

Advaxis, Inc.
Form 10-Q
March 10, 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 January 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

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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of March 7, 2017 was 40,295,359.

INDEX

	Page No.
PART I FINANCIAL INFORMATION	
Item 1. <u>Condensed Financial Statements (unaudited)</u>	
<u>Condensed Balance Sheets at January 31, 2017 (unaudited) and October 31, 2016</u>	F-1
<u>Condensed Statements of Operations for the three month periods ended January 31, 2017 and 2016 (unaudited)</u>	F-2
<u>Condensed Statements of Cash Flow for the three month periods ended January 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>	12
Item 4. <u>Controls and Procedures</u>	12
PART II OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	13
Item 1A. <u>Risk Factors</u>	13
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	13
Item 6. <u>Exhibits</u>	14
<u>SIGNATURES</u>	15

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 obtain and maintain approval of our product candidates for trial initiation;
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-K. 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**

	January 31, 2017 (unaudited)	October 31, 2016
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$57,566,606	\$112,750,980
Investments – Held-to-Maturity	79,295,379	39,336,548
Interest Receivable	180,964	80,142
Prepaid Expenses	577,770	812,830
Income Tax Receivable	-	2,549,862
Deferred Expenses - current	4,435,025	4,291,385
Other Current Assets	132,797	53,451
Total Current Assets	142,188,541	159,875,198
Property and Equipment (net of accumulated depreciation)	5,242,857	4,389,074
Intangible Assets (net of accumulated amortization)	4,336,143	4,329,121
Other Assets	426,287	450,667
TOTAL ASSETS	\$152,193,828	\$169,044,060
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$3,534,440	\$1,720,428
Accrued Expenses	7,676,443	10,905,003
Deferred Revenue	14,047,906	15,020,576
Lease Incentive Obligation	40,226	40,226
Common Stock Warrant Liability	10,652	20,156
Total Current Liabilities	25,309,667	27,706,389
Deferred Rent	534,160	475,749
Deferred Revenue	18,666,396	21,234,568
Lease Incentive Obligation- net of current portion	315,104	325,160
Total Liabilities	44,825,327	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 January 31, 2017 and October 31, 2016.	-	-
Liquidation preference of \$0 at January 31, 2017 and October 31, 2016.		
Common Stock - \$0.001 par value; 65,000,000 shares authorized, 40,186,693 shares issued and outstanding at January 31, 2017 and 40,057,067 shares issued and 40,041,047 shares outstanding at October 31, 2016.	40,187	40,057
Additional Paid-In Capital	332,116,142	327,098,749
Treasury Stock, at cost, 0 shares at January 31, 2017 and 16,020 shares October 31, 2016	-	(129,787)
Accumulated Deficit	(224,787,828)	(207,706,825)
Total Shareholders' Equity	107,368,501	119,302,194
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$152,193,828	\$169,044,060

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

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

	Three Months Ended January 31,	
	2017	2016
Revenue	\$3,790,842	\$250,000
Operating Expenses:		
Research and Development Expenses	13,648,554	13,064,954
General and Administrative Expenses	7,327,809	7,136,823
Total Operating Expenses	20,976,363	20,201,777
Loss from Operations	(17,185,521)	(19,951,777)
Other Income (Expense):		
Interest Income	145,137	71,800
Net Changes in Fair Value of Derivative Liabilities	9,504	49,282
Other Income (Expense), Net	(123)	(4)
Loss before benefit for income taxes	(17,031,003)	(19,830,699)
Income Tax Expense	50,000	14,236
Net Loss	\$(17,081,003)	\$(19,844,935)
Net Loss Per Share, Basic and Diluted	\$(0.43)	\$(0.59)
Weighted Average Number of Shares Outstanding, Basic and Diluted	40,115,178	33,684,715

