

Advaxis, Inc.  
Form 10-Q  
September 11, 2017

**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, 2017

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

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

Commission file number 000-28489

**ADVAXIS, INC.**

(Exact name of registrant as specified in its charter)

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

**Delaware**                                **02-0563870**  
(State or other jurisdiction of     (IRS Employer

incorporation or organization) Identification No.)

305 College Road East, Princeton, NJ 08540

(Address of principal executive offices)

(609) 452-9813

(Registrant’s telephone number)

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

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

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

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

Large Accelerated Filer         Accelerated Filer      
Non-accelerated Filer      (Do not check if smaller reporting company) Smaller Reporting Company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of August 31, 2017 was 41,065,835.

**INDEX**

	Page No.
<b>PART I <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Financial Statements (unaudited)</u>	F-1
<u>Condensed Balance Sheets at July 31, 2017 (unaudited) and October 31, 2016</u>	F-1
<u>Condensed Statements of Operations for the three month and nine month periods ended July 31, 2017 and 2016 (unaudited)</u>	F-2
<u>Condensed Statements of Cash Flows for the nine month periods ended July 31, 2017 and 2016 (unaudited)</u>	F-3
<u>Notes to Condensed Financial Statements</u>	F-5
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	4
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	14
Item 4. <u>Controls and Procedures</u>	14
<b>PART II <u>OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	15
Item 1A. <u>Risk Factors</u>	15
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	15
Item 6. <u>Exhibits</u>	16
<u>SIGNATURES</u>	17

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*

*This quarterly report on Form 10-Q (“Form 10-Q”) includes statements that are, or may be deemed, “forward-looking statements.” In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.*

*By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-Q, they may not be predictive of results or developments in future periods.*

*Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:*

*the success and timing of our clinical trials, including patient accrual;*  
*our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing;*  
*our ability to obtain the appropriate labeling of our products under any regulatory approval;*  
*our plans to develop and commercialize our products;*  
*the successful development and implementation of our sales and marketing campaigns;*  
*the loss of key scientific or management personnel;*  
*the size and growth of the potential markets for our product candidates and our ability to serve those markets;*  
*our ability to successfully compete in the potential markets for our product candidates, if commercialized;*  
*regulatory developments in the United States and foreign countries;*

*the rate and degree of market acceptance of any of our product candidates;  
new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors*

*and the timing of these introductions or announcements;  
market conditions in the pharmaceutical and biotechnology sectors;  
our available cash;  
the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;  
our ability to obtain additional funding;  
our ability to obtain and maintain intellectual property protection for our product candidates;  
the success and timing of our preclinical studies including IND enabling studies;  
the ability of our product candidates to successfully perform in clinical trials;  
our ability to initiate trials, enroll our trials, obtain and maintain approval of our product candidates;  
our ability to manufacture and the performance of third-party manufacturers;  
the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; and  
our ability to successfully implement our strategy.*

*Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the “Risk Factors” section of the Company’s annual report on Form 10-K for the year ended October 31, 2016, as filed with the SEC on January 9, 2017, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate.*

*This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.*

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

	July 31, 2017 (unaudited)	October 31, 2016
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$15,013,455	\$112,750,980
Investments – Held-to-Maturity	74,391,856	39,336,548
Interest Receivable	226,798	80,142
Prepaid Expenses	1,283,010	812,830
Income Tax Receivable	-	2,549,862
Deferred Expenses	5,368,234	4,291,385
Other Receivable	1,500,000	-
Other Current Assets	99,903	53,451
Total Current Assets	97,883,256	159,875,198
Property and Equipment (net of accumulated depreciation)	7,337,337	4,389,074
Intangible Assets (net of accumulated amortization)	4,942,161	4,329,121
Deferred Expenses- net of current portion	59,487	-
Other Assets	499,427	450,667
<b>TOTAL ASSETS</b>	<b>\$110,721,668</b>	<b>\$169,044,060</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$2,981,478	\$1,720,428
Accrued Expenses	6,162,454	10,905,003
Deferred Revenue	12,106,973	15,020,576
Lease Incentive Obligation	40,226	40,226
Common Stock Warrant Liability	-	20,156
Total Current Liabilities	21,291,131	27,706,389
Deferred Rent	646,025	475,749
Deferred Revenue- net of current portion	14,130,329	21,234,568
Lease Incentive Obligation – net of current portion	294,991	325,160

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

Total Liabilities	36,362,476	49,741,866
Commitments and Contingencies		
Shareholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at July 31, 2017 and October 31, 2016. Liquidation preference of \$0 at July 31, 2017 and October 31, 2016.	-	-
Common Stock - \$0.001 par value; 65,000,000 shares authorized, 40,996,342 shares issued and outstanding at July 31, 2017 and 40,057,067 shares issued and 40,041,047 shares outstanding at October 31, 2016.	40,996	40,057
Additional Paid-In Capital	352,199,274	327,098,749
Treasury Stock, at cost, 0 shares at July 31, 2017 and 16,020 shares at October 31, 2016.	-	(129,787 )
Accumulated Deficit	(277,881,078)	(207,706,825)
Total Shareholders' Equity	74,359,192	119,302,194
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 110,721,668</b>	<b>\$ 169,044,060</b>

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



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

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2017	2016	2017	2016
Revenue	\$3,051,620	\$-	\$10,267,842	\$250,000
Operating Expenses				
Research and Development Expenses	17,798,139	10,142,232	47,755,429	31,965,596
General and Administrative Expenses	18,063,555	6,423,988	33,171,062	20,395,635
Total Operating Expenses	35,861,694	16,566,220	80,926,491	52,361,231
Loss from Operations	(32,810,074)	(16,566,220)	(70,658,649)	(52,111,231)
Other Income (expense):				
Interest Income	184,479	73,872	514,363	216,061
Net Changes in Fair Value of Derivative Liabilities	-	6,340	20,156	56,214
Other Expense	-	-	(123)	(201)
Net Loss Before Income Taxes	(32,625,595)	(16,486,008)	(70,124,253)	(51,839,157)
Income Tax Expense	-	-	50,000	14,236
Net Loss	(32,625,595)	(16,486,008)	(70,174,253)	(51,853,393)
Net Loss Per Share, Basic and Diluted	\$(0.80)	\$(0.48)	\$(1.74)	\$(1.52)
Weighted Average Number of Shares Outstanding, Basic and Diluted	40,609,794	34,375,814	40,315,356	34,061,127

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,	
	2017	2016
<b>OPERATING ACTIVITIES</b>		
Net loss	\$(70,174,253 )	\$(51,853,393 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	24,694,464	19,369,948
Gain on change in value of warrants and embedded derivative	(20,156 )	(56,214 )
Loss on disposal of property and equipment	3,187	-
Impairment of intangible assets	107,626	-
Employee stock purchase plan	223,119	28,189
Depreciation expense	553,779	163,581
Amortization expense of intangible assets	239,155	183,184
Lease incentive obligation	(30,169 )	375,443
Amortization of premium on held-to-maturity investments	150,062	218,733
Deferred rent	170,276	374,724
<u>Change in operating assets and liabilities:</u>		
Interest receivable	(146,656 )	5,128
Prepaid expenses	(470,180 )	(428,788 )
Income tax receivable	2,549,862	1,609,349
Other receivable	(1,500,000 )	-
Other current assets	(46,452 )	(13,714 )
Deferred expenses	(1,136,336 )	(3,614,485 )
Other assets	(48,760 )	(320,109 )
Accounts payable and accrued expenses	(3,634,230 )	2,817,033
Deferred revenue	(10,017,842 )	-
Net cash used in operating activities	(58,533,504 )	(31,141,391 )
<b>INVESTING ACTIVITIES</b>		
Purchases of held-to-maturity investments	(73,425,703 )	(24,248,963 )
Proceeds from maturities and redemptions on held-to-maturity investments	38,220,333	20,649,000
Purchase of property and equipment	(3,419,298 )	(2,003,804 )
Cost of intangible assets	(959,821 )	(602,827 )
Net cash used in investing activities	(39,584,489 )	(6,206,594 )
<b>FINANCING ACTIVITIES</b>		
Net proceeds of issuance of common stock	705,868	-
Proceeds from exercise of warrants	1,125	614,368
Taxes paid related to net share settlement of equity awards	(354,262 )	(52,752 )

