31, 2015, 23,955 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 \$264,552.

During the nine months ended July 31, 2015, 239,850 shares of Common Stock (226,423 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 \$967,631.

*Stock Options*

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

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2014:	467,968	\$ 15.51
Granted	1,618,995	\$ 13.29
Exercised *	(137,667 )	\$ 12.29
Expired	(16,142 )	\$ 36.42
Outstanding at July 31, 2015	1,933,154	\$ 13.70
Vested and Exercisable at July 31, 2015	712,957	\$ 14.18

\* Includes the cashless exercise of 117,667 options that resulted in the issuance of 45,167 shares of common stock.

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three and nine months ended July 31, 2015, was approximately \$1,959,000 and \$6,824,000, respectively. For the three and nine months ended July 31, 2014, compensation cost related to the Company's outstanding stock options was approximately \$212,000 and \$729,000 respectively.

During the nine months ended July 31, 2015, 1,618,995 options were granted with a total grant date fair value of approximately \$28,318,000. During the nine months ended July 31, 2014, 36,000 options were granted with a total grant date fair value of approximately \$145,000.

During the nine months ended July 31, 2015, options to purchase 137,667 shares of common stock were exercised, which resulted in cash proceeds of \$58,400.

As of July 31, 2015, there was approximately \$21,714,000 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 1.62 years.

As of July 31, 2015, the aggregate intrinsic value of vested and exercisable options was approximately \$2,289,000.



In determining the fair value of the stock options granted during the nine months ended July 31, 2015 and 2014, the Company used the following inputs in its BSM:

	Nine Months Ended	
	July 31, 2015	July 31, 2014
Expected Term	5-10 years	5 years
Expected Volatility	108.72%-154.54%	151.38%-171.12%
Expected Dividends	0	% 0
Risk Free Interest Rate	1.41%-2.27	% 1.39-1.72

*Shares Issued to consultants*

During the three months ended July 31, 2015, 75,628 shares of Common Stock valued at \$1,390,107 were issued to consultants for services. During the nine months ended July 31, 2015, 319,278 shares of Common Stock valued at \$3,768,014 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

The following table summarizes share-based compensation expense included in the Statement of Operations by expense category for the three and nine months ended July 31, 2015 and 2014, respectively:

	Three Months Ended		Nine Months Ended July	
	July 31,		31,	
	2015	2014	2015	2014
Research and development	\$2,499,097	\$303,516	\$4,896,922	\$888,457
General and administrative	3,537,359	1,435,521	10,939,570	3,710,802
Total	\$6,036,456	\$1,739,037	\$15,836,492	\$4,599,259

**9. COMMITMENTS AND CONTINGENCIES:**

*Legal Proceedings*

*Iliad Research and Trading*

On March 24, 2014, Iliad Research and Trading, L.P. (“Iliad”) filed a Complaint against the Company in the Third Judicial District Court of Salt Lake County, Utah. On June 30, 2014, after Iliad had filed an Amended Complaint, the Company removed the action to the United States District Court for the District of Utah. On August 1, 2014, Iliad filed a Second Amended Complaint (the “SAC”). Iliad alleged that the Company granted a participation right to Tonaquint, Inc. (“Tonaquint”) in a securities purchase agreement between Tonaquint and the Company (the “Purchase Agreement”), pursuant to which Tonaquint was entitled to participate in transactions that the Company structured in accordance with Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleged that the Company’s settlement with Ironridge Global IV, Ltd. (“Ironridge”), pursuant to which the Company issued certain shares of its Common Stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, Iliad alleged that it acquired all of Tonaquint’s rights under the Purchase Agreement in April 2013. The SAC purports to assert claims for breach of contract (express and implied), fraud (federal securities, state securities and common law) and conversion.

