

Advaxis, Inc.
Form 10-Q
June 07, 2018

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 April 30, 2018

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

For the transition period from _____ to _____

Commission file number 001-36138

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

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

Delaware **02-0563870**
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification No.)

305 College Road East, Princeton, NJ 08540

(Address of principal executive offices)

(609) 452-9813

(Registrant's telephone number)

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

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

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

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

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

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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of June 4, 2018 was 52,621,490.

TABLE OF CONTENTS

	Page No.
PART I <u>FINANCIAL INFORMATION</u>	4
Item 1. <u>Financial Statements (unaudited)</u>	4
<u>Condensed Balance Sheets</u>	4
<u>Condensed Statements of Operations</u>	5
<u>Condensed Statements of Cash Flows</u>	6
<u>Notes to the Condensed Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
PART II <u>OTHER INFORMATION</u>	21
Item 1. <u>Legal Proceedings</u>	21
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
Item 6. <u>Exhibits</u>	21
<u>SIGNATURES</u>	22

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,” “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 release the clinical hold and reduce the impact to our trials;
- 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 change 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 other countries;
the rate and degree of market acceptance of any of our product candidates;
new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
market conditions in the pharmaceutical and biotechnology sectors;
our available cash;
the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
our ability to obtain additional funding;
our ability to obtain and maintain intellectual property protection for our product candidates;
the success and timing of our preclinical studies including IND enabling studies;
the ability of our product candidates to successfully perform in clinical trials;
our ability to initiate trials, enroll our trials, obtain and maintain approval of our product candidates;
our ability to manufacture and the performance of third-party manufacturers;
the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; and
our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the “Risk Factors” section of the Company’s annual report on Form 10-K for the year ended October 31, 2017, as filed with the SEC on December 21, 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.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I - FINANCIAL INFORMATION**Item 1. Financial Statements****ADVAXIS, INC.****CONDENSED BALANCE SHEETS**

(Unaudited)

	April 30, 2018	October 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	\$48,876,630	\$23,899,809
Restricted cash	977,000	587,000
Short-term investment securities	8,988,858	46,398,304
Income tax receivable	-	4,452,682
Deferred expenses	2,867,882	2,986,385
Prepaid expenses and other current assets	3,765,872	2,918,644
Total current assets	65,476,242	81,242,824
Property and equipment (net of accumulated depreciation)	7,748,273	7,111,081
Intangible assets (net of accumulated amortization)	5,352,487	4,856,775
Other assets	592,598	431,098
Total assets	\$79,169,600	\$93,641,778
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$7,408,687	\$5,121,406
Accrued expenses	4,236,983	8,700,036
Deferred revenue	7,163,628	6,995,336
Other current liabilities	47,520	47,520
Total current liabilities	18,856,818	20,864,298
Deferred revenue	13,758,091	17,478,758
Other liabilities	1,099,373	1,038,555
Total liabilities	33,714,282	39,381,611

Commitments and contingencies – Note 9

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

Stockholders' equity:

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at April 30, 2018 and October 31, 2017.	-	-
Liquidation preference of \$0 at April 30, 2018 and October 31, 2017.		
Common stock - \$0.001 par value; 95,000,000 shares authorized, 52,561,996 and 41,206,538 shares issued and outstanding at April 30, 2018 and October 31, 2017.	52,563	41,207
Additional paid-in capital	380,444,520	355,361,187
Accumulated deficit	(335,041,765)	(301,142,227)
Total stockholders' equity	45,455,318	54,260,167
Total liabilities and stockholders' equity	\$79,169,600	\$93,641,778

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.**CONDENSED STATEMENTS OF OPERATIONS**

(Unaudited)

	Three Months Ended		Six Months Ended	
	April 30,		April 30,	
	2018	2017	2018	2017
Revenue	\$1,747,480	\$3,425,380	\$3,803,107	\$7,216,222
Operating expenses:				
Research and development expenses	10,832,692	16,306,860	27,902,958	29,955,414
General and administrative expenses	4,467,142	7,778,228	9,999,974	15,106,037
Total operating expenses	15,299,834	24,085,088	36,902,932	45,061,451
Loss from operations	(13,552,354)	(20,659,708)	(34,099,825)	(37,845,229)
Other income (expense):				
Interest income, net	150,995	184,747	290,517	329,761
Net changes in fair value of derivative liabilities	-	10,652	-	20,156
Other expense	(5,713)	(3,346)	(40,230)	(3,346)
Net loss before benefit for income taxes	(13,407,072)	(20,467,655)	(33,849,538)	(37,498,658)
Income tax expense	-	-	50,000	50,000
Net loss	\$(13,407,072)	\$(20,467,655)	\$(33,899,538)	\$(37,548,658)
Net loss per common share, basic and diluted	\$(0.27)	\$(0.51)	\$(0.74)	\$(0.93)
Weighted average number of common shares outstanding, basic and diluted	49,864,795	40,295,941	45,576,580	40,204,062