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

Employee tax withholdings paid on equity awards	(1,547,612 )	(1,926,763 )
Tax shares sold to pay for employee tax withholdings on equity awards	1,575,349	1,893,645
Net cash provided by financing activities	380,468	528,498
Net decrease in cash and cash equivalents	(97,737,525 )	(36,819,487)
Cash and cash equivalents at beginning of period	112,750,980	66,561,683
Cash and cash equivalents at end of period	\$ 15,013,455	\$ 29,742,196

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

F-3

**Supplemental Disclosures of Cash Flow Information**

	Nine months ended July 31,	
	2017	2016
Cash paid for taxes	\$50,000	\$50,000

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

	Nine months ended July 31,	
	2017	2016
Accrued expenses from consultants settled with common stock	\$75,000	\$55,000
Conversion of notes payable into common stock	\$-	\$29,549
Property and equipment included in accounts payable and accrued expenses	\$85,931	\$34,797

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

**ADVAXIS, INC.**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**1. NATURE OF OPERATIONS**

Advaxis, Inc. (“Advaxis” or the “Company”) is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*” or “*Lm* Technology”) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based 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.

Advaxis has developed a strong foothold in the development of immunotherapies, including both axalimogene filolisbac and ADXS-DUAL (ADXS-602) for HPV-related cancers. Axalimogene filolisbac is an *Lm*-based antigen delivery product directed against the Human Papilloma Virus (“HPV”) and designed to target cells expressing the HPV. ADXS-DUAL, the Company’s second immunotherapy targeting HPV-associated cancers, is an *Lm*-based immunotherapy that secretes a fusion protein containing E7 protein antigens from both major families of HPV.

The Company completed a randomized Phase 2 study in 110 patients with recurrent metastatic cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”) Foundation, Inc., now part of NRG Oncology, conducted a cooperative group / Company sponsored Phase 2 open-label clinical study of axalimogene filolisbac in patients with persistent or recurrent metastatic cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed the first and second stages in its Simon 2-stage design. Upon early closure of this study, the results from both stages totaling 50 patients dosed resulted in a 12-month survival rate of 38.0% with a manageable safety profile. The Company has initiated a registrational Phase 3 clinical trial for the adjuvant treatment of women with high-risk locally advanced cervical cancer and, pending FDA feedback, is planning to initiate a global, randomized, registrational quality clinical trial in 1H 2018 in the metastatic cervical cancer setting with ADXS-DUAL in combination with Bristol-Myers Squibb’s (“BMS”) PD-1 immune checkpoint inhibitor, OPDIVO (nivolumab). The Company also plans to pursue registrational opportunities in Europe in 2017 for the metastatic cervical cancer setting as a monotherapy with axalimogene filolisbac.

Axalimogene filolisbac has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and has received European Medicines Agency (“EMA”) orphan drug designation for anal cancer. Axalimogene filolisbac has been designated by the FDA as a Fast Track product for adjuvant therapy for high-risk locally advanced cervical cancer patients. It has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s Committee for Advanced Therapies (“CAT”). Axalimogene filolisbac is subject to an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for the Phase 3 AIM2CERV trial in patients with high-risk, locally advanced cervical cancer. It is also being evaluated in Company-sponsored trials executed under an Investigational New Drug (“IND”) which include the following: (i) a Phase 1/2 clinical trial alone and in combination with MedImmune, LLC’s (“MedImmune”) investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic cervical cancer or patients with HPV-associated head and neck cancer; and (ii) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer. In addition to the Company-sponsored trials, axalimogene filolisbac is also being evaluated in two investigator-initiated clinical trials as follows: neoadjuvant treatment of HPV-positive head and neck cancer (Mount Sinai & Baylor College of Medicine), and locally advanced high risk anal cancer (Brown University).

ADXS-PSA (ADXS31-142) is the Company’s *Lm*-based product candidate designed to target the Prostate Specific Antigen (“PSA”) associated with prostate cancer which is being evaluated in a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck & Co.’s (“Merck”) humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer.

ADXS-HER2 (ADXS31-164) is the Company’s *Lm*-based product candidate designed for the treatment of Human Epidermal Growth Factor Receptor 2 (“HER2”) expressing cancers, including human and canine osteosarcoma. ADXS-HER2 was evaluated in a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. The Company has evaluated the data, and based on the Company’s priorities, has determined not to pursue further clinical study of ADXS-HER2 at this time but remains open to investigator-initiated research or licensing proposals. 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 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017.

ADXS-NEO is the Company's individual *Lm*-based antigen delivery product combined with a fusion protein based on information captured by comparing a patient's own DNA with the DNA from that patient's tumor. The FDA has cleared the Company's IND application for clinical investigation of a new precision immunotherapy for the treatment of cancers. The Company plans to initiate a Phase 1 study in first half of 2018.

The Company has focused its development efforts on establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, with clinical trials currently targeting HPV-associated cancers (cervical cancer, head and neck cancer, and anal cancer), prostate cancer, and canine osteosarcoma. Although no immunotherapies have been commercialized to date, the Company continues to invest in research and development to advance the technology and make it available to patients with many different types of cancer. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting and expanding its clinical development programs. In addition to its existing single antigen vectors that target one tumor associated antigen, the Company is actively engaged in the development of new constructs that will address multiple targets that are common to tumor types, as well as mutation-associated epitopes that are specific to an individual patient's tumor. The Company is also leveraging its *Lm* Technology™ to target common (public or shared) mutations (hotspots) in tumor driver genes, which it refers to as ADXS-HOT. Lastly, the Company completed construction for its pilot plant at the state-of-the-art manufacturing facility in Princeton, NJ, to produce supplies for its neoepitope and other development programs.

#### *Liquidity and Financial Condition*

The Company's products are being developed and have not generated significant revenues. As of July 31 2017, the Company had approximately \$89.4 million in cash, cash equivalents and investments on its balance sheet. The Company believes its current cash position is sufficient to fund its business plan into approximately fiscal 2019. The estimate is based on assumptions that may prove to be wrong, and the Company could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of its current product candidates.

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

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

*Basis of Presentation - Unaudited Interim Financial Information*

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information, and in accordance with the rules and regulations of the SEC with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, necessary to represent a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2016 and notes thereto contained in the Company’s annual report on Form 10-K for the year ended October 31, 2016, as filed with the SEC on January 9, 2017.

The information presented in the accompanying unaudited condensed balance sheet as of October 31, 2016 has been derived from the Company’s October 31, 2016 audited financial statements.

*Estimates*

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

*Reclassifications*

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



### *Collaboration Agreements*

The Company evaluates whether an arrangement is a collaborative arrangement under the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 808, *Collaborative Arrangements*, at its inception based on the facts and circumstances specific to the arrangement. The Company also reevaluates whether an arrangement qualifies or continues to qualify as a collaborative arrangement whenever there is a change in either the roles of the participants or the participants’ exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor. For those collaborative arrangements where it is determined that the Company is the principal participant, costs incurred and revenue generated from third parties are recorded on a gross basis in the financial statements.

From time to time, the Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of products and product candidates. These collaborations generally provide for non-refundable, upfront license fees, research and development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. The Company’s collaboration agreements with third parties are performed on a “best efforts” basis with no guarantee of either technological or commercial success.

### *Revenue Recognition*

The Company is expected to derive the majority of its revenue from patent licensing and research and development services associated with 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.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestones as revenue on a straight-line basis over the remaining expected performance period under the arrangement. All such recognized revenues are included in collaborative licensing and

development revenue in the Company's statements of operations.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value.

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.

Deferred revenue represents the portion of payments received for which the earnings process has not been completed. Deferred revenue expected to be recognized within the next 12 months is classified as a current liability.

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.

#### *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, 2017 and October 31, 2016, the Company had approximately \$8.3 million and \$106.7 million, respectively, in cash equivalents.

#### *Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$13.7 million is subject to credit risk at July 31, 2017. 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.