On November 24, 2014, in response to the Company’s motion to dismiss, the Court dismissed the conversion claim but denied the remainder of the motion. On December 8, 2014, Advaxis filed its answer to the SAC and a counterclaim (the “Counterclaim”), alleging that Iliad – by purporting to have surreptitiously preserved its claim for breach of Tonaquint’s alleged right to participate in the Ironridge transaction – had fraudulently induced Advaxis to enter into the parties’ post-assignment Exchange and Settlement Agreement and, in the alternative, had breached the covenant of good faith and fair dealing implied therein. On January 23, 2015, Iliad filed its Reply to Counterclaim. On May 4, 2015, in response to Iliad’s motion for partial summary judgment concerning liability on the express contract claim and Advaxis’ Rule 56(d) motion to deny that motion and allow discovery, the Court found that Advaxis had materially breached the Purchase Agreement.

On September 10, 2015, the parties entered into a definitive confidential settlement agreement, pursuant to which Iliad will file a stipulation of dismissal shortly, and the Company accrued such amounts.

*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 the Company has until September 21, 2015 to either answer or move to dismiss the complaint. The Company intends to defend itself vigorously.

*Numoda*

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

On October 1, 2014, the Company filed a Complaint against Numoda seeking a declaratory judgment that, with its tender to Numoda of a check for \$68,884, the Company had fully performed the parties’ Project Agreement and that Numoda was not entitled to interest, costs or attorneys’ fees thereunder or otherwise. On January 9, 2015, Numoda filed papers in support of its motion to dismiss the Complaint. On January 23, 2015, the Company filed an Amended Complaint against Numoda seeking an order directing Numoda to specifically perform its obligation to deliver to Advaxis all materials, information and other data generated under the parties’ Project Agreement. On February 25, 2015, the Court endorsed a letter from Numoda’s counsel withdrawing its motion to dismiss the Complaint in light of the Amended Complaint. On February 20, 2015, Numoda filed an Answer denying liability and asserting a number of affirmative defenses. With Court approval of a stipulation of the parties, the Preliminary Conference was adjourned from May 28, 2015 until October 29, 2015.

*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 us 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 April 1, 2011, the Company entered into a sublease agreement for such office, and the agreement has a termination date of November 29, 2015.

In May 2015, the Company signed a direct lease for an expansion area, as well as a direct lease for the existing office, lab and vivarium space upon the expiration of the sublease agreement, which is approximately 20,000 square foot of space in Princeton, NJ. The lease term is seven years and expires on November 30, 2022. The Company paid a security deposit of \$82,426. The lease requires base annual rent of approximately \$442,000 with annual increases in increments between 2% and 4% throughout the remainder of the lease. Rent expense will be recognized on a straight line basis over the term of the lease. The lease contains two options to renew for five years each.

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

Year ended October 31,

2015 (Remaining)	\$60,000
2016	424,927
2017	450,451
2018	468,947
2019	488,153
Thereafter	1,625,308

The Company plans to continue to rent necessary offices and laboratories to support its business.

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## 10. SHAREHOLDERS' EQUITY

### *Registered Direct Offerings*

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

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

### *Public Offerings*

On May 5, 2015, the Company closed on an underwritten public offering of 2,800,000 shares of Common Stock at a public offering price of \$19.00 per share. On May 20, 2015, the Company closed the Underwriters' overallotment option to purchase 420,000 shares of its Common Stock at a public offering price of \$19.00 per share. The Company received gross proceeds of approximately \$61.2 million from the May 2015 public offerings. After deducting offering expenses, the net proceeds from the May 2015 public offerings were approximately \$56.7 million.

## 11. FAIR VALUE

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

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

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

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

The following table provides the liabilities carried at fair value measured on a recurring basis as of July 31, 2015 and October 31, 2014:

July 31, 2015	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$5.63 - \$18.75 from May 2015 through August 2017	\$ -	\$ -	\$295,183	\$295,183

  

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

**Common stock warrant liability:**

	July 31, 2015 (Unaudited)
Beginning balance: October 31, 2014	\$ 32,091
Issuance of additional warrants due to anti-dilution provisions	8,169
Change in fair value	254,923
Balance at July 31, 2015	\$ 295,183

## 12. SUBSEQUENT EVENTS

On August 10, 2015, the Company issued 58,126 shares of Common Stock valued at \$921,297 to an accredited investor as payment for consulting services rendered.