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

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

	Three Months Ended January 31,	
	2017	2016
OPERATING ACTIVITIES		
Net loss	\$(17,081,003)	\$(19,844,935)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	5,110,425	9,529,008
(Gain) on change in fair value of derivative liabilities	(9,504)	(49,282)
Employee stock purchase plan	67,923	9,673
Depreciation expense	157,580	46,034
Amortization of intangible assets	74,410	57,946
Deferred rent	58,411	11,182
Lease incentive obligation	(10,056)	
Amortization of premium on held to maturity investments	44,005	82,491
Change in operating assets and liabilities:		
Interest receivable	(100,822)	(7,008)
Prepaid expenses	235,060	132,075
Income tax receivable	2,549,862	1,609,349
Other current assets	(79,346)	(135,823)
Deferred expenses	(143,640)	569,284
Other assets	24,380	(152,375)
Accounts payable and accrued expenses	(1,454,011)	3,250,088
Deferred revenue	(3,540,842)	-
Net cash used in operating activities	(14,097,168)	(4,892,293)
INVESTING ACTIVITIES		
Purchases of held to maturity investments	(46,525,169)	(5,068,339)
Proceeds from maturities and redemptions on held to maturity investments	6,522,333	2,450,000
Purchase of property and equipment	(1,127,000)	(445,197)
Cost of intangible assets	(81,432)	(170,391)
Net cash used in investing activities	(41,211,268)	(3,233,927)
FINANCING ACTIVITIES		
Proceeds from exercise of warrants	-	614,368
Taxes paid related to net share settlement of equity awards	(9,810)	(17,709)
Employee tax withholdings paid on equity awards	(204,614)	(698,398)
Tax shares sold to pay for employee tax withholdings on equity awards	338,486	336,754
Net cash provided by financing activities	124,062	235,015
Net decrease in cash and cash equivalents	(55,184,374)	(7,891,205)

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

Cash and cash equivalents at beginning of period	112,750,980	66,561,683
Cash and cash equivalents at end of period	\$57,566,606	\$58,670,478

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

F-3

Supplemental Disclosures of Cash Flow Information

	Three months ended January 31,	
	2017	2016
Cash paid for taxes	\$50,000	\$50,000

Supplemental Schedule of Non-Cash Investing and Financing Activities

	Three months ended January 31,	
	2017	2016
Accrued expenses from consultants settled with Common Stock	\$75,000	\$55,000
Sale of treasury shares pending settlement	\$-	\$2,144
Property and equipment included in accounts payable and accrued expenses	\$115,637	\$-

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

ADVAXIS, INC.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. NATURE OF OPERATIONS

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

Axalimogene filolisbac is our lead *Lm*-based product candidate for the treatment of Human Papilloma Virus (“HPV”) - associated cancers. The Company completed a randomized Phase 2 study in 110 patients with recurrent cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”) Foundation, Inc., now part of NRG Oncology, conducted a cooperative group / Company sponsored Phase 2 open-label clinical study of axalimogene filolisbac in patients with persistent or recurrent cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed the first and second stages in its Simon 2-stage design. The results from both stages combined demonstrate a 38% 12-month overall survival. Upon early closure of this study, a total of 50 patients were dosed resulting 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 is planning to initiate a registrational Phase 3 clinical trial in 2017 in the metastatic cervical cancer setting. The Company also plans to pursue registrational opportunities in Europe in 2017 for the metastatic cervical cancer setting.

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 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 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 is being evaluated in a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. The Company received orphan drug designation from both the FDA and EMA for ADXS-HER2 in osteosarcoma and have received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. Clinical research with ADXS-HER2 in canine osteosarcoma is being developed by 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 technology 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 of a new precision immunotherapy for the treatment of cancers. The Company plans to initiate a Phase 1 study in 2017.

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 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. The Company is exploring a preclinical infectious disease program as well to examine potential applications of its *Lm* Technology™. Lastly, the Company is continuing to build-out its manufacturing capabilities 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 January 31, 2017, the Company had approximately \$136.9 million in cash, cash equivalents and investments on its balance sheet. The Company believes its current cash position is sufficient to fund its business plan approximately through the second quarter of fiscal 2019. The estimate is based on assumptions that may prove to be wrong, and the Company could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of its current product candidates.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation - Unaudited Interim Financial Information

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information, and in accordance with the rules and regulations of the SEC with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, necessary to represent a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 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. Generally Accepted Accounting Principles (“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 property and equipment intangible assets (patents and licenses), the fair value of investments, the fair value of options, the fair value of 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.

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 January 31, 2017 and October 31, 2016, the Company had approximately \$49.0 million and \$106.7 million in cash equivalents.

Concentration of Credit Risk

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$53.9 million is subject to credit risk at January 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.