F-7

*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,	
	2017	2016
Warrants	3,094,173	3,110,575
Stock Options	3,893,558	3,351,794
Restricted Stock Units	1,527,693	762,909
Total	8,515,424	7,225,278

*Stock Based Compensation*

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

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

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

#### *Recent Accounting Pronouncements*

In May 2014, as part of its ongoing efforts to assist in the convergence of GAAP and International Financial Reporting Standards, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, which is a new standard related to revenue recognition. Under the new standard, recognition of revenue occurs when a customer obtains control of promised services or goods in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. The standard must be adopted using either a full retrospective approach for all periods presented in the period of adoption or a modified retrospective approach. In July 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers - Deferral of the Effective Date, which defers the implementation of this new standard to be effective for fiscal years beginning after December 15, 2017. Early adoption is permitted effective January 1, 2017. In March 2016, the FASB issued ASU 2016-08, Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations in the new revenue recognition standard pursuant to ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, Identifying Performance Obligations and Licensing, in May 2016, the FASB issued ASU 2016-12, Narrow-Scope Improvements and Practical Expedients, and in December 2016 the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amend certain aspects of the new revenue recognition standard pursuant to ASU 2014-09. We are currently evaluating which transition approach we will utilize and the impact of adopting this accounting standard on the Company’s financial statements.

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

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

In January 2017, the FASB issued ASU No. 2017-01, “Business Combinations (Topic 805): Clarifying the Definition of a Business.” The amendments in this Update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of businesses. The amendments in this Update provide a screen to determine when a set is not a business. If the screen is not met, it (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) removes the evaluation of whether a market participant could replace the missing elements. This Update is the final version of Proposed ASU 2015-330 Business Combinations (Topic 805) – Clarifying The Definition of a Business, which has been deleted. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company’s financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting” to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This Update is the final version of Proposed ASU 2016-360—Compensation—Stock Compensation (Topic 718)—Scope of Modification Accounting, which has been deleted. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company’s financial statements.

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

### 3. INVESTMENTS

The following table summarizes the Company's investment securities at amortized cost as of July 31, 2017 and October 31, 2016:

	July 31, 2017			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross Unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 17,185,953	\$ -	\$ -	\$ 17,185,953
Domestic Governmental Agency Loans	2,666,361	-	795	2,665,566
U.S Treasury Notes	54,539,542	-	50,347	54,489,195
Total short-term investment securities	\$ 74,391,856	\$ -	\$ 51,142	\$ 74,340,714

	October 31, 2016			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 10,737,563	\$ -	\$ -	\$ 10,737,563
Domestic Governmental Agency Loans	2,500,000	-	250	2,499,750
U.S Treasury Notes	26,098,985	2,404	7,556	26,093,833
Total short-term investment securities	\$ 39,336,548	\$ 2,404	\$ 7,806	\$ 39,331,146

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

**4. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

	July 31, 2017	October 31, 2016
Leasehold Improvements	\$2,010,952	\$1,835,602
Laboratory Equipment	4,028,027	2,038,704
Furniture and Fixtures	721,577	549,025
Computer Equipment	394,523	240,910
Construction in Progress	1,152,067	151,368
Total Property and Equipment	8,307,146	4,815,609
Accumulated Depreciation	(969,809 )	(426,535 )
Net Property and Equipment	\$7,337,337	\$4,389,074

Depreciation expense for the three and nine months ended July 31, 2017 and 2016 was \$216,376, \$553,779, \$68,457 and \$163,581, respectively.

**5. INTANGIBLE ASSETS**

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

	July 31, 2017	October 31, 2016
License	\$776,992	\$776,992
Patents	5,763,542	4,980,610
Software	83,639	19,625
Total Intangibles	6,624,173	5,777,227
Accumulated Amortization	(1,682,012)	(1,448,106)
Intangible Assets	\$4,942,161	\$4,329,121

The expirations of the existing patents range from 2017 to 2037 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. Patent applications having a net book value of \$17,745 and \$107,626 were abandoned and charged to *Research and Development Expenses* in the statement of operations for the three and nine months ended July 31, 2017. No patent applications were abandoned during the three or nine months ended July 31, 2016. Amortization expense for intangible assets is included in research and development expenses and aggregated \$87,000, \$239,155, \$64,440 and \$183,184 for the three and nine months ended July 31, 2017 and 2016, respectively.

At July 31, 2017, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows:

2017 (Remaining)	\$87,001
2018	348,003
2019	345,603
2020	329,959
2021	320,124
Thereafter	3,511,471
Total	\$4,942,161

#### 6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	July 31, 2017	October 31, 2016
Salaries and Other Compensation	\$2,834,381	\$2,467,650
Vendors	516,648	2,098,792
Professional Fees	2,811,425	6,338,561
	\$6,162,454	\$10,905,003

## 7. DERIVATIVE INSTRUMENTS

### *Warrants*

A summary of changes in warrants for the nine months ended July 31, 2017 is as follows:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding Warrants at October 31, 2016:	3,110,575	\$ 5.04
Issued	-	\$ -
Exercised	(225 )	\$ 5.00
Expired	(16,177 )	\$ 10.63
Outstanding Warrants at July 31, 2017	3,094,173	\$ 5.01

At July 31, 2017 and October 31, 2016, the Company had 3,092,395 and 3,092,619 outstanding warrants classified as equity (equity warrants) out of it total 3,094,173 and 3,110,575 warrants, respectively. At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders' equity section of the balance sheet. The equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions.

### *Warrant Liability*

At July 31, 2017, the Company had approximately 2,000 of its total approximately 3.09 million outstanding warrants classified as liabilities (liability warrants). At October 31, 2016, the Company had approximately 18,000 of its total approximately 3.11 million outstanding warrants classified as liabilities (liability warrants). The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. The liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

At July 31, 2017 and October 31, 2016, the fair value of the warrant liability was \$0 and \$20,156, respectively. For the three months ended July 31, 2017 and 2016, the Company reported a gain of \$0 and \$6,340, respectively, due to changes in the fair value of the warrant liability. For the nine months ended July 31, 2017 and 2016, the Company reported a gain of \$20,156 and \$56,214, respectively, due to changes in the fair value of the warrant liability. In

determining the fair value of the warrant liability at July 31, 2017 and October 31, 2016, the Company used the following inputs in its BSM:

	July 31, 2017	October 31, 2016
Exercise Price	\$18.75	\$10.63-18.75
Stock Price	\$6.47	\$8.09
Expected term	0.01 years	0.55-0.75 years
Expected Volatility	67.34 %	81.84%-87.09 %
Risk Free Interest Rate	1.00 %	0.51%-0.66 %

## 8. SHARE BASED COMPENSATION

### *Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the nine months ended July 31, 2017 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2016:	719,448	\$ 10.77
Granted	1,579,934	\$ 7.95
Vested	(722,089 )	\$ 9.03
Cancelled	(49,600 )	\$ 8.89
Balance at July 31, 2017	1,527,693	\$ 8.73

As of July 31, 2017, there was approximately \$11,266,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 2.18 years.

As of July 31, 2017, the aggregate intrinsic value of non-vested RSUs was approximately \$9,884,000.

### *Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 463,985 shares (452,084 shares on a net basis after employee taxes) and 152,056 shares (149,833 shares on a net basis after employee taxes) for the three months ended July 31, 2017 and 2016, respectively. Total stock compensation expense associated with these awards for the three months ended July 31, 2017 and 2016 was \$4,259,656 and \$1,220,832 respectively.

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 717,505 shares (674,543 shares on a net basis after employee taxes) and 539,512 shares (532,933 shares on a net basis after employee taxes) during the nine months ended July 31, 2017 and 2016, respectively. Total stock compensation expense associated with these awards for the nine months ended July 31, 2017 and 2016 was \$7,328,591 and \$4,075,393, respectively.

Furthermore, employees were entitled to receive a performance-based year-end cash bonus. Several employees voluntarily requested to be paid all or a portion of their cash bonus in the Company's Common Stock instead of cash. During the nine months ended July 31, 2016, the total fair value of these equity purchases were \$102,022, or 9,150 shares of the Company's Common Stock.