On August 13, 2015, the Board of Directors appointed The Honorable Tom Ridge, the first Secretary of the U.S. Department of Homeland Security and 43<sup>rd</sup> Governor of Pennsylvania, to the Board. Governor Ridge will serve as a director until his term expires at the 2016 annual meeting of stockholders, at which time he will stand for election by the Company's stockholders. In consideration for his services as a director, Governor Ridge received 636 shares of common stock valued at \$10,952 and options to purchase 50,000 shares of common stock at an exercise price of \$17.22. The options vest on August 13, 2016 and expire in 10 years. Governor Ridge was also granted 15,240 RSUs, with 2,740 RSU's vesting on October 31, 2015 and the remaining 12,500 RSUs vesting quarterly such that 100% of the RSUs will have vested by October 31, 2016.

On August 17, 2015, the Company issued 1,250 shares of common stock to an employee which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On August 18, 2015, The Company issued 2,379 shares of common stock to employees in connection with the Employee Stock Purchase Plan.

On August 26, 2015, the Company entered into a licensing agreement with Knight Therapeutics Inc. ("Knight"), a Canadian-based specialty pharmaceutical company focused on acquiring, in-licensing, selling and marketing innovative prescription and over-the-counter pharmaceutical products, to commercialize in Canada the Company's product candidates. Under the terms of the licensing agreement, Knight will be responsible to conduct and fund all regulatory and commercial activities in Canada. The Company is eligible to receive royalty and sales milestones as defined in the agreement.

In connection with the licensing agreement, the Company sold directly to Knight 359,454 shares of the common stock at \$13.91 per share. In addition, the Company sold directly to Sectoral Asset Management, a leading Canadian-based global healthcare investment advisor, 1,437,815 shares of common stock at \$13.91 per share. The combined net proceeds to the Company from these direct investments is approximately \$25 million. The sale of the shares closed on August 28, 2015.

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On August 31, 2015, the Company issued 1,020 shares of Common Stock to management, pursuant to their Employment Agreements.

On September 8, 2015, the Company issued 8,750 shares of Common Stock to employees which represents the initial vesting period of inducement grants pursuant to their employment agreements.

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

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

You should read the following discussion and analysis in conjunction with the unaudited consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our annual report on Form 10-K for the year ended October 31, 2014.

### Overview

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

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

Axalimogene filolismbac (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. 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*) that was conducted exclusively in India in 110 women with recurrent/refractory cervical cancer. The final results were presented at the 2014 American Society of Clinical Oncology (“ASCO”) Annual Meeting, and showed that 32% (35/109) of patients were alive at 12 months, 22% (24/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months, and 18% (16/91 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 an ECOG performance status of 2, a patient population that is often times excluded from clinical trials. Furthermore, a 10% objective response rate (including 5 complete responses and 6 partial responses) and a disease control rate of 38% (42/109) was observed. The addition of cisplatin chemotherapy to axalimogene filolisbac (ADXS-HPV) in this study did not significantly improve overall survival or objective tumor response ( $p=0.9981$ ). 109 patients received 254 doses of axalimogene filolisbac (ADXS-HPV). Axalimogene filolisbac (ADXS-HPV) was found to be well tolerated with 38% (41/109) of patients experiencing mild to moderate Grade 1 or 2 transient adverse events associated with infusion; 1 patient experienced a Grade 3 SAE. All observed treatment related adverse events either self-resolved or responded readily to symptomatic treatment.