Fair Value of Financial Instruments

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

Net Loss per Share

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

	As of January 31,	
	2017	2016
Warrants	3,110,575	3,110,575
Stock Options	3,897,558	3,357,074
Restricted Stock Units	1,111,059	975,256
Convertible Debt (using the if-converted method)	-	1,576
Total	8,119,192	7,442,905

F-7

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

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

In February 2016, the FASB issued ASU 2016-02, “Leases (“Topic 842”) (“ASU 2016-02”). The standard amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective beginning in the first quarter of 2019. Early adoption of ASU 2016-02 is permitted. The new leases standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company’s financial statements.

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

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

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 January 31, 2017 and October 31, 2016:

	January 31, 2017			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$25,010,270	\$ -	\$ -	\$25,010,270
Domestic Governmental Agency Loans	5,664,336	49	512	5,663,873
U.S Treasury Notes	48,620,773	3,591	8,569	48,615,795
Total short-term investment securities	\$79,295,379	\$ 3,640	\$ 9,081	\$79,289,938

	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:

January 31, 2017	October 31, 2016
---------------------	---------------------

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

Leasehold Improvements	\$1,972,498	\$1,835,602
Laboratory Equipment	2,839,843	2,038,704
Furniture and Fixtures	637,761	549,025
Computer Equipment	285,209	240,910
Construction in Progress	91,661	151,368
Total Property and Equipment	5,826,972	4,815,609
Accumulated Depreciation and Amortization	(584,115)	(426,535)
Net Property and Equipment	\$5,242,857	\$4,389,074

Depreciation expense for the three months ended January 31, 2017 and 2016 was \$157,580 and \$46,034 respectively.

5. INTANGIBLE ASSETS

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

	January 31, 2017	October 31, 2016
License	\$776,992	\$776,992
Patents	5,056,042	4,980,610
Software	25,625	19,625
Total intangibles	5,858,659	5,777,227
Accumulated Amortization	(1,522,516)	(1,448,106)
Intangible Assets	\$4,336,143	\$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. No patent applications with future value were abandoned or expired and charged to expense in the three months ended January 31, 2017 or 2016. Amortization expense for intangible assets is included in research and development expenses and aggregated \$74,410 and \$57,946 for the three months ended January 31, 2017 and 2016, respectively.

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

Year ended October 31,

2017 (Remaining)	\$223,000
2018	299,000
2019	296,000
2020	290,000
2021	290,000

6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	January 31, 2017	October 31, 2016
Salaries and Other Compensation	\$2,799,348	\$2,467,650
Vendors	2,882,186	2,098,792
Professional Fees	1,994,909	6,338,561
	\$7,676,443	\$10,905,003

7. DERIVATIVE INSTRUMENTS

Warrants

A summary of changes in warrants for the three months ended January 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	-	\$ -
Expired	-	\$ -
Outstanding Warrants at January 31, 2017	3,110,575	\$ 5.04

At January 31, 2017 and October 31, 2016, the Company had approximately 3.09 million of its total 3.11 million outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders' equity section of the balance sheet. The Company's equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions.

Warrant Liability

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

At January 31, 2017 and October 31, 2016, the fair value of the warrant liability was \$10,652 and \$20,156, respectively. For the three months ended January 31, 2017 and 2016, the Company reported a gain of \$9,504 and \$49,282, respectively, due to changes in the fair value of the warrant liability. In determining the fair value of the warrant liability, at January 31, 2017 and October 31, 2016, the Company used the following inputs in its BSM:

	January 31, 2017	October 31, 2016
Exercise Price	\$10.63-18.75	\$ 10.63-18.75
Stock Price	\$8.96	\$8.09
Expected term	0.29-0.50 years	0.55-0.75 years
Expected Volatility	60.72%-81.39 %	81.84%-87.09 %
Risk Free Interest Rate	0.52%-0.64 %	0.51%-0.66 %

As of January 31, 2017, there were outstanding warrants to purchase 3,110,575 shares of the Company's Common Stock with exercise prices ranging from \$3.75 to \$18.75 per share.

As of January 31, 2017, the aggregate intrinsic value of outstanding warrants was approximately \$12,248,000.