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.**CONDENSED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Six Months Ended	
	April 30,	
	2018	2017
OPERATING ACTIVITIES		
Net loss	\$(33,899,538)	\$(37,548,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	4,033,726	10,324,150
Gain on change in value of warrants and embedded derivative	-	(20,156)
Loss on disposal of property and equipment	27,361	3,187
Write-off of intangible assets	305,004	89,881
Depreciation expense	543,806	337,403
Amortization expense of intangible assets	188,809	152,155
Net amortization (accretion) of premiums and discounts	(4,380)	99,523
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(603,725)	(5,719,085)
Income tax receivable	4,452,682	2,549,862
Other assets	(161,500)	97,520
Accounts payable and accrued expenses	(2,187,479)	2,818,357
Deferred revenue	(3,552,375)	(6,966,222)
Other liabilities	60,818	94,231
Net cash used in operating activities	(30,796,791)	(33,687,852)
INVESTING ACTIVITIES		
Restricted cash established with letter of credit agreements	(390,000)	-
Purchases of short-term investment securities	(12,487,174)	(67,215,523)
Sales of short-term investment securities	49,901,000	21,152,333
Purchase of property and equipment	(1,276,652)	(2,342,515)
Cost of intangible assets	(989,525)	(607,184)
Net cash provided by (used in) investing activities	34,757,649	(49,012,889)
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock	21,041,820	-
Proceeds from employee stock purchase plan	9,482	135,202
Tax withholdings paid related to net share settlement of equity awards	(40,438)	(264,986)
Employee tax withholdings paid on equity awards	(269,407)	(523,513)
Tax shares sold to pay for employee tax withholdings on equity awards	274,506	627,121
Net cash provided by (used in) financing activities	21,015,963	(26,176)

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

Net increase (decrease) in cash and cash equivalents	24,976,821	(82,726,917)
Cash and cash equivalents at beginning of period	23,899,809	112,750,980
Cash and cash equivalents at end of period	\$48,876,630	\$30,024,063

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for taxes	\$50,000	\$50,000
---------------------	----------	----------

SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES

Accounts payable and accrued expenses settled with common stock	\$-	\$75,000
Property and equipment included in accounts payable and accrued expenses	56,707	175,062

The accompanying notes should be read in conjunction with the financial statements.

ADVAXIS, INC.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. NATURE OF OPERATIONS

Advaxis, Inc. (“Advaxis” or the “Company”) is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Listeria monocytogenes* (“*Lm*”) based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient’s immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology. Advaxis’ proprietary approach deploys a unique mechanism of action that awakens the immune system to attack cancer in three distinct ways by:

- Awakening the immune system by activating multiple pathways in Antigen-presenting cells (“APCs”) with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the Tumor Microenvironment (“TME”) that shields the tumor from the immune system. This enables the activated T cells to begin working to eliminate the tumor.

Advaxis’ proprietary *Lm* platform technology has been clinically validated and dosed in over 530 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile, and most product candidates are immediately available for treatment with a low cost of goods.

Liquidity and Financial Condition

The Company’s products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. 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 May 2018, we raised approximately \$245.2 million in gross proceeds from various public and private offerings of our common stock.

As of April 30, 2018, the Company had approximately \$58.8 million in cash, restricted cash, cash equivalents and short-term investment securities on its balance sheet and working capital of \$46.6 million. The Company has completed a thorough analysis of operating expenses, as well as research and development (“R&D”) programs. Accordingly, Management’s plans to mitigate such shortfall of cash flows include the approval of a work force reduction effective June 7, 2018, and also cost reductions regarding select ongoing programs for clinical trials. Based upon these actions, we believe our current working capital position as of April 30, 2018 and cash flows expected to be generated from future operations is sufficient to enable the Company to meet its obligations as they become due in the ordinary course of business for a period of at least one year from the issuance of these financial statements. Had these actions not been taken, the Company’s future cash flows may not have been sufficient for the Company to meet its obligations as they become due. The actual amount of cash that we will need to operate is subject to many factors, and the Company has the ability to further reduce other variable costs if needed. Should further financing be needed, the Company could access additional capital through the equity capital or debt markets although no assurance can be provided that the Company would be successful in any capital raising efforts.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation/Estimates

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 (“U.S. 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 and the accompanying unaudited condensed balance sheet as of October 31, 2017 has been derived from the Company’s October 31, 2017 audited financial statements. In the opinion of management, the unaudited interim condensed financial statements furnished include all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods presented. Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year.