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 (ADXS-HPV) 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) in the U.S. The first stage of enrollment in GOG-0265 has successfully been completed with 26/29 patients treated and has met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. As of January 2015, 27% (7/26) of patients were alive at one year (the predefined criteria for 12-month survival was  $\geq 20\%$ ); 6 additional patients were still alive, but with less than 12 months follow up, i.e., these 6 patients are eligible to exceed 12 month survival. The adverse events observed in the first stage of the study have been consistent with those reported in other clinical studies with axalimogene filolisbac (ADXS-HPV). The second stage of the study will include approximately 37 additional patients is now enrolling and has been amended to permit only one prior chemotherapy regimen for the treatment of their recurrent/metastatic disease and allows patients to continue to receive repeat cycles of therapy until disease progression. On September 17, 2015, the final clinical data from the first stage of GOG-0265 will be presented at the American Gynecological & Obstetrical Society (“AGOS”) annual meeting.

We have completed an End-of-Phase 2 (“EOP2”) meeting with the FDA. The purpose of the EOP2 meeting was to discuss axalimogene filolisbac (ADXS-HPV)’s preclinical data, Chemistry, Manufacturing and Controls (“CMC”) and clinical program prior to moving axalimogene filolisbac (ADXS-HPV) forward into a registrational trial in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We 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 (ADXS-HPV). Contingent upon the outcome of the forgoing, we plan to initiate, in collaboration with the GOG Foundation, Inc., an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies, a registrational clinical trial in cervical cancer in 2015 to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

Subject to FDA concurrence under our request for a SPA, the registrational clinical trial that we plan to conduct will be a Phase 3 study of adjuvant axalimogene filolisbac (ADXS-HPV) following chemoradiation as primary treatment for patients with high risk locally advanced cervical cancer compared to chemoradiation alone. This population has a high risk of recurrence and once the disease has recurred there is no available cure. This study will evaluate both the time it takes for the cancer to recur as well as the overall survival. Our goal is to develop a treatment to prevent or reduce the risk of recurrence of cervical cancer after primary treatment interventions have ceased.

Biocon Limited (“Biocon”), our co-development and commercialization partner for axalimogene filolisbac (ADXS-HPV) 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 (ADXS-HPV) 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 (132,000 new cases per year with 74,000 death 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.

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

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

We have entered into a clinical trial collaboration agreement with Incyte where we plan to conduct a Phase 2, open-label, multicenter study to evaluate the safety and immunogenicity of axalimogene filolisbac (ADXS-HPV) as a monotherapy and in combination with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), in patients with Stage I-IIa HPV-associated cervical cancer. The FDA has cleared the IND application and Incyte plans to initiate this Phase 2 trial in 2015.

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

### Head and Neck Cancer

SCCHN is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of SCCHNs originate from the mucosal linings of the oral cavity, pharynx, or larynx and 60-80% of these cancers are caused by HPV. According to the American Cancer Society, head and neck cancer accounts for about 3% to 5% of all cancers in the United States with the incidence of HPV-associated head and

neck cancers increasing at an epidemic rate. Approximately 12,000 new cases will be diagnosed in the United States in 2015.

The safety and immunogenicity of axalimogene filolisbac (ADXS-HPV) 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 (ADXS-HPV) in patients when they are initially diagnosed with HPV-associated head and neck cancer and is currently enrolling patients.

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

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

### Anal Cancer

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

The safety and efficacy of axalimogene filolisbac (ADXS-HPV) is being evaluated in a Phase 2 study under an investigator-sponsored IND by Brown University in patients with high risk locally advanced anal cancer. As of March 2015, 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 (ADXS-HPV) 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 initiate a Company sponsored single arm Phase 2 monotherapy study in patients with persistent/recurrent, loco-regional or metastatic squamous cell carcinoma of the anorectal canal in 2015. This study will consist of two stages and enroll a total of 55 patients.

Axalimogene filolisbac (ADXS-HPV) has received orphan drug designation for HPV-associated 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. The overall HPV prevalence in lung cancer patients varies from 0 to 78.3%, with a higher prevalence in Asia (especially Taiwan and mainland China), compared with the low or no HPV prevalence in Europe and America.

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 and will enroll up to 124 patients.