### *Director Stock Awards*

Common stock issued to Directors for compensation related to board and committee membership totaled 0 shares and 31,767 shares for the three months ended July 31, 2017 and 2016, respectively. Total Director stock compensation expense for the three months ended July 31, 2017 and 2016 was \$101,628 and \$311,205, respectively.

Common stock issued to Directors for compensation related to board and committee membership totaled 30,000 and 125,501 shares for the nine months ended July 31, 2017 and 2016, respectively. Total Director stock compensation expense for the nine months ended July 31, 2017 and 2016 was \$301,572 and \$933,615, respectively.

### *Stock Options*

A summary of changes in the stock option plan for the nine months ended July 31, 2017 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2016:	3,351,795	\$ 13.31
Granted	556,952	\$ 7.71
Exercised	-	\$ -
Cancelled	(4,000 )	\$ 3.42
Expired	(11,189 )	\$ 17.88
Outstanding at July 31, 2017	3,893,558	\$ 12.51
Vested and Exercisable at July 31, 2017	2,795,826	\$ 13.05

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended July 31, 2017 and 2016, was approximately \$9,698,000 and \$3,108,000, respectively. For the nine months ended July 31, 2017 and 2016, compensation cost related to the Company's outstanding stock options was approximately \$15,889,000 and \$13,060,000, respectively.

During the nine months ended July 31, 2017, 556,952 options were granted with a total grant date fair value of approximately \$3,542,000. During the nine months ended July 31, 2016, 1,385,000 options were granted with a total grant date fair value of approximately \$14,838,000.

As of July 31, 2017, there was approximately \$6,342,000 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 1.29 years.

As of July 31, 2017, the aggregate intrinsic value of vested and exercisable options was approximately \$27,000.

In determining the fair value of the stock options granted during the nine months ended July 31, 2017 and 2016, the Company used the following inputs in its BSM:

	Nine Months Ended	
	July 31, 2017	July 31, 2016
Expected Term	5.50-6.50 years	5.51-6.51 years
Expected Volatility	107.07%-110.93 %	109.23%-115.25 %
Expected Dividends	0 %	0 %
Risk Free Interest Rate	1.26%-1.58 %	1.65%-2.00 %

*Shares Issued to Consultants*

During the three months ended July 31, 2017, 48,737 shares of Common Stock valued at \$416,000 were issued to consultants for services, of which \$247,100 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$141,800 for shares earned pursuant to consulting agreements but not delivered. During the three months ended July 31, 2016, 31,030 shares of Common Stock valued at \$252,000 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

During the nine months ended July 31, 2017, 125,549 shares of Common Stock valued at \$1,108,950 were issued to consultants for services, of which \$75,000 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$141,800 for shares earned pursuant to consulting agreements but not delivered. During the nine months ended July 31, 2016, 120,047 shares of Common Stock valued at \$1,097,088 were issued to consultants for services. 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, 2017 and 2016, respectively:

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2017	2016	2017	2016
Research and development	\$1,517,585	\$1,014,034	\$4,271,073	\$7,088,377
General and administrative	12,852,729	3,994,331	20,423,391	12,281,571
Total	\$14,370,314	\$5,008,365	\$24,694,464	\$19,369,948

**9. COLLABORATION AND LICENSING AGREEMENTS***Amgen*

On August 1, 2016, the Company entered into a global agreement (the “Amgen Agreement”) with Amgen for the development and commercialization of the Company’s ADXS-NEO, a novel, preclinical investigational immunotherapy, using the Company’s proprietary *Listeria monocytogenes* attenuated bacterial vector which activates a patient’s immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient’s tumor. Under the terms of the Amgen Agreement, Amgen receives an exclusive worldwide license to develop and commercialize ADXS-NEO. Advaxis and Amgen will collaborate through a joint steering committee for the development and commercialization of ADXS-NEO. Under the Amgen Agreement, Amgen will fund the

clinical development and commercialization of ADXS-NEO and Advaxis will retain manufacturing responsibilities. The Company considered the provisions of the research and development and collaboration guidance in determining how to recognize the clinical development payments to be received from Amgen. The Company determined the clinical development payments should be accounted for within the scope of collaboration arrangement accounting guidance. As a result, the Company will account for the clinical development payments as a reduction of *Research and Development Expenses* in the statement of operations. During the nine months ended July 31, 2017, the Company received clinical development payments from Amgen totaling \$4,500,000. In addition, the Company recorded an expected clinical development payment of \$1,500,000 as *Other Receivables* on the balance sheet. In August 2017, the Company received the \$1,500,000 expected clinical development payment from Amgen.

#### *Especificos Stendhal SA de CV*

On February 3, 2016, the Company entered into a Co-Development and Commercialization Agreement (the “Stendhal Agreement”) with Especificos Stendhal SA de CV (“Stendhal”), for Advaxis’ lead *Lm* Technology™ immunotherapy, Axalimogene filolisbac, in HPV-associated cancers. Under the terms of the Stendhal Agreement, Stendhal will pay \$10 million (“Support Payments”) towards the expense of AIM2CERV over the duration of the trial. Certain internal expenses of Stendhal up to \$1 million shall be counted towards the \$10 million in Support Payments. The Support Payments are contingent upon Advaxis achieving annual project milestones. The Company considered the provisions of the research and development and collaboration guidance in determining how to recognize the Support Payments to be received from Stendhal. The Company determined the Stendhal Agreement should be accounted for within the scope of collaboration arrangement accounting guidance. Furthermore, the Company determined that Advaxis is the principal in the Stendhal Agreement. As a result, the Company will account for the Support Payments as a reduction of *Research and Development Expenses* in the statement of operations. During the nine months ended July 31, 2017, the Company reached the annual project milestones and received a \$3,000,000 Support Payment from Stendhal.

#### *Sellas Life Science Group*

On February 27, 2017, the Company entered into a license agreement with Sellas Life Science Group (“Sellas”) to develop a novel cancer immunotherapy agent using Advaxis’ proprietary *Lm*-based antigen delivery product with SELLAS’ patented WT1 targeted heteroclitic peptide antigen mixture (galinpepimut-S)). Pursuant to the agreement, Advaxis will conduct all pre-clinical activities required for an IND filing and Sellas will be responsible for all clinical development and commercial activities. Advaxis will receive future payments of up to \$358 million from SELLAS if certain development, regulatory, and commercial milestones are met. SELLAS has agreed to pay Advaxis single-digit to low double-digit royalties based on worldwide net sales upon commercialization. If SELLAS sublicenses its rights, Advaxis will receive a percentage of applicable sublicense revenue paid.

## 10. COMMITMENTS AND CONTINGENCIES

### *Legal Proceedings*

#### *Knoll*

On August 21, 2015, Knoll Capital Management L.P. filed a complaint against the Company in the Delaware Court of Chancery. In lieu of continuing to unnecessarily incur litigation expenses, on April 27, 2017, the Company settled the matter for a non-material amount, predominately reimbursed by the Company's insurance, and the parties entered into a definitive confidential settlement agreement. The Company expressly denies any admission or wrongdoing and the settlement was entered into solely for the purpose of avoiding the burden, inconvenience, and expense of further litigation. On May 11, 2017, following resolution of the matter by the parties, the Court granted a Stipulation Of Dismissal With Prejudice.

#### *Bono*

On August 20, 2015, a derivative complaint was filed by a purported Company shareholder in the United States District Court for the District of New Jersey styled David Bono v. O'Connor, et al., Case No. 3:15-CV-006326-FLW-DEA (D.N.J. Aug. 20, 2015) (the "Bono Action"). The complaint is based on general allegations related to certain stock options granted to the individual defendants and generally alleges counts for breaches of fiduciary duty and unjust enrichment. The complaint also alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. The complaint seeks damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief.