8. SHARE BASED COMPENSATION

Employment Agreements

Management voluntarily purchases restricted stock directly from the Company at market price. The respective stock purchases occur on the last trading day of each month. This voluntary election is outlined in each of Daniel J. O'Connor, Chief Executive Officer and President, Robert G. Petit, Executive Vice President, Chief Scientific Officer, and Sara M. Bonstein, Executive Vice President and Secretary, Chief Financial Officer, (each an "Executive"), employment agreements. The table below reflects the purchases of each Executive:

Executive	ANNUALIZED		
	Annual Amount to be Purchased	For the Three Months Ended January 31, 2017	
		Gross Purchase	Net Purchase
	\$	\$	\$
		# of shares	# of shares
Daniel J. O'Connor	\$ 54,547	\$13,627 1,713	\$10,644 1,335
Robert G. Petit	\$ 33,061	\$8,212 1,032	\$6,699 842
Sara M. Bonstein	\$ 29,261	\$7,333 922	\$5,033 623

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

For the three months ended January 31, 2017, the Company recorded stock compensation expense of \$42,016 in the statement of operations for the portion of management salaries voluntarily paid in stock representing 5,316 shares of its Common Stock (4,071 shares on a net basis after employee payroll taxes). For the three months ended January 31, 2016, the Company recorded a similar stock compensation expense of \$64,332 in the statement of operations representing 7,060 shares of its Common Stock (4,947 shares on a net basis after employee payroll taxes).

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

Restricted Stock Units (RSUs)

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

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2016:	719,448	\$ 10.77
Granted	487,282	\$ 8.35
Vested	(87,235)	\$ 8.62
Cancelled	(8,436)	\$ 8.31
Balance at January 31, 2017	1,111,059	\$ 9.89

As of January 31, 2017, there was approximately \$9,175,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 2.28 years.

As of January 31, 2017, the aggregate intrinsic value of non-vested RSUs was approximately \$9,955,000.

F-11

Employee Stock Awards

During the three months ended January 31, 2017, 88,660 shares of Common Stock were issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards. Total stock compensation expense associated with these awards was \$1,314,623.

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

Furthermore, non-executive employees were entitled to receive a performance-based year-end cash bonus. Several non-executive employees voluntarily requested to be paid all or a portion of their cash bonus in the Company's Common Stock instead of cash. During the three months ended January 31, 2016, the Company recorded a liability on its balance sheet for \$102,022 for bonuses that will be paid in Common Stock.

Director Stock Awards

During the three months ended January 31, 2017, total stock compensation expense to the Directors for amortization of unvested awards was \$101,628.

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

Stock Options

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

Number of Options	Weighted-Average Exercise Price
----------------------	------------------------------------

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

Outstanding at October 31, 2016:	3,351,795	\$	13.31
Granted	556,952	\$	7.71
Exercised	-	\$	-
Expired	(11,189)	\$	17.88
Outstanding at January 31, 2017	3,897,558	\$	12.50
Vested and Exercisable at January 31, 2017	1,800,252	\$	13.46

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended January 31, 2017 was \$3,183,458. For the three months ended January 31, 2016, compensation cost related to the Company's outstanding stock options was \$6,671,986.

During the three months ended January 31, 2017, 556,952 options were granted with a total grant date fair value of \$3,542,215. During the three months ended January 31, 2016, 1,385,000 options were granted with a total grant date fair value of \$14,837,970.

As of January 31, 2017, there was approximately \$19,688,000 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 1.65 years.

As of January 31, 2017, the aggregate intrinsic value of vested and exercisable options was approximately \$74,000.

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

	Three Months Ended January 31,	
	2017	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 January 31, 2017, 32,500 shares of Common Stock valued at \$313,600 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 \$230,100 for shares earned pursuant to consulting agreements but not delivered. The common stock share values were based on the dates the shares vested.