#### *ADXS-PSA Franchise*

##### Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in seven will get prostate cancer during his lifetime, and one man in 36 will die of this disease. About 220,800 new cases will be diagnosed in the United States in 2015.

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

We have entered into a clinical trial collaboration and supply agreement with Merck & Co. (“Merck”) to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. This study is currently enrolling patients.

#### *ADXS-HER2 Franchise*

##### HER2 Expressing Solid Tumors

HER2 is expressed in a percentage of solid tumors such as breast, gastric, bladder, brain, pancreatic, ovarian and osteosarcoma. The American Cancer Society estimates that in 2015 in the United States alone there will be 231,840 new cases of invasive breast cancer; 24,590 new cases of gastric cancer; 74,000 new cases of bladder cancer; 22,850 new cases of brain/spinal cancer; 48,960 new cases of pancreatic cancer; 21,290 new cases of ovarian cancer; and 800 new cases of osteosarcoma.

ADXS-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 plan to initiate a Phase 1b study in patients with metastatic HER2-expressing cancers in 2015. Thereafter, we intend to initiate

a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma.

## Osteosarcoma

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

Based on encouraging 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.

ADXS-HER2 has received 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 of the study 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; median survival in disease-matched cohort of control dogs (n=13) was 316 days ( $p < 0.00001$ ). Immunological analyses are also being conducted in this study to further evaluate the immune response to ADXS-HER2. 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. As of June 2015, of the 12 canine patients recruited to date, seven were alive with current survival times ranging from 66 to 479 days. The median survival time of dogs receiving palliative radiation plus ADXS-HER2 has not been reached. The median time to progression of these 12 canine patients is 238 days. The reported median survival time for historical control dogs with osteosarcoma that do not undergo amputation but instead receive the same palliative radiation protocol without ADXS-HER2 is 136 days.

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 that the efficacy data previously submitted for product license for AT-014, the cancer immunotherapy for canine osteosarcoma, licensed from us, was accepted to provide a reasonable expectation of efficacy to support conditional licensure. While Aratana needs to complete additional steps, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2016. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals. Aratana is further responsible for the conduct of clinical research with ADXS-Survivin in canine/feline lymphoma, as well as pending investigation of two additional Advaxis constructs in animals.

#### *Lm-LLO Combination Franchise*

#### Axalimogene filolisbac (ADXS-HPV) and Durvalumab (MEDI4736)

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



Axalimogene filolisbac (ADXS-HPV) and Epacadostat (INCB24360)

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

ADXS-PSA and KEYTRUDA® (pembrolizumab)

As stated above, we have entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, two part study in patients with previously treated metastatic, castration-resistant prostate cancer. This Phase 1/2 study is currently enrolling patients.

Lm-LLO Immunotherapy and GRU

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

Lm-LLO Immunotherapy and Sorrento

We have 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 targeting immune checkpoints, including GITR, OX40, LAG-3 and/or TIM-3, in two clinical trials.

*Corporate*

In 2015, we were added to four indexes: MSCI U.S. Small Cap 1750, Russell Global, Russell 2000 and the Russell 3000 Indexes. These indexes are widely used by leading investors to build and manage their portfolios.

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

### *Revenue*

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

### *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 \$7.3 million for the three months ended July 31, 2015, compared with approximately \$3.0 million for the three months ended July 31, 2014, an increase of approximately \$4.3 million. The increase was a result of higher third-party costs, specifically related to axalimogene filolisbac (ADXS-HPV) 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 start-up support. In addition, greater stock based compensation costs of approximately \$2.2 million due to a rise in our share price, and an increased headcount, contributed to the increase.

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

### *General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses were approximately \$6.3 million for the three months ended July 31, 2015, compared with approximately \$3.0 million for the three months ended July 31, 2014, an increase of approximately \$3.3 million. The increase was primarily due to greater stock based compensation costs of approximately \$2.1 million attributable to a rise in our share price, an increase in cash-related public relations costs of approximately \$0.3 million and greater legal costs of approximately \$0.3 million for consultation on a variety of corporate matters.