Operating results for interim periods are not necessarily indicative of the results to be expected for the full year. The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates include the timelines associated with revenue recognition on upfront payments received, the fair value and recoverability of the carrying value of property and equipment and intangible assets, the grant date fair value of options, deferred tax assets and any related valuation allowance 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 could materially differ from these estimates.

These unaudited interim condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2017 and notes thereto contained in the Company's annual report on Form 10-K for the year ended October 31, 2017, as filed with the SEC on December 21, 2017.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentration of credit risk, consist principally of cash and cash equivalents. All the Company's cash and cash equivalents are deposited in accounts with financial institutions that management believes are of high credit quality and at times exceed the federally insured limits. The Company had not experienced losses in such accounts and believes it is not exposed to any significant credit risk.

Restricted Cash and Letters of Credit

During July 2017 and January 2018, the Company established two letters of credit with a financial institution as security for the purchase of custom equipment and as security for application fees associated with the Company's Marketing Authorization Application ("MAA") in Europe. The letters of credit are collateralized by cash which is unavailable for withdrawal or for usage for general obligations. No amount is outstanding under either letter of credit as of April 30, 2018.

Net Income (Loss) per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units 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 April 30,	
	2018	2017
Warrants	3,092,395	3,110,575
Stock Options	4,643,012	3,893,558
Restricted Stock Units	1,089,475	1,146,435
Total	8,824,882	8,150,568

Recent Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU 2014-09”), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to customers.

Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (“ASU 2016-08”); ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing (“ASU 2016-10”); ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients (“ASU 2016-12”); and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers (“ASU 2016-20”). The Company must adopt ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 with ASU 2014-09 (collectively, the “new revenue standards”). The new revenue standards may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating which transition approach we will utilize and the impact of adopting this accounting standard on our unaudited condensed financial statements. This update will be effective for the Company beginning in the first quarter of fiscal 2019.

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 fiscal 2020. 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.

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. SHORT-TERM INVESTMENT SECURITIES

The following table summarizes the Company's investment securities at amortized cost as of April 30, 2018 and October 31, 2017:

	April 30, 2018			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$490,000	\$ -	\$ -	\$490,000
U.S Treasury Notes	8,498,858	-	4,268	8,494,590
Total short-term investment securities	\$8,988,858	\$ -	\$ 4,268	\$8,984,590

	October 31, 2017			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$11,391,147	\$ -	\$ -	\$11,391,147
Domestic Governmental Agency Loans	499,957	-	162	499,795
U.S Treasury Notes	34,507,200	-	25,351	34,481,849
Total short-term investment securities	\$46,398,304	\$ -	\$ 25,513	\$46,372,791

All the Company's short-term investment securities mature within the next 12 months.

4. PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

	April 30, 2018	October 31, 2017
Leasehold improvements	\$2,254,727	\$2,167,990

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

Laboratory equipment	5,411,376	4,143,106
Furniture and fixtures	745,804	728,725
Computer equipment	394,523	394,523
Construction in progress	692,234	883,322
Total property and equipment	9,498,664	8,317,666
Accumulated depreciation and amortization	(1,750,391)	(1,206,585)
Net property and equipment	\$7,748,273	\$7,111,081

Depreciation expense for the three and six months ended April 30, 2018 and 2017 was \$278,817, \$543,806, \$179,823 and \$337,403, respectively.

5. INTANGIBLE ASSETS

Intangible assets, net consist of the following:

	April 30, 2018	October 31, 2017
Patents	\$6,337,436	\$5,727,298
Licenses	776,992	776,992
Software	117,196	108,604
Total intangibles	7,231,624	6,612,894
Accumulated amortization	(1,879,137)	(1,756,119)
Intangible assets	\$5,352,487	\$4,856,775

The expirations of the existing patents range from 2018 to 2038 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. Patent applications having a net book value of \$161,889, \$305,004, \$89,881 and \$89,881 were abandoned and were charged to research and development expenses in the Statement of Operations for the three and six months ended April 30, 2018 and 2017, respectively. Amortization expense for intangible assets aggregated \$96,284, \$188,809, \$77,745 and \$152,155 for the three and six months ended April 30, 2018 and 2017, respectively.