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

The following table summarizes share-based compensation expense included in the Statement of Operations by expense category for the three months ended January 31, 2017 and 2016, respectively:

	Three Months Ended January 31,	
	2017	2016
Research and development	\$1,222,483	\$5,106,640
General and administrative	3,887,942	4,422,368
Total	\$5,110,425	\$9,529,008

9. COMMITMENTS AND CONTINGENCIES:*Legal Proceedings**Knoll*

On August 21, 2015, Knoll Capital Management L.P. (“KCM”) filed a complaint against the Company in the Delaware Court of Chancery. The complaint alleges the existence of an oral agreement for the purchase by Knoll from the Company of 1,666,666.67 shares of Company stock at a price of \$3.00 per share. KCM alleges that the Company breached this alleged agreement and seeks specific performance or, alternatively, money damages for breach of contract. KCM served the Company with the complaint on August 31, 2015, and then served an amended complaint

on October 16, 2015. The Company moved to dismiss the amended complaint on October 26, 2015 and that motion was denied on January 29, 2016. The Company filed an answer to the amended complaint on February 12, 2016. The parties are currently in the process of producing document discovery. A bench trial has been set for November 7, 2017. The Company intends to defend itself vigorously.

Larkin and 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. The court denied the motion to dismiss as to the breach of fiduciary duty claim and unjust enrichment claim against the three members of the Compensation Committee, but dismissed without prejudice the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants. The court dismissed without prejudice the Section 14(a) disclosure claim and waste claims against all defendants. On October 5, 2016, the court denied plaintiff's motion for reconsideration of its May 23 order.

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

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.

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

Year ended October 31,

2017 (Remaining)	\$736,397
2018	1,041,895
2019	1,107,385
2020	1,232,907
2021	1,317,640
Thereafter	5,747,340
Total	11,183,564

10. FAIR VALUE

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

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

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

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

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

The following table provides the liabilities carried at fair value measured on a recurring basis as of January 31, 2017 and October 31, 2016:

January 31, 2017	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63- \$18.75 from February 2017 through August 2017	\$ -	\$ -	\$ 10,652	\$ 10,652
October 31, 2016	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63- \$18.75 from November 2016 through August 2017	\$ -	\$ -	\$ 20,156	\$ 20,156

Common stock warrant liability:

	January 31, 2017 (Unaudited)
Beginning balance: October 31, 2016	\$ 20,156
Change in fair value	(9,504)
Balance at January 31, 2017	\$ 10,652

11. SUBSEQUENT EVENTS

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 technology 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.

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

We are a clinical-stage biotechnology company focused on the discovery, development and commercialization of our proprietary *Lm*-based antigen delivery system with our 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.

Axalimogene filoliscac Franchise

Axalimogene filoliscac is an *Lm*-based directed against HPV and designed to target cells expressing the HPV. It is currently under investigation in three HPV-associated cancers: cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination.

Cervical Cancer

There are 527,624 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2016 (“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 a third of young women being vaccinated in the United States and even less in other countries around the world.

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

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

We have reached an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for a Phase 3 trial evaluating axalimogene filolisbac in patients with high-risk, locally advanced cervical cancer (“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. 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, 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.

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

We 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 1×10^9 CFU for axalimogene filolisbac and 10 mg/kg for durvalumab. In early data reported from this ongoing trial, one patient with cervical cancer achieved a complete response, which remains ongoing after 16 months of follow-up and one patient, also with cervical cancer, achieved a partial response with subsequent disease progression. In addition, two patients with HNSCC achieved stable disease. Treatment related adverse events (“TRAE”) were reported in 91 percent 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 have been consistent with those reported in other clinical studies with axalimogene filolisbac. It was well-tolerated, with Grade 1-2 fatigue, chills, and fever the most commonly reported Adverse Events ("AE"); six patients experienced a treatment-related Grade 3 or Grade 4 AE, which was considered possibly-related to axalimogene filolisbac.

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 the clinical hold in October 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 with 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 percent using the key predictors from the patients enrolled in the study. The 12 month survival rate of 38 percent of axalimogene filolisbac represents a 52 percent improvement over the expected 12-month milestone survival rate of 24.5 percent. In the second stage of the study, 15 out of 24 patients experienced a Grade 1 or Grade 2 TRAE associated with axalimogene filolisbac infusion. The most common Grade 1 or Grade 2 TRAEs were hypotension and symptoms related to cytokine release (e.g., nausea, chills, fever). Nine out of 24 patients experienced a Grade 3 TRAE and two out of 24 patients experienced a Grade 4 TRAE, which were hypotension and symptoms related to cytokine release.

In October 2016, upon review of these findings, the Company announced early closure of GOG-0265. Based on these data, the Company plans on pursuing regulatory opportunities for this unmet medical need in Europe in 2017, and is planning to initiate a Phase 3 registrational trial in 2017 in the metastatic cervical cancer setting. Results from the GOG-0265 study will be presented at the Society of Gynecologic Oncology (“SGO”) meeting on March 14, 2017 and was selected for an oral late-breaker presentation.