Defendants filed a motion to dismiss the Bono Action. On May 23, 2016, the United States District Court for the District of New Jersey issued an opinion and order granting in part and denying in part defendants' motion to dismiss. Specifically, the court denied the motion to dismiss as to the breach of fiduciary duty claim and unjust enrichment claim against the three members of the Compensation Committee, but dismissed without prejudice the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants [O'Connor, Khleif, McKearn, Patton, Bonstein, Mauro, Mayes, and Petit]. The court dismissed without prejudice the Section 14(a) disclosure claim and waste claims against all defendants. On October 5, 2016, the court denied plaintiff's motion for reconsideration of its May 23 order. On April 13, 2017, the parties advised the Court that they had reached a tentative agreement in principle to settle the action, which is still subject to negotiating an award of attorneys' fees and expenses to Plaintiffs' counsel and a stipulation of settlement, and, ultimately, Court approval.



*General*

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

*Operating Leases*

The Company's corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540.

At July 31, 2017 future minimum lease payments by fiscal year of the Company's operating leases are as follows:

2017 (Remaining)	\$245,466
2018	1,041,895
2019	1,107,385
2020	1,232,907
2021	1,317,640
Thereafter	5,747,340
Total	\$10,692,633

## 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 financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited financial statements included in our annual report on Form 10-K for the year ended October 31, 2016.

### Overview

Advaxis is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products with the lead program in Phase 3 development. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based 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.

Advaxis will continue to invest in its core clinical franchises and will also remain opportunistic based on Investigator Sponsored Trials ("ISTs") as well as licensing opportunities. Our proprietary *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2037.

### *HPV Related Cancers*

We have developed a strong franchise in HPV-related cancers including both axalimogene filolisbac and ADXS-DUAL. Axalimogene filolisbac is an *Lm*-based antigen delivery product directed against HPV and designed to

target cells expressing the HPV. ADXS-DUAL, our second immunotherapy targeting HPV-associated cancers, is an *Lm*-based immunotherapy that secretes a fusion protein containing E7 protein antigens from both alpha 7 (HPV18) and alpha 9 (HPV 16) families, and has the potential to promote more potent T-cell responses for patients with metastatic cancer and a greater disease burden. We developed ADXS-DUAL by building on our learnings from the clinical development of axalimogene filolisbac and have incorporated an additional HPV target antigen into our *Lm* bacterial vector. Our HPV-related products are currently under investigation in three HPV-associated cancers: cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination.

### Cervical Cancer

There are approximately 527,000 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2017 (“WHO”). Current preventative vaccines cannot protect all women who are infected with this very common virus. Challenges with acceptance, accessibility, and compliance have resulted in approximately 30% of young women and 7% of young men being vaccinated in the United States with even lower vaccination rates in other countries around the world.

We completed a randomized Phase 2 clinical study (*Lm*-LLO-E7-15), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results showed that 34.9% (38/109) of patients were alive at 12 months, 24.8% (27/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months. Of the 15 patients consenting to further follow-up beyond 18 months, 12 (11%) achieved 24-month OS status (range 24 – 34+ months) at the time of study closure. LTS included not only patients with tumor shrinkage but also patients who had experienced stable disease or increased tumor burden. Investigator assessment of best Overall Response (“OR”) was assessed in the efficacy population. These data demonstrated a best objective response rate (ORR; CR + PR) of 17.1% (*N*= 6). The mean duration of OR was 7.2 months. The disease control rate (CR + PR + SD) was 62.9% (*N*= 22) and the mean duration of stable disease was 5.2 months. The addition of cisplatin chemotherapy to axalimogene filolisbac (*N*=54) in this study did not significantly improve overall survival or objective tumor response (*p* =0.9981).

In this study, 109 patients received 254 doses of axalimogene filolisbac. Axalimogene filolisbac was found to be well tolerated with the majority of the AEs were mild to moderate in severity (566 of 704 reported AEs, 80.4%) and were not related to study drug (539 of 704 reported AEs, 76.6%). Four patients experienced a Grade 3 treatment-associated Serious Adverse Events (“SAE”). All observed treatment-related adverse events were infusion related and either self-resolved or responded readily to symptomatic treatment.

We have reached an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, to conduct a Phase 3 trial evaluating axalimogene filolisbac in patients with high-risk, locally advanced cervical (“AIM2CERV” or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”). Pursuant to the SPA, the study has been determined by FDA to be adequate, well-designed, and suitable for registration if successful. This study will be conducted in collaboration with the GOG/NRG Oncology, an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies, and we have initiated the AIM2CERV study to support a Biologics License Application (“BLA”) submission in the U.S.

and regulatory registration in other territories around the world.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 study of adjuvant axalimogene filolisbac, following primary chemoradiation treatment of women with high-risk locally advanced cervical cancer (“HRLACC”). The primary objective of AIM2CERV is to compare the disease free survival of axalimogene filolisbac to placebo administered in the adjuvant setting following standard concurrent chemotherapy and radiotherapy (“CCRT”) administered with curative intent to patients with HRLACC. Secondary endpoints include examining overall survival and safety. Our goal is to develop a treatment to prevent or reduce the risk of cervical cancer recurrence after primary, standard of care treatment in women who are at high risk of recurrence. The study is active in eight countries and is currently enrolling.

Biocon Limited (“Biocon”), our co-development and commercialization partner for axalimogene filolisbac in India and key emerging markets, filed a Marketing Authorization Application (“MAA”) for licensure of this immunotherapy in India. The companies are currently evaluating next steps.

We have a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and efficacy of axalimogene filolisbac, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated Squamous Cell Carcinoma of the Head and Neck (“SCCHN”). For the axalimogene filolisbac and durvalumab dose escalation portion of the study, the dose-escalation phase has been completed. As reported at the Society for Immunotherapy of Cancer (“SITC”) 2016 annual meeting, preliminary results from the dose escalation portion of the study showed that there were no dose limiting toxicities observed, and the safety profile was consistent with previous findings for both axalimogene filolisbac and durvalumab. The recommended phase 2 dose was established as  $1 \times 10^9$  Colony Forming Units (“CFU”) for axalimogene filolisbac and 10 mg/kg for durvalumab. As previously reported in preliminary data reported from this ongoing trial, one patient with cervical cancer achieved a complete response and one patient, also with cervical cancer, achieved a partial response with subsequent disease progression. In addition, two patients with SCCHN achieved stable disease. Treatment related adverse events (“TRAE”) were reported in 91% of patients; the majority were either grade 1 or grade 2 events such as chills, fever, nausea and hypotension. Grade 3 TRAEs occurred in three patients, and one patient experienced a grade 4 event. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases. Accrual is ongoing.

The GOG Foundation, Inc. (now a member of NRG Oncology), under the sponsorship of the Cancer Therapy Evaluation Program (“CTEP”) of the National Cancer Institute (“NCI”), conducted GOG-0265, an open-label, single arm Phase 2 study of axalimogene filolisbac in persistent or recurrent cervical cancer (patients must have received at least 1 prior chemotherapy regimen for the treatment of their recurrent/metastatic disease, not including that administered as a component of primary treatment) at numerous clinical sites in the U.S. The study was a Simon 2-stage design. The primary efficacy endpoint was the 12-month survival rate, with the objective of the secondary efficacy endpoints to evaluate progression-free survival, overall survival and objective tumor response. The primary safety endpoints were to evaluate the number of patients with dose-limiting toxicities and the frequency and severity of adverse effects.

In order to evaluate the study's primary endpoint of the 12-month overall survival rate, the GOG's protocol featured a prospectively-defined logistic model-based calculation of the expected 12-month survival rate using key predictive factors significantly related to survival and derived from 17 serially conducted GOG/NRG 2-stage studies of inactive agents in PRmCC involving approximately 500 patients. This accumulated data by GOG used a consistent protocol design and a similar data collection methodology resulting in a robust and homogeneous patient dataset for the per protocol analysis of the primary endpoint. Per the study protocol, this logistic model-based calculation was then used as a comparator for evaluating the 12-month survival rate of axalimogene filolisbac actually observed.

The first stage of enrollment in GOG-0265 was successfully completed with 26 patients treated and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Clinical data from the first stage of GOG-0265 was presented at the American Gynecological & Obstetrical Society ("AGOS") annual meeting on September 17, 2015. Overall survival at 12 months was 38.5% (10/26) (the conditional power needed in order to progress to Stage 2 was  $\geq 20\%$ ), and, among patients who had received the full treatment regimen of 3 doses of axalimogene filolisbac, the 12-month survival rate was 55.6% (10/18). The adverse events observed in the first stage of the study were consistent with those reported in other clinical studies with axalimogene filolisbac.