At April 30, 2018, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows:

Year ended October 31,

2018 (Remaining)	\$ 196,506
2019	390,610
2020	373,755
2021	353,945
2022	353,945
Thereafter	3,683,726
Total	\$5,352,487

6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	April 30, 2018	October 31, 2017
Salaries and other compensation	\$2,382,100	\$2,652,583
Vendors	1,017,033	2,811,956
Professional fees	837,850	3,235,497
Total accrued expenses	\$4,236,983	\$8,700,036

7. WARRANTS

At April 30, 2018 and October 31, 2017, the Company had 3,092,395 warrants outstanding at a weighted average exercise price of \$5.00 and a weighted average remaining contractual life of 0.42 and 0.92 years, respectively. At April 30, 2018 and October 31, 2017, all of the Company's outstanding warrants were classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the relative fair value method, in the stockholders' 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.

8. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the Statement of Operations:

	Three Months Ended April 30,		Six Months Ended April 30,	
	2018	2017	2018	2017
Research and development	\$ 525,822	\$ 1,531,005	\$ 1,798,818	\$ 2,753,488
General and administrative	698,787	3,682,720	2,234,908	7,570,662
Total	\$ 1,224,609	\$ 5,213,725	\$ 4,033,726	\$ 10,324,150

Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the six months ended April 30, 2018 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2017	1,363,119	\$ 8.54
Granted	335,424	3.22
Vested	(461,111)	8.27
Cancelled	(147,957)	9.98
Balance at April 30, 2018	1,089,475	\$ 6.82

As of April 30, 2018, there was approximately \$6,061,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.85 years.

As of April 30, 2018, the aggregate intrinsic value of non-vested RSUs was approximately \$1,743,160.

Employee Stock Awards

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 256,610 shares (208,094 shares on a net basis after employee taxes) and 159,544 shares (129,728 shares on a net basis after employee taxes) during the three months ended April 30, 2018 and 2017 respectively. Total stock compensation expense associated with employee awards for the three months ended April 30, 2018 and 2017 was \$619,740 and \$1,712,297, respectively

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 453,777 shares (403,140 shares on a net basis after employee taxes) and 253,520 shares (222,459 shares on a net basis after employee taxes) during the six months ended April 30, 2018 and 2017 respectively. Total stock compensation expense associated with employee awards for the six months ended April 30, 2018 and 2017 was \$1,973,925 and \$3,068,936, respectively.

Included in compensation expense for the three and six months ended April 30, 2018 is \$210,146 recognized as a result of the modification of certain RSU's associated with the resignation of the Company's Chief Financial Officer in April 2018. Pursuant to the separation agreement, the vesting was accelerated on all the outstanding RSU's.

Director Stock Awards

Common stock issued to Directors for compensation related to board and committee membership totaled 30,000 shares for each of the three months ended April 30, 2018 and 2017, respectively. During the three months ended April 30, 2018 and 2017, total stock compensation expense associated with Director awards was \$5,616 and \$98,315, respectively.

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

Common stock issued to Directors for compensation related to board and committee membership totaled 30,000 shares for each of the six months ended April 30, 2018 and 2017, respectively. During the six months ended April 30, 2018 and 2017, total stock compensation expense associated with Director awards was \$107,244 and \$199,943, respectively.

Included in compensation expense for the three and six months ended April 30, 2018 is \$9,850 recognized as a result of the modification of certain RSU's associated with a Board member that decided not to run for re-election in March 2018. The vesting was accelerated on all the outstanding RSU's.

Stock Options

A summary of changes in the stock option plan for the six months ended April 30, 2018 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2017:	3,893,558	\$ 12.51
Granted	1,764,185	2.26
Canceled or Expired	(1,014,731)	11.07
Outstanding at April 30, 2018	4,643,012	8.93
Vested and Exercisable at April 30, 2018	2,823,762	\$ 12.58

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended April 30, 2018 and 2017 was \$599,254 and \$3,006,763, respectively. For the six months ended April 30, 2018 and 2017, compensation cost related to the Company's outstanding stock options was \$1,997,558 and \$6,190,221, respectively. Included in compensation expense for the three and six months ended April 30, 2018 is \$76,784 recognized as a result of the modification of certain option agreements associated with two Board members that decided not to run for re-election in March 2018. For the modified options, the vesting was accelerated and the expiration dates were changed to the earlier of the original expiration date or March 21, 2023.

During the six months ended April 30, 2018, 1,764,185 options were granted with a total grant date fair value of \$3,122,924. During the six months ended April 30, 2017, 556,952 options were granted with a total grant date fair value of \$3,542,215.

As of April 30, 2018, there was approximately \$3,634,000 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 2.07 years.

As of April 30, 2018, the aggregate intrinsic value of vested and exercisable options was \$0.