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 commenced the CAT certification procedure and review of preclinical and CMC information is underway for potential inclusion in the Marketing Authorization Application.

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. Approximately 12,000 new cases will be diagnosed in the United States in 2016 according to the Surveillance, Epidemiology, and End Results (“SEER”) database.

The safety and immunogenicity of axalimogene filolisbac is being evaluated in a Phase 2 study under an investigator-sponsored IND at Mount Sinai 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 percent 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.

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 squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN.

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

Anal Cancer

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

The safety and efficacy of axalimogene filolisbac 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 treatment experienced a six-month complete response (n=9), with no evidence of recurrence. Expected complete response rate at six-months is approximately 50% and the complete response rate in this study is 90% (9 out of 10 treated patients). The follow-up duration is six-months to 33 months. In consideration of these data, no further enrollment in this study is planned and the investigator at Brown University is evaluating the opportunity to transition this study into a NCI-funded cooperative group trial to evaluate the safety and efficacy of axalimogene filolisbac in a pivotal Phase 2/3 anal cancer trial, to be conducted by NRG Oncology. In advance of the foregoing, we have entered into a clinical trial collaboration agreement with the Radiation Therapy Oncology Group (“RTOG”) Foundation for the conduct of such study. Depending on the Company’s ability to agree upon the study design and budget, the Company plans to initiate a registrational study in high-risk locally advanced anal cancer.

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. Stage 1 of the trial enrolled 36 patients with anal cancer whose disease recurred after receiving treatment. Enrollment of Stage 2 will begin following the evaluation of Stage 1 and is targeting enrollment of 60 patients. Patients will receive axalimogene filolisbac 1×10^9 CFU doses every three weeks for up to two years.

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. About 180,890 new cases will be diagnosed in the United States in 2016 according to the SEER database and accounts for approximately 11% of all new cancer cases.

ADXS-PSA is an *Lm* –based antigen delivery system 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 5×10^9 CFU and 1×10^{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[®] (pembrolizumab).

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 system designed to target HER2 expressing solid tumors including human and canine osteosarcoma. The FDA has cleared our IND application and we have initiated a Phase 1b study in patients with metastatic HER2-expressing cancers. Thereafter, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma.

Osteosarcoma

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

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

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

Canine Osteosarcoma

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

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary Medicine is conducting studies in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of naturally occurring canine osteosarcoma. In the initial study, the primary endpoint was to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study were progression-free survival and overall survival. The findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to 3.3×10^9 CFU with no evidence of significant cardiac, hematological, or other systemic toxicities. The study determined that ADXS-HER2 is able to delay or prevent metastatic disease and significantly prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). This work was recently published in the September 2016 issue of Clinical Cancer Research. Dogs receiving ADXS-HER2 following standard of care (n=18) had a progression free survival of 615 days and a median survival time of 956 days. These results compared favorably to a historical control group where the median survival time was 423 days. A second study conducted by Dr. Mason has evaluated the effects of combination palliative radiation with ADXS-HER2 on dogs with primary osteosarcoma who were unsuitable for amputation (n=15). Preliminary data was presented at the 2015 ACVIM Forum and showed that repeat doses of ADXS-HER2 administered after palliative radiation were well tolerated with no systemic or cardiac toxicity. In long-term follow-up, several dogs have experienced prolonged survival times ranging from 21 to 30 months.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana Therapeutics Inc. (“Aratana”), where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request has been filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the USDA. Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed 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.

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 individual *Lm*-based antigen delivery technology combined with a fusion protein based on information captured by comparing a patient’s own DNA with the DNA from that patient’s tumor. It will target multiple patient specific neoantigens resulting from mutations found within each individual patient’s tumor 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 the 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 2017 under our Agreement with Amgen.