Stage 2 of the study began enrollment in February 2015 which included a protocol amendment to allow patients to continue to receive repeat cycles of therapy until disease progression. Stage 2 enrollment was temporarily suspended with a clinical hold in October 2015 that resolved in mid-December 2015. Prior to re-initiating enrollment of a new cohort of Stage 2 patients, Advaxis and the GOG Foundation/NRG Oncology examined the 12-month survival rate and safety data obtained from the 24 patients who had previously enrolled in Stage 2. The Stage 2 population demonstrated that treatment with axalimogene filolisbac resulted in a 37.5% (9/24) 12-month survival rate. This data was consistent with the findings in Stage 1 that showed a 38.5% 12-month survival rate, despite a greater proportion of Stage 2 patients having failed bevacizumab treatment. Taken together, the available data from both stages of GOG-0265 comprise a Phase 2 clinical trial in 50 subjects with a 12 month survival rate of 38% (19/50). The protocol defined logistic model-based calculation of the expected 12-month milestone survival rate was calculated to be 24.5% using the key predictors from the patients enrolled in the study. The 12 month survival rate of 38% for patients receiving axalimogene filolisbac in the study represented a 52% improvement over the expected 12-month milestone survival rate of 24.5%.

Overall, 28 out of 50 (56%) patients experienced a Grade 1 or Grade 2 TRAE associated with axalimogene filolisbac infusion. The most common (>30%) Grade 1 or Grade 2 TRAEs were fatigue, chills, anemia, nausea and fever. Eighteen (36%) patients experienced a Grade 3 TRAE and two patients experienced a Grade 4 AE, including a Klebsiella lung infection in one patient, and hypotension/cytokine related symptoms in another patient, which were considered possibly related to treatment.

In October 2016, upon review of these findings, we announced early closure of GOG-0265. Results from the GOG-0265 study were presented as an oral late-breaker presentation at the Society of Gynecologic Oncology (“SGO”) annual meeting on March 14, 2017. Based on these data, we plan on pursuing regulatory opportunities for this unmet medical need in Europe in 2017.

We have entered into a clinical development collaboration agreement with BMS to evaluate their PD-1 immune checkpoint inhibitor, OPDIVO® (nivolumab), in combination with ADXS-DUAL as a potential treatment option for women with metastatic cervical cancer. We plan to file our IND application for ADXS-DUAL in 2017. Pending FDA feedback, we plan to initiate a global, randomized, registrational quality trial in 1H 2018 and will evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy. Under the terms of the agreement, each party will bear its own internal costs and provide its immunotherapy agents. Advaxis will sponsor the study and pay third-party costs. Subject to the positive outcome of this study, we plan to file a BLA for approval of ADXS-DUAL for metastatic cervical cancer in combination treatment.

Axalimogene filolisbac has received FDA orphan drug designation for invasive FIGO Stage II-IV cervical cancer, and has received Fast Track designation from the FDA for high-risk locally advanced cervical cancer patients. Axalimogene filolisbac has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s Committee for Advanced Therapies (“CAT”). The CAT is the EMA’s committee responsible for assessing the quality, safety and efficacy of ATMPs. The Company has completed the CAT certification procedure and the CAT has certified the preclinical and quality information have met the scientific and technical standards for a MAA.

### 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 70% of these cancers are caused by HPV, with the incidence increasing every year. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. According to the 2017 American Cancer Society data report, approximately 30,000 new cases will be diagnosed in the United States in 2017.

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

We will continue to be opportunistic as it relates to IST development in HPV-positive head and neck cancer patients.

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

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

### Anal Cancer

According to the American Cancer Society, nearly all squamous cell anal cancers are linked to infection by HPV, the same virus that causes cervical cancer. According to the 2017 American Cancer Society data report, approximately 8,200 new cases will be diagnosed in the United States in 2017.

The safety and efficacy of axalimogene filolisbac was 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 December 2016, 11 patients were enrolled and all patients who have completed radiation treatment and received treatment experienced a



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

six-month complete response (n=9), with no evidence of recurrence. Eight of 9 patients (89%) are disease-free at a median follow-up of 34 months. No further enrollment in this study is planned. These data were accepted and published in the on-line journal at American Society of Clinical Oncology (“ASCO”) 2017.

We are conducting a Phase 2 multi-center, open-label, Simon two-stage study (“FAWCETT” or “Fighting Anal-Cancer with CTL Enhancing Tumor Therapy”), testing axalimogene filolisbac in patients with persistent or recurrent metastatic anal cancer. FAWCETT is designed to evaluate the efficacy and safety of axalimogene filolisbac as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. Patients will receive IV axalimogene filolisbac monotherapy ( $1 \times 10^9$  CFU) every 3 weeks for  $\leq 2$  years or until a discontinuation criterion is met. Stage 1 of the trial targeted enrollment of 36 patients with anal cancer whose disease recurred after receiving treatment, with an interim analysis planned on enrollment of 31 evaluable pts ( $\geq 1$  post-baseline scan) and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment.

Preliminary Stage 1 results from 29 of the planned evaluable patients showed 1 (3.5%) patient had a durable partial response lasting  $> 6$  months (after progression on prior anti-PD-1 therapy) and 7 had stable disease (24%). Disease control rate was 28%. The current Kaplan Meier 6-month PFS estimate is 22%, indicating the study can proceed to Stage 2 of enrollment. Common ( $\geq 30\%$ ) TRAEs were grade 1-2 chills/rigors, fever, hypotension and vomiting. Grade 3 TRAEs of cytokine related symptoms (n=1; SAE), infusion related reactions (n=2; 1 SAE) and hypotension (n=2; 1 SAE) were reported. These results were reported at the annual meeting of the European Society for Medical Oncology (ESMO) in September 2017.

The Company is evaluating the potential for collaborative external opportunities to further develop our HPV program in anal cancer.

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

#### *ADXS-PSA Franchise*

#### Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in seven will get prostate cancer during his lifetime, and one man in 36 will die of this disease. According to the 2017 American Cancer Society data report, approximately 161,000 new cases will be diagnosed in the United States in 2017.

ADXS-PSA is an *Lm*-based antigen delivery product designed to target the PSA antigen commonly overexpressed in prostate cancer.

We have entered into a clinical trial collaboration and supply agreement with Merck & Co. (“Merck”) to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose escalation and expansion study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, cohorts were successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The ADXS-PSA monotherapy dose-determination phases of the trial have been completed. The Recommendation Phase 2 Dose (“RP2D”) is  $1 \times 10^9$  ADXS-PSA and 200 mg KEYTRUDA® (pembrolizumab). Enrollment in the expansion cohort phase using the RP2D combination is underway.

Preliminary data identifying potential pharmacodynamics biomarkers of clinical response and preliminary immune correlative data in mCRPC patients treated with ADXS-PSA monotherapy, as well as preclinical data regarding molecular biomarkers associated with tumor regression in a murine HPV+ tumor model were presented at the third annual CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in September 2017.

#### *ADXS-NEO Franchise*

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

ADXS-NEO is an individualized *Lm*-based antigen delivery product combined with a fusion protein based on information captured by whole-genome sequencing of a patient’s tumor and comparing the patient’s DNA from normal tissue with that from the patient’s tumor. It will target multiple patient-specific neoantigens resulting from those mutations that are not present in normal cells. Each ADXS-NEO construct is designed to target the non-synonymous mutations found in the tumor, which is unique to each patient’s cancer. ADXS-NEO works by presenting a large payload of neoantigens directly into dendritic cells within the patient’s immune system and stimulating a T-cell response against cancerous cells. The FDA has cleared the IND application of our new precision immunotherapy (ADXS-NEO) for the treatment of cancers and we plan to initiate a Phase 1 study in first half of 2018. The initial tumor types for the Phase 1 are metastatic colon, head and neck, and non-small cell lung cancers.