*Changes in Fair Values*

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

For the three months ended July 31, 2014, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$210,298 due to the expiration of some liability warrants in addition to a smaller range of share prices used in the calculation of the BSM volatility input.

*Other Income*

Other income was \$34,869 for the three months ended July 31, 2015 compared to \$9,553 for the three months ended July 31, 2014. Interest income earned for the three months ended July 31, 2015 and 2014 reflected interest income earned on the Company's savings account balance.

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED JULY 31, 2015 AND 2014**

*Revenue*

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

During the nine months ended July 31, 2014, we transitioned from a development stage company to an operating company. On March 19, 2014, we and Aratana entered into the Agreement pursuant to which we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis 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. Under the terms of the agreement, Aratana paid us an upfront payment of \$1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana upon execution of the Agreement, we properly recorded the \$1 million payment as licensing revenue in the nine months ended July 31, 2014.

*Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was approximately \$17.0 million for the nine months ended July 31, 2015, compared with approximately \$6.1 million for the nine months ended July 31, 2014, an increase of approximately \$10.9 million. The increase was primarily a result of higher third-party costs, specifically related to axalimogene filolisbac (ADXS-HPV) 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 start-up support. In addition, greater stock based compensation costs of approximately \$4.0 million due to a rise in our share price, and an increased headcount, contributed to the increase.

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

*General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expense was \$17.2 million for the nine months ended July 31, 2015, compared with approximately \$9.4 million for the nine months ended July 31, 2014, an increase of approximately \$7.8 million. The increase was due to greater stock based compensation costs of approximately \$7.2 million attributable to a rise in our share price and greater legal costs of approximately \$0.5 million for consultation on a variety of corporate matters.

*Interest Expense*

Interest expense was \$0 for the nine months ended July 31, 2015, compared with \$5,253 for the nine months ended July 31, 2014. The decrease in interest was due to the repayment of debt in the prior year.

*Gain on Note Retirement and Accounts Payable*

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For the nine months ended July 31, 2014, we recorded non-cash income of \$6,243 primarily resulting from the settlement of outstanding payables with shares of our common stock at a discount.

### *Debt Conversion Expense*

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

### *Changes in Fair Values*

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

For the nine months ended July 31, 2014, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$616,095 due to a decrease value of liability warrants due to a decrease in our share price from \$3.74 at October 31, 2013 to \$2.84 at July 31, 2014 in addition to a smaller range of share prices used in the calculation of the BSM volatility input.

### *Other Income*

Other income was \$55,608 for the nine months ended July 31, 2015 compared with \$28,874 for the nine months ended July 31, 2014. Interest income earned for the nine months ended July 31, 2015 and 2014 reflected interest income earned on the Company's savings account balance.

### *Income Tax Benefit*

We may be eligible, from time to time, to receive cash from the sale of our Net Operating Losses, or NOLs, under the State of New Jersey NOL Transfer Program. In the nine months ended July 31, 2014, we received a net cash amount of \$625,563 from the sale of our state NOLs and research and development tax credits for the periods ended October 31, 2010 and 2011.

## Liquidity and Capital Resources

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through July 2015, 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 October 2018. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through July 31, 2015, the Company has reported accumulated net losses of approximately \$121.4 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

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

Cash used in operating activities for the nine months ending July 31, 2014 was approximately \$12.1 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$0.6 million) primarily from spending associated with our clinical trial programs and general & administrative spending. Total spending included one-time non-recurring costs associated with our October 2013 financing, March 2014 financing, certain compensation costs and the settlement of legal claims.