The goal of MINE™ is to use our *Lm* Technology™ to develop patient specific neo-epitope targeted immunotherapies based on mutations found in an individual patient’s tumor (“ADXS-NEO”). MINE™ will first focus on a preclinical study of our new construct approach to evaluate the immunologic effects and anti-tumor activity of a personalized immunotherapy in mouse tumor models to inform subsequent clinical trials. Clinical studies using ADXS-NEO are in active development in collaboration with our partner, Amgen. Further, we have entered into various research collaboration, including the Parker Institute for Cancer Immunotherapy, to advance the study of neoepitope-based, personalized cancer therapy as part of the Tumor neoantigen Selection Alliance (“TESLA”) initiative.

ADXS-HOT Franchise (preclinical)

We are developing *Lm*-based constructs 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. ADXS-HOT products are expected to be “off the shelf” and ready to administer for multiple patients. DNA sequencing is not required and presence of the hot-spot target can usually be determined by a rapid biomarker test. The ability to combine multiple constructs may increase coverage and the potential for clinical benefit.

Lm-based Combination Franchise

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-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 5×10^9 CFU and 1×10^{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® (pembrolizumab).

Lm-based Antigen Delivery System- (preclinical)

We are developing other ways to exploit the potential of our *Lm* Technology™ including, but not limited to, the use of *Lm* Technology™ in Infectious Disease. We have various preclinical collaborations with academic and other centers of excellence to explore the potential opportunities in this disease area. Preclinical data of detoxified Listeriolysin O (“dtLLO”) shows potential use as an immunologic adjuvant or carrier for vaccinations. We intend to continue to explore the potential of dtLLO as an adjuvant molecule in cancer as well as development of potential vaccines for infectious diseases.

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

During the quarter ended January 31, 2017, the Company recorded revenue of \$3,790,842. The Company recognized \$3,540,842 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 quarter ended January 31, 2016, the Company recorded revenue of \$250,000 due to the receipt of an annual exclusive license fee from GBP for the development and commercialization of Axalimogene filolisbac.

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 January 31, 2017 and 2016 were categorized as follows:

	Three Months Ended January 31,	
	2017	2016
Axalimogene filolisbac Franchise	\$3,964,585	\$2,910,121
ADXS-PSA Franchise	886,630	597,458
ADXS-HER2 Franchise	470,964	35,150
ADXS-NEO Franchise	397,774	310,510
Personnel Expenses	4,754,838	7,412,671
Professional Fees	1,570,729	1,403,138
Laboratory Costs	1,269,731	251,688
Other Expenses	333,303	144,218
Total Research & Development Expense	13,648,554	13,064,954

Axalimogene Filolisbac Franchise

Axalimogene filolisbac expenses were \$3,964,585 for the three months ended January 31, 2017 compared to \$2,910,121 for the three months ended January 31, 2016, an increase of \$1,054,464. The increase resulted from close-out costs associated with the Phase 2 GOG-0265 trial and manufacturing related costs to support the clinical program.

ADXS-PSA Franchise

PSA expenses were \$886,630 for the three months ended January 31, 2017 as compared to \$597,458 for the three months ended January 31, 2016, an increase of \$289,172. The increase resulted from higher costs incurred on the Phase 1/2 study in combination with Merck's KEYTRUDA® (pembrolizumab).

ADXS-HER2 Franchise

HER2 expenses were \$470,964 for the three months ended January 31, 2017 compared to \$35,150 for the three months ended January 31, 2016, and increase of \$435,814. The increase was attributable to higher manufacturing costs to support the clinical program.

ADXS-NEO Franchise

NEO expenses were \$397,774 for the three months ended January 31, 2017 compared to \$310,510 for the three months ended January 31, 2016, an increase of \$87,264. The increase was attributable to pre-IND activities.

Personnel Expenses

Personnel expenses were \$4,754,838 for the three months ended January 31, 2017 compared to \$7,412,671 for the three months ended January 31, 2016, a decrease of \$2,657,833. Stock based compensation pertaining to present and past employees decreased by approximately \$3,778,000 which was partially offset by an increase in headcount.

Professional Fees

Professional fees were \$1,570,729 for the three months ended January 31, 2017 compared to \$1,403,138 for the three months ended January 31, 2016. Professional fees during the quarter ended January 31, 2017 were consistent with the comparable prior period.

Laboratory Costs

Laboratory costs were \$1,269,731 for the three months ended January 31, 2017 compared to \$251,688 for the three months ended January 31, 2016, an increase of \$1,018,043. An increase in headcount and the expansion of laboratory space accounted for the increase.