Clinical studies using ADXS-NEO are in active development in collaboration with our partner, Amgen. Further, we have entered into various research collaborations, including the Parker Institute for Cancer Immunotherapy, to advance the study of neopeptide-based, personalized cancer therapy as part of the Tumor neoantigen Selection Alliance (“TESLA”) initiative.

#### *ADXS-HOT Franchise (preclinical)*

We are developing multiple *Lm*-based products that could target common (public or shared) or “hot-spot” mutations in tumor driver genes. ADXS-HOT products may target acquired public mutations in tumor driver genes that are shared by multiple patients, and could have greater immunogenicity than the natural sequence peptides in normal cells. DNA sequencing is not required, and the ADXS-HOT products are expected to be “off the shelf” and ready to administer for multiple patients. The Company plans to file INDs in 2018.

#### *ADXS-HER2 Franchise*

##### HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to the SEER database and recent published literature, approximately 60-70% of osteosarcoma are HER2 positive, which is associated with poor outcomes for patients.

ADXS-HER2 is an *Lm*-based antigen delivery product designed to target HER2 expressing solid tumors including human and canine osteosarcoma. The dose finding phase of the trial is complete. The Company has evaluated the data and decided not to proceed to the expansion phase of the trial. In addition, based on the Company’s priorities, the ADXS-HER2 development program, which includes Pediatric Osteosarcoma, will be discontinued but remains open to investigator-initiated research or licensing proposals.

##### Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana Therapeutics Inc. (“Aratana”), where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that

will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request has been filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the USDA. Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed and data, when available, needs to be analyzed, including in the areas of manufacturing and safety, we understand that Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017. The Company does not anticipate significant revenue from this collaboration in 2017. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals. Aratana is further responsible for the conduct of clinical research with ADXS-Survivin in canine/feline lymphoma, as well as pending investigations of two additional Advaxis constructs in animals.

*Strategic Clinical Collaborations, focused on combination therapies*

#### Axalimogene filolisbac and Durvalumab

As further described above, we have entered into a clinical trial collaboration agreement with MedImmune to conduct a Phase 1/2, open-label, multicenter, two part study to evaluate safety and efficacy of axalimogene filolisbac, in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. For the axalimogene filolisbac and durvalumab dose escalation portion of the study, the dose-escalation cohort has been completed. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases. Accrual is ongoing.

#### ADXS-DUAL and OPDIVO® (nivolumab)

As further described above, we have entered into a clinical development collaboration agreement with BMS to evaluate their PD-1 immune checkpoint inhibitor, OPDIVO® (nivolumab), in combination with ADXS-DUAL as a potential treatment option for women with metastatic cervical cancer. Pending FDA feedback, we plan to initiate a global, randomized, registrational quality trial in 1H 2018 and will evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy.

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

As further described 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, dose escalation and expansion study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, cohorts were successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The ADXS-PSA monotherapy portion of this clinical trial has been completed and accrual and patient treatment has begun in the cohort combining ADXS-PSA and KEYTRUDA<sup>®</sup> (pembrolizumab).

**RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JULY 31, 2017 AND 2016***Revenue*

During the quarter ended July 31, 2017, the Company recorded revenue of \$3,051,620. The Company recognized revenue from the collaboration agreement with Amgen related to amortization of the upfront fees received.

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

*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 expenses for the three months ended July 31, 2017 and 2016 were categorized as follows:

	Three Months Ended July 31,	
	2017	2016
Axalimogene filolisbac Franchise	\$5,686,197	\$2,698,005
ADXS-PSA Franchise	1,366,225	564,831
ADXS-HER2 Franchise	519,790	476,644
ADXS-NEO Franchise	553,289	373,006
Personnel Expenses	6,455,302	3,301,179
Professional Fees	5,751,377	1,520,417
Laboratory Costs	2,560,697	994,686
Other Expenses	905,262	213,464
Partner Reimbursements	(6,000,000 )	-
Total Research & Development Expense	\$17,798,139	\$10,142,232

*Axalimogene Filolisbac Franchise*

Axalimogene filolisbac expenses were \$5,686,197 for the three months ended July 31, 2017 compared to \$2,698,005 for the three months ended July 31, 2016, an increase of \$2,988,192. The increase resulted from startup activities for additional countries in the Phase 3 AIM2CERV study.

*ADXS-PSA Franchise*

PSA expenses were \$1,366,225 for the three months ended July 31, 2017 as compared to \$564,831 for the three months ended July 31, 2016, an increase of \$801,394. The increase resulted from higher costs incurred due to the active enrollment of an expansion cohort on the Phase 1/2 study in combination with Merck's KEYTRUDA® (pembrolizumab).

*ADXS-HER2 Franchise*

HER2 expenses were \$519,790 for the three months ended July 31, 2017 compared to \$476,644 for the three months ended July 31, 2016, an increase of \$43,146. HER2 expenses during the three months ended July 31, 2017 were consistent with the comparable prior period.

*ADXS-NEO Franchise*

NEO expenses were \$553,289 for the three months ended July 31, 2017 compared to \$373,006 for the three months ended July 31, 2016, an increase of \$180,283. The increase was attributable to Phase 1 start-up costs incurred during the three months ended July 31, 2017.

*Personnel Expenses*

Personnel expenses were \$6,455,302 for the three months ended July 31, 2017 compared to \$3,301,179 for the three months ended July 31, 2016, an increase of \$3,154,123. The increase was attributable to an increase in headcount.

*Professional Fees*



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

Professional fees were \$5,751,377 for the three months ended July 31, 2017 compared to \$1,520,417 for the three months ended July 31, 2016, and increase of \$4,230,960. The increase was attributable to an increase in drug manufacturing process validation costs and drug stability studies.

*Laboratory Costs*

Laboratory costs were \$2,560,697 for the three months ended July 31, 2017 compared to \$994,686 for the three months ended July 31, 2016, an increase of \$1,566,011. An increase in technical operation support as well as the expansion of laboratory space accounted for the increase.

*Other Expenses*

Other expenses were \$905,262 for the three months ended July 31, 2017 compared to \$213,464 for the three months ended July 31, 2016, an increase of \$691,798. The increase was due to additional infrastructure costs incurred to support the increased headcount and laboratory expansion.

*Partner Reimbursements*

Partner reimbursements for the three months ended July 31, 2017 were \$6,000,000. For the three months ended July 31, 2017, the Company received clinical development payments from Amgen for ADXS-NEO totaling \$4,500,000 and recorded an additional expected payment of \$1,500,000, which was received in August 2017.

*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 \$18.1 million for the three months ended July 31, 2017, compared with approximately \$6.4 million for the three months ended July 31, 2016, an increase of approximately \$11.7 million. The increase is primarily attributable to stock and cash compensation expense for past employees, of which approximately \$9.5 million was a non-cash expense. In addition, there was an increase to legal costs on general corporate matters.

*Interest Income*

Interest income was \$184,479 for the three months ended July 31, 2017, compared with \$73,872 for the three months ended July 31, 2016. The increase in interest income earned was attributable to an increase in interest rates as well as cash resulting from sales of the Company's common share and an up-front payment received in conjunction with the collaboration agreement with Amgen. The cash was invested in held-to-maturity investments and a savings account.

*Changes in Fair Values*

For the three months ended July 31, 2017, the Company recorded \$0 non-cash income as the fair value of the warrant liability remained \$0. Most of the liability warrants have expired and the remaining liability warrants expire in August 2017.

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

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED JULY 31, 2017 AND 2016***Revenue*

During the nine months ended July 31, 2017, the Company recorded revenue of \$10,267,842. The Company recognized \$10,017,842 of revenue from the collaboration agreement with Amgen related to amortization of the upfront fees received. In addition, \$250,000 of revenue was due to the receipt of an annual exclusive license fee from GBP for the development and commercialization of axalimogene filolisbac.