In determining the fair value of the stock options granted during the six months ended April 30, 2018 and 2017, the Company used the following inputs in its BSM:

	Six Months Ended April 30,	
	2018	2017
Expected Term	5.35 – 6.51 years	5.50-6.50 years
Expected Volatility	95.11 – 100.34 %	107.07-110.93 %
Expected Dividends	0 %	0 %
Risk Free Interest Rate	1.81 – 2.66 %	1.26-1.58 %

2018 Employee Stock Purchase Plan

During the six months ended April 30, 2018, the Company issued 10,681 shares that were purchased in fiscal 2017 under the 2011 Employee Stock Purchase Plan (“ESPP”).

The Advaxis, Inc. 2018 ESPP was approved by the Company’s shareholders on March 21, 2018. The ESPP allows eligible employees to purchase shares of our common stock at a 15% discount to the closing market price on designated exercise dates. 1,000,000 shares of the Company common stock are reserved for issuance under the ESPP.

9. COMMITMENTS AND CONTINGENCIES:

Legal Proceedings

Bono

On August 20, 2015, a derivative complaint was filed by a purported Company stockholder 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 was based on general allegations related to certain stock options granted to the individual defendants and generally alleged counts for breaches of fiduciary duty and unjust enrichment. The complaint also alleged additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. The complaint sought 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 Court issued an opinion and order granting in part and denying in part defendants' motion to dismiss. On October 5, 2016, the Court denied plaintiff's motion for reconsideration of its May 23 order. On April 13, 2017, the parties advised the Court that they had reached a tentative agreement in principle to settle the action, subject to negotiating an award of attorneys' fees and expenses to plaintiff's counsel and a stipulation of settlement, and, ultimately, Court approval. The parties subsequently executed the stipulation of settlement on October 2, 2017. The Court entered an order preliminarily approving the settlement on November 7, 2017. The final fairness hearing was held January 29, 2018, and the Order and Final Judgment approving the settlement and dismissing the action with prejudice was entered on January 29, 2018. This matter is now concluded.

Corporate Office & Manufacturing Facility Lease

The Company leases its corporate office and manufacturing facility under an operating lease expiring in November 2025.

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

Year ended October 31,

2018 (remaining)	\$ 523,676
2019	1,107,385
2020	1,232,907
2021	1,317,640
2022	1,368,819
Thereafter	4,378,521
Total	\$9,928,948

11. INCOME TAXES

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly revises U.S. corporate income taxation by, among other things, lowering the U.S. corporate income tax rate from 35.0 % to 21.0% effective January 1, 2018. The decrease in the U.S. federal corporate tax rate from 35.0% to 21.0% will result in a blended statutory tax rate of 23.2% for the fiscal year ending October 31, 2018. The Company does not anticipate any impact to tax expense due to the full valuation allowance of the Company and believes that the most significant impact on its financial statements will be reduction of approximately \$32.7 million for the deferred tax assets related to net operating losses and other assets. Such reduction is offset by changes to the Company's valuation allowance.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin 118, which allows a measurement period, not to exceed one year, to finalize the accounting for the income tax impacts of the Tax Act. Until the accounting for the income tax impacts of the Tax Act is complete, the reported amounts are based on reasonable estimates, are disclosed as provisional and reflect any adjustments in subsequent periods as they refine their estimates or complete their accounting of such tax effects.

12. STOCKHOLDERS' EQUITY

During the six months ended January 31, 2018, the Company sold 881,629 shares of its Common Stock at-the-market transactions resulting in net proceeds of approximately \$2,659,000.

During February 2018, the Company issued 10,000,000 shares of the Company's common stock in a public offering at \$2.00 per share, less underwriting discounts and commissions. The net proceeds to the Company from the transaction was approximately \$18,383,000.

On March 21, 2018, the Company's shareholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase our authorized shares of common stock by 30,000,000 to 95,000,000.

13. SUBSEQUENT EVENTS

Following the close of the second quarter, the Company is announcing a work force reduction effective June 7, 2018. As part of this plan, the Company will reduce employee headcount by approximately 24% as of this date. The Company intends to pay separation payments which will reflect both employee salary and healthcare coverage. Charges related to work force reduction are estimated to be approximately \$905,000 which will be reflected in the third quarter results of operations.

On June 6, 2018 the Company announced that Molly Henderson joined the Company as Chief Financial Officer effective as of June 6, 2018.

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, 2017. In addition, we intend to use our media and investor relations website ([http:// http://ir.advaxis.com/](http://ir.advaxis.com/)), SEC filings, press releases, public conference calls and webcasts as well as social media to communicate with our subscribers and the public about Advaxis, its services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, in light of the SEC's guidance, we encourage investors, the media, and others interested in Advaxis to review the information we post on the U.S. social media channels listed on our website.