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

Cash used in investing activities, for the nine months ended July 31, 2014, was approximately \$313,000 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 nine months ended July 31, 2015 was approximately \$95.5 million, resulting primarily from registered direct offerings of 7,008,896 shares of our Common Stock resulting in net proceeds of approximately \$38.1 million and a public offering of 2,800,000 shares of Common Stock resulting in net proceeds of approximately \$56.7 million. In addition, the Company received \$2.4 million from the proceeds received on option and warrant exercises. This was partially offset by approximately \$1.7 million of taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities for the nine months ended July 31, 2014, was approximately \$14.0 million, primarily resulting from the public offering of 4,692,000 shares of Common Stock at \$3.00 per share, resulting in net proceeds of approximately \$12.6 million. In addition, the Company sold 306,122 shares of Advaxis's Common Stock to Aratana at a price of \$4.90 per share, resulting in net proceeds of approximately \$1.5 million. The Company also received approximately \$0.4 million from the sale of Common Stock under Stock Purchase Agreement with GBP and issued GBP 108,724 shares of our Common Stock. This was partially offset by approximately \$0.8 million of taxes paid related to the net share settlement of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of July 31, 2015 and October 31, 2014, we had an accumulated deficit of \$121,442,293 and \$86,991,137, respectively and shareholders' equity of \$97,534,684 and \$20,629,986, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately through October 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of our current product candidates.

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

### **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.

### *Stock Based Compensation*

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

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

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



### *Fair Value of Financial Instruments*

The carrying amounts of financial instruments, including cash, receivables, accounts payable and accrued expenses approximated fair value, as of the balance sheet date presented, because of the relatively short maturity dates on these instruments. The carrying amounts of the financing arrangements issued approximate fair value, as of the balance sheet date presented, because interest rates on these instruments approximate market interest rates after consideration of stated interest rates, anti-dilution protection and associated warrants. The estimate of fair value of such financial instruments involves the exercise of significant judgment and the use of estimates by management.

### *Derivative Financial instruments*

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

### **New Accounting Pronouncements**

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

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

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

**Not Applicable**

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

#### *Evaluation of Disclosure Controls and Procedures*

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

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

During the quarter ended July 31, 2015, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

#### *Limitations on Effectiveness of Controls*

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

instances of fraud, if any, within our company have been detected.

## **PART II - OTHER INFORMATION**

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

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. Refer to Footnote 10: Commitments and Contingencies for more information on legal proceedings.

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

There have been no material changes in our risk factors disclosed in our Annual Report on Form 10-K for the year ended October 31, 2014.

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

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

On May 8, 2015, the Company issued 58,126 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On May 11, 2015, the Company issued 21,250 shares of Common Stock to a current Executive which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.



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On May 21, 2015, the Company issued 689 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On May 29, 2015 the Company issued 584 shares of Common Stock to management, pursuant to their Employment Agreements.

On June 3, 2015, the Company issued 10,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On June 3, 2015, the Company issued 8,870 shares of Common Stock to a current Executive which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On June 30, 2015, the Company issued 774 shares of Common Stock to management, pursuant to their Employment Agreements.

On July 23, 2015, the Company issued 265 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On July 29, 2015, the Company issued 570 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On July 31, 2015, the Company issued 988 shares of Common Stock to management, pursuant to their Employment Agreements.

On July 31, 2015, the Company issued 10,136 shares of Common Stock to a current Executive which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On July 31, 2015, the Company issued 5,975 shares of Common Stock to accredited investor, as payment for consulting services rendered.

On August 10, 2015, the Company issued 58,126 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On August 13, 2015, the Company issued 636 shares of Common Stock to a Director for services rendered.

On August 31, 2015, the Company issued 1,020 shares of Common Stock to management, pursuant to their Employment Agreements.

**ITEM 5. OTHER INFORMATION**

None

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**ITEM 6. EXHIBITS**

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

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

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

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

101.INS\*\* XBRL INSTANCE DOCUMENT

101.SCH\*\* XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

101.CAL\*\* XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

101.DEF\*\* XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

101.LAB\*\* XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE\*\* XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith

\*\* Furnished herewith

**SIGNATURES**

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

**ADVAXIS, INC.**

Registrant

Date: September 11, 2015 By: */s/ Daniel J. O'Connor*  
Daniel J. O'Connor  
Chief Executive Officer

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