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

*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 expenses for the nine months ended July 31, 2017 and 2016 were categorized as follows:

	Nine Months Ended July 31,	
	2017	2016
Axalimogene filolisbac Franchise	\$ 14,652,010	\$ 8,232,741
ADXS-PSA Franchise	3,015,505	1,582,037
ADXS-HER2 Franchise	1,510,336	1,409,379
ADXS-NEO Franchise	1,597,141	780,092
Personnel Expenses	17,010,426	13,600,354
Professional Fees	10,450,279	4,117,140
Laboratory Costs	6,661,265	1,632,662
Other Expenses	1,858,467	611,191
Partner Reimbursements	(9,000,000 )	-
Total Research & Development Expense	\$ 47,755,429	\$ 31,965,596

*Axalimogene Filolisbac Franchise*

Axalimogene filolisbac expenses were \$14,652,010 for the nine months ended July 31, 2017 compared to \$8,232,741 for the nine months ended July 31, 2016, an increase of \$6,419,269. The increase resulted from an increase in startup activities for additional countries in AIM2CERV.

*ADXS-PSA Franchise*

PSA expenses were \$3,015,505 for the nine months ended July 31, 2017 as compared to \$1,582,037 for the nine months ended July 31, 2016, an increase of \$1,433,468. The increase resulted from higher costs incurred due to the active enrollment of an expansion cohort on the Phase 1/2 study in combination with Merck's KEYTRUDA® (pembrolizumab).

*ADXS-HER2 Franchise*

HER2 expenses were \$1,510,336 for the nine months ended July 31, 2017 compared to \$1,409,379 for the nine months ended July 31, 2016, an increase of \$100,957. HER2 expenses during the nine months ended July 31, 2017 were consistent with the comparable prior period.

*ADXS-NEO Franchise*

NEO expenses were \$1,597,141, for the nine months ended July 31, 2017 compared to \$780,092 for the nine months ended July 31, 2016, an increase of \$817,049. The increase was attributable to Phase 1 start-up costs incurred during the nine months ended July 31, 2017.

*Personnel Expenses*

Personnel expenses were \$17,010,426 for the nine months ended July 31, 2017 compared to \$13,600,354 for the nine months ended July 31, 2016, an increase of \$3,410,072. The increase was attributable to an increase in headcount that was somewhat offset by stock based compensation for past employees in the prior period.

*Professional Fees*

Professional fees were \$10,450,279 for the nine months ended July 31, 2017 compared to \$4,117,140 for the nine months ended July 31, 2016, an increase of \$6,333,139. The increase was attributable to an increase in drug manufacturing process validation costs and drug stability studies.

*Laboratory Costs*

Laboratory costs were \$6,661,265 for the nine months ended July 31, 2017 compared to \$1,632,662 for the nine months ended July 31, 2016, an increase of \$5,028,603. An increase in technical operation support as well as the expansion of laboratory space accounted for the increase.

*Other Expenses*

Other expenses were \$1,858,467 for the nine months ended July 31, 2017 compared to \$611,191 for the nine months ended July 31, 2016, an increase of \$1,247,726. The increase was due to additional infrastructure costs incurred to support the increased headcount, laboratory expansion and abandoned patent applications.

*Partner Reimbursements*

Partner reimbursements for the nine months ended July 31, 2017 were \$9,000,000. For the nine months ended July 31, 2017, the Company received clinical development payments from Amgen for work performed on ADXS-NEO totaling \$4,500,000 and recorded an additional expected payment of \$1,500,000, which was received in August 2017. In addition, the Company received \$3,000,000 in Support Payments from Stendhal for work performed on AXAL.

*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 were approximately \$33.2 million for the nine months ended July 31, 2017, compared with

approximately \$20.4 million for the nine months ended July 31, 2016, an increase of approximately \$12.8 million. The increase is primarily attributable to stock and cash compensation expense for past employees, of which approximately \$9.5 million was a non-cash expense. In addition, there was an increase to legal costs on general corporate matters, office expenses that resulted from an increase in headcount, and a litigation settlement.

#### *Interest Income*

Interest income was \$514,363 for the nine months ended July 31, 2017, compared with \$216,061 for the nine months ended July 31, 2016. The increase in interest income earned was attributable to an increase in interest rates as well as cash resulting from sales of the Company's common share and an up-front payment received in conjunction with the collaboration agreement with Amgen. The cash was invested in held-to-maturity investments and a savings account.

#### *Changes in Fair Values*

For the nine months ended July 31, 2017, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$20,156 due to a smaller range of share prices used in the calculation of the Black-Scholes Model ("BSM") volatility input and the expiration of most of the liability warrants.

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

#### *Income Tax Expense*

During the nine months ended July 31, 2017, we paid \$50,000 in Taiwanese withholding taxes in connection with the revenue generated from an annual exclusive license fee from GBP.

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





## Liquidity and Capital Resources

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through August 2017, we raised approximately \$222.5 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. As of July 31, 2017, the Company had approximately \$89.4 million in cash, cash equivalents and investments on its balance sheet. We believe our current cash position is sufficient to fund our business plan approximately into fiscal 2019. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through July 31, 2017, the Company has reported accumulated net losses of approximately \$277.9 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities for the nine months ended July 31, 2017 was approximately \$58.5 million (including proceeds from the sale of our state NOLs and Research and Development (R&D) tax credits of approximately \$2.5 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

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

Cash used in investing activities for the nine months ended July 31, 2017 was approximately \$39.6 million resulting from investments in held-to-maturity investments, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

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

Cash provided by financing activities for the nine months ended July 31, 2017 was approximately \$380,000. The Company sold 92,145 shares of common stock under an at-the-market facility for net proceeds of approximately \$706,000. This was partially offset by approximately \$354,000 in taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities for the nine months ended July 31, 2016 was approximately \$528,000, resulting from approximately \$614,000 in proceeds received on option and warrant exercises. This was partially offset by approximately \$53,000 in taxes paid related to the net share settlement of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of July 31, 2017 and October 31, 2016, we had an accumulated deficit of \$277,881,078 and \$207,706,825, respectively, and shareholders' equity of \$74,359,192 and \$119,302,194, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately into fiscal 2019. 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.

### **Contractual Commitments and Obligations**

The disclosure of our contractual obligations and commitments was reported in our Annual Report on Form 10-K for the year ended October 31, 2016. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report on Form 10-K other than the changes described in Note 10, "Commitments and Contingencies" in this Quarterly Report on Form 10-Q.

**Off-Balance Sheet Arrangements**

As of July 31, 2017, we had no off-balance sheet arrangements.

### **Critical Accounting Estimates**

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

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

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

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

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

### **New Accounting Pronouncements**

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

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

At July 31, 2017, the Company had approximately \$89.4 million in cash, cash equivalents and investments, which consisted primarily of bank deposits, money market funds and short-term investments such as certificates of deposit, domestic governmental agency loans and U.S treasury notes. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

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

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

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

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

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

During the quarter ended July 31, 2017, 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, 2016.

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

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

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

On May 10, 2017, the registrant issued 20,000 shares of Common Stock to an accredited investor as payment for consulting services.

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

On May 19, 2017, the registrant issued 8,737 shares of Common Stock to accredited investors as payment for consulting services.

On May 31, 2017, the registrant issued 1,299 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On June 30, 2017, the registrant issued 2,324 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On July 31, 2017, the registrant issued 1,108 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On August 17, 2017, the registrant issued 30,358 shares of Common Stock to accredited investors as payment for consulting services.

On August 31, 2017, the registrant issued 903 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

### Treasury Share Repurchases

The following table represents treasury share repurchases during the three months ended July 31, 2017:

	(a) Total Number of Shares Purchased (1)	(b) Average Price Paid Per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program
May 1, 2017 – May 31, 2017	-	\$ -	N/A	N/A
June 1, 2017 – June 30, 2017	-	\$ -	N/A	N/A
July 1, 2017 – July 31, 2017	119,128	\$ 6.70	N/A	N/A
Total	119,128	\$ 6.70	N/A	N/A

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



**ITEM 6. EXHIBITS**

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

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

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

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

101.INS XBRL INSTANCE DOCUMENT

101.SCH XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

101.CAL XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

101.DEF XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

101.LAB XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith

**SIGNATURES**

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

**ADVAXIS, INC.**

Registrant

Date: September 11, 2017 By: */s/ Anthony A Lombardo*  
Anthony A. Lombardo  
Interim Chief Executive Officer

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