Overview

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Listeria monocytogenes* ("Lm") based antigen delivery products. The Company is using its Lm platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated Lm called Lm Technology. Advaxis' proprietary approach deploys a unique mechanism of action that awakens the immune system to attack cancer in three distinct ways by:

- Awakening the immune system by activating multiple pathways in Antigen-presenting cells ("APCs") with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the Tumor Microenvironment ("TME") that shields the tumor from the immune system. This enables the activated T cells to begin working to eliminate the tumor.

During the second fiscal quarter, the Company began assessing the clinical and commercial viability of its R&D programs in order to determine which were best suited for internal development and which were better suited for external development opportunities, as well as determine other ways to reduce operating expenses, all in order to find ways to treat cancer patients and maximize stockholder value. In particular, we have determined to take the following actions:

While the Company's lead HPV program, axalimogene filolisbac, has shown meaningful clinical efficacy and supports the manageable safety profile of the *Lm* platform in HPV-related cancers, the Company intends to minimize future investment in cervical cancer and focus on potential partnership opportunities. Our plan is to expand our search for a U.S. and/or European partner, who will need to take on all development and commercialization activities and costs. In the event no partner emerges, the Company intends to wind down the ongoing trial in high risk locally advanced cervical cancer (AIM2CERV) and would not conduct the PD-1 combination trial in metastatic cervical cancer (ADVANCE), which has not yet been initiated.

The Company intends to continue to evaluate cost effective ways to invest in axalimogene filolisbac in head-and-neck cancer. These may be internal or external investments, or both.

With respect to the Company's ongoing trial in metastatic prostate cancer with ADXS-PSA in combination with KEYTRUDA ("pembrolizumab"), early clinical data have proven worthy of continued evaluation. The Company intends to continue to evaluate this program.

In addition, on June 7, 2018, the Company announced that it would be implementing a reduction in force to align its staffing needs with its intended strategy. The reduction involves the elimination approximately 24% of the Company's work force. Overall the cost of separation payments will be slightly higher than the savings of the work force reduction in the third quarter by approximately \$140,000 dollars. Beginning with the Company's fourth quarter, results of operations net quarterly savings will be approximately \$1,150,000, or a total annualized workforce payroll savings of approximately \$4,600,000. The net savings generated by the elimination of these positions, in conjunction with the reduction in clinical expenditures, will significantly lower the Company's operating expenses and align its operations to focus on priority programs.

As previously reported, the Company's clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, related to the 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 was placed on clinical hold by FDA on March 9, 2018 following its review of a safety report regarding a Grade 5 Serious Adverse Event occurring on February 27, 2018 and involving respiratory failure which followed a sixth combination cycle (11th dose of axalimogene filolisbac, 21st dose of durvalumab) in the trial. Over 430 patients have received axalimogene filolisbac, and approximately 1,259 doses have been delivered across multiple trials in HPV-associated cancers, to date, and this is the first time we have seen this type of event. Enrollment and further dosing are on hold for this trial, and we are working closely with the site investigator and FDA to review this event in detail and to determine a path forward from this clinical hold. The Company anticipates submitting a response to the FDA shortly, intended to reach agreement on the appropriate measures to lift the clinical hold. We expect a response from the FDA to this letter within 30 days of submission. At this time, this hold does not affect any other current clinical trials or programs.

On June 6, 2018 the Company announced that Molly Henderson joined the Company as Chief Financial Officer effective as of June 6, 2018.

ADXS-HOT

The Company is currently prioritizing product development in the most prevalent cancers, with the first tumor type to be NSCLC. Advaxis plans to file multiple ADXS-HOT INDs in 2018, with a first-in-human trial in NSCLC to commence in 2018. Going forward, the Company plans to submit additional INDs for the ADXS-HOT program in 2019.

ADXS-HOT preclinical data was presented in a poster presentation at the 2018 AACR Annual Meeting. The study, entitled “Targeting Shared Hotspot Cancer Mutations with a *Listeria monocytogenes* Immunotherapy Induce Potent Anti-Tumor Immunity” demonstrated that the ADXS-HOT platform could effectively target common (public or shared) mutations (hotspots) and control tumor growth with both single and multi-target constructs.

ADXS-NEO

Preclinical findings in the ADXS-NEO program were discussed in poster presentations at the 2018 American Association for Cancer Research (AACR) Annual Meeting. Additionally, portions of these data were presented by Amgen at a podium presentation during the European Neoantigen Summit 2018.

The first study, as discussed in a poster presentation at AACR entitled “Neoantigens that fail to elicit measurable T cell responses following peptide immunization can control tumor growth when delivered using a *Listeria*-based immunotherapy platform,” showed that ADXS-NEO generates T cell responses against neoantigen peptides that control tumor growth, even when they were identified as “non-immunogenic” using a conventional peptide-adjuvant immunization.