Other Expenses

Other expenses were \$333,303 for the three months ended January 31, 2017 compared to \$144,218 for the three months ended January 31, 2016, an increase of \$189,085. The increase was due to additional infrastructure costs incurred to support the increased headcount and laboratory expansion.

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

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses were approximately \$7.3 million for the three months ended January 31, 2017, compared with approximately \$7.1 million for the three months ended January 31, 2016, an increase of approximately \$0.2 million. Costs pertaining to the Company's infrastructure expansion, including leased space and information technology related costs, increased by approximately \$0.4 million. Investor relations costs increased by approximately \$0.3 million. This was partially offset by a decrease in legal costs of approximately \$0.4 million.

Interest Income

Interest income was \$145,137 for the three months ended January 31, 2017, compared with \$71,800 for the three months ended January 31, 2016. The increase in interest income earned was attributable to an increase in cash resulting from sales of the Company's common shares. The cash was invested in held-to-maturity investments and a

savings account.

Changes in Fair Values

For the three months ended January 31, 2017, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$9,504 due to a smaller range of share prices used in the calculation of the Black-Scholes Model (“BSM”) volatility input.

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

Income Tax Expense

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

Liquidity and Capital Resources

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through February 2017, we raised approximately \$221.8 million in gross proceeds from various public and private offerings of our common stock. We have not yet commercialized any drug, and we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approvals for our drug, successfully complete any post-approval regulatory obligations, successfully compete with other available treatment options in the marketplace, overcome any clinical holds that the FDA may impose and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate revenues from our drug candidates. As of January 31, 2017, the Company had approximately \$136.9 million in cash, cash equivalents and investments on its balance sheet. We believe our current cash position is sufficient to fund our business plan approximately through the second quarter of fiscal 2019. The actual amount of

cash that we will need to operate is subject to many factors.

Since our inception through January 31, 2017, we reported accumulated net losses of approximately \$224.8 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities for the three months ended January 31, 2017 was approximately \$14.1 million (including proceeds from the sale of our state NOLs and 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 three months ended January 31, 2016 was approximately \$4.9 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$1.6 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Cash used in investing activities for the three months ended January 31, 2017 was approximately \$41.2 million resulting from investments in held-to-maturity investments, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash used in investing activities for the three months ended January 31, 2016 was approximately \$3.2 million resulting from investments in held-to-maturity investments, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities for the three months ended January 31, 2017 was approximately \$124,000, resulting from net cash received related to employee withholdings of equity awards.

Cash provided by financing activities for the three months ended January 31, 2016 was approximately \$235,000, resulting from approximately \$614,000 in proceeds received on option and warrant exercises. This was partially offset by approximately \$379,000 in net cash paid related to employee withholdings of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of January 31, 2017 and October 31, 2016, we had an accumulated deficit of \$224,787,828 and \$207,706,825, respectively, and shareholders' equity of \$107,368,501 and \$119,302,194, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately through second quarter of 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 9, “Commitments and Contingencies” in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of January 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 January 31, 2017, the Company had approximately \$136.9 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 January 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 9: Commitments and Contingencies for more information on legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes in our risk factors disclosed in our Annual Report on Form 10-K for the year ended October 31, 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(2) thereof and/or Regulation D promulgated thereunder. All recipients had adequate access to information about us. We have not furnished information under this item to the extent that such information previously has been included under Item 3.02 in a Current Report on Form 8-K.

On November 16, 2016, the registrant issued 32,500 shares of Common Stock to accredited investors as payment for consulting services.

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

On November 30, 2016, the registrant issued 1,205 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 30, 2016, the Company issued 1,931 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On January 31, 2017, the Company issued 935 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On February 15, 2017, the Company issued 30,000 shares of Common Stock to accredited investors as payment for consulting services.

On February 28, 2017, the Company issued 1,066 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

ITEM 6. EXHIBITS

- 31.1* Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 31.2* Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 32.1* Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 32.2* Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS** XBRL INSTANCE DOCUMENT
- 101.SCH** XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
- 101.CAL** XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
- 101.DEF** XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
- 101.LAB** XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
- 101.PRE** XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

ADVAXIS, INC.
Registrant

Date: March 10, 2017 By: */s/ Daniel J. O'Connor*
Daniel J. O'Connor
Chief Executive Officer, President and Director

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