In the second study, discussed in a poster presentation at AACR entitled “Targeting frameshift mutations with a *Listeria monocytogenes* immunotherapy drives neoantigen-specific antitumor immunity in MC38 and CT26 mouse tumor models,” Advaxis’ *Lm* platform was shown to target frameshift mutations and generate T cells to multiple neoantigens per frameshift in these models. This data highlighted the physical capacity of the Advaxis *Lm* platform and its ability to target frameshift mutations of greater than 90 amino acids, and to generate T cells to multiple neoantigens per frameshift in tumor mouse models.

The initial tumor types for the trial are microsatellite stable colorectal cancer, head and neck cancer, and NSCLC. The first patient, being treated for NSCLC, will be dosed in June 2018.

ADXS-PSA

Advaxis is conducting a trial in collaboration with Merck & Co. (“Merck”) evaluating 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 determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (Keynote-046). The Company presented data at the 2018 American Society of Clinical Oncology (“ASCO”) annual meeting. ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. Overall, the safety profile was consistent with findings from prior clinical studies using the *Lm* platform. Treatment-related adverse events (TRAEs) were mostly mild or moderate constitutional symptoms such as fever, chills, rigors, hypotension, nausea and fatigue, consistent with immune activation and manageable with standard care. There were no new toxicities observed with the combination therapy. In all treated patients, those who received the combination therapy experienced the longest overall survival (OS) at data cut-off. Additional efficacy related data include:

Median overall survival had not been reached in the combination arm after 13 months of follow-up (95%CI 7.16-NR), and was 7.79 months (95%CI 3.52-11.9) in the monotherapy arm.

56.8% of patients on combination therapy and 38.5% of patients on monotherapy did not experience disease progression.

The percentage of patients with PSA declines from baseline in the combination therapy arm was 40.5%, and 15.4% in the monotherapy arm.

In all treated patients, an improvement in survival was observed in patients with PSA declines from baseline of 50% or greater vs. those with PSA declines of less than 50%. There were 7 patients in the combination arm with 50% or greater declines in PSA from baseline, and none in the monotherapy arm.

HPV Related Cancers

We have several programs in HPV-related cancers based on axalimogene filolisbac, an *Lm* –based antigen delivery product designed to target cells expressing HPV. Axalimogene filolisbac 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 with other therapies, and has shown encouraging safety and efficacy in numerous clinical studies to date.

Cervical Cancer

We completed a randomized Phase 2 clinical study (*Lm*-LLO-E7-15), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results showed that 34.9% (38/109) of patients were alive at 12 months, 24.8% (27/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months. Of the 15 patients consenting to further follow-up beyond 18 months, 12 (11%) achieved 24-month OS status (range 24 – 34+ months) at the time of study closure. Axalimogene filolisbac was found to be well tolerated with the majority of the AEs were mild to moderate in severity (566 of 704 reported AEs, 80.4%) and were not related to study drug (539 of 704 reported AEs, 76.6%). These data were published in the May 2018 edition of the peer-reviewed *International Journal of Gynecological Cancer*.

Our ongoing Phase 3 trial is evaluating axalimogene filolisbac in patients with high-risk, locally advanced cervical (“AIM2CERV” or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”). The study is being conducted under a Special Protocol Assessment (“SPA”), and has been determined by the FDA to be adequate, well-designed, and suitable for registration if successful. This study is being conducted in collaboration with the GOG/NRG Oncology, and we have initiated the AIM2CERV study to support a Biologics License Application (“BLA”) submission in the U.S. and regulatory registration in other territories around the world.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 study of adjuvant axalimogene filolisbac, following primary chemoradiation treatment of women with high-risk locally advanced cervical cancer (“HRLACC”). The primary objective of AIM2CERV is to compare the disease free survival of axalimogene filolisbac to placebo administered in the adjuvant setting following standard concurrent chemotherapy and radiotherapy (“CCRT”) administered with curative intent to patients with HRLACC. Secondary endpoints include examining overall survival and safety. Our goal is to develop a treatment to prevent or reduce the risk of cervical cancer recurrence after primary, standard of care treatment in women who are at high risk of recurrence. The study is active in fourteen countries with 129 sites open to date.

In February 2018, the Company submitted a conditional MAA to the European Medicines Agency’s (“EMA”) Committee for the Company’s lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of persistent/recurrent metastatic cervical cancer (“PRmCC”). The MAA submission was primarily based on data from the GOG-0265 study, as well as supportive data from other clinical trials evaluating axalimogene filolisbac and was validated by the EMA in March 2018.

The Company is seeking a U.S. and/or European partner to fund the development and commercialization of axalimogene filolisbac in cervical cancer including the completion of the AIM2CERV study. If a partner is not found, the program would be wound down in the near future in a clinically responsible manner. In the short term, patients on trial would continue treatment.

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 SCCHN. For the axalimogene filolisbac and durvalumab dose escalation portion of the study, the dose-escalation phase has been completed. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases; however, this trial was placed on clinical hold by FDA on March 9, 2018, following its review of a safety report regarding a Grade 5 Serious Adverse Event occurring on February 27, 2018 and involving respiratory failure which followed a sixth combination cycle (11th dose of axalimogene filolisbac, 21st dose of durvalumab) in the trial. Over 430 patients have received axalimogene filolisbac, and approximately 1,259 doses have been delivered across multiple trials in HPV-associated cancers, to date, and this is the first time we have seen this type of event. Enrollment and further dosing are on hold for this trial, and we are working closely with the site investigator and FDA to review this event in detail. The Company anticipates submitting a response to the FDA shortly, intended to reach agreement on the appropriate measures to lift the clinical hold. We expect a response to this letter from the FDA within 30 days of submission. At this time, this hold does not affect any other current clinical trials or programs.

We had entered into a clinical development collaboration agreement with BMS to evaluate their PD-1 immune checkpoint inhibitor, OPDIVO® (nivolumab), in combination with axalimogene filolisbac as a potential treatment option for women with metastatic cervical cancer. The ADVANCE trial was planned to evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy. Under the terms of the agreement, each party would bear its own internal costs and provide its immunotherapy agents. This trial has not yet been initiated as the Company is seeking a U.S. and/or European partner to fund the cervical cancer program. If a partner is not found, the study will not be initiated.

Head and Neck Cancer

We have entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part trial 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. Part 1 of this trial is complete, and the Company has commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases; however, this trial was placed on clinical hold as detailed above.

The Company is evaluating opportunities to conduct a capital efficient trial evaluating axalimogene filolisbac in head and neck cancer. We will announce more details on this program soon.

Results of Operations for the Three Months Ended April 30, 2018 and 2017

Revenue

Revenue decreased \$1,677,900 to \$1,747,480 for the three months ended April 30, 2018 compared to \$3,425,380 for the three months ended April 30, 2017. The decrease was due to a change in the estimated performance period associated with upfront fees received from Amgen in conjunction with the collaboration agreement signed in August 2016.

Research and Development Expenses

We make significant investments in research and development to support our pre-clinical and clinical development programs. Research and development expenses for the three months ended April 30, 2018 and 2017 were categorized as follows:

	Three Months Ended April 30,	
	2018	2017
HPV-associated cancers	\$4,386,321	\$5,001,228
Prostate cancer	681,001	762,650
Neoantigen therapy	530,630	646,078
Other clinical trial expenses	7,597	519,582
Other external research & development expenses	1,687,400	5,959,010
All other expenses	5,133,300	6,418,312
Partner reimbursements	(1,593,557)	(3,000,000)
Total research & development expense	\$10,832,692	\$16,306,860

Axalimogene Filolisbac

HPV-associated expenses decreased \$614,907 to \$4,386,321 for the three months ended April 30, 2018 compared to \$5,001,228 for the three months ended April 30, 2017. The decrease results primarily from slower enrollment activities associated with the Phase 3 AIM2CERV trial.

Other Clinical Trial Expenses

Other clinical trial expenses decreased \$511,985 to \$7,597 for the three months ended April 30, 2018 compared to \$519,582 for the three months ended April 30, 2017. The decrease relates to the dose findings of a HER2 Phase 1b trial being completed in fiscal 2017 and the Company's decision not to proceed to the expansion phase of the trial.

Other External Research & Development Expenses

Other external research & development expenses consist primarily of professional fees and laboratory costs that have not been specifically allocated to one of our franchises. The decrease of \$4,271,610 to \$1,687,400 for the three months ended April 30, 2018 compared to \$5,959,010 for the three months ended April 30, 2017 is primarily attributable to a decrease in laboratory costs and drug manufacturing process validation and drug stability studies supporting the MAA which was filed in February 2018.

All Other Expenses

All other expenses include salary and benefit costs, stock based compensation expense, equipment costs and other internal costs associated with our research & development activities. The decrease of \$1,285,012 to \$5,133,300 for the three months ended April 30, 2018 compared to \$6,418,312 for the three months ended April 30, 2017 is primarily attributable to a decrease in stock compensation resulting from a reduction in headcount.

Partner reimbursements

Partner reimbursements decreased \$1,406,443 to \$1,593,557 for the three months ended April 30, 2018 compared to \$3,000,000 for the three months ended April 30, 2017. The decrease relates to \$3,000,000 from Stendhal for partner reimbursements supporting AIM2CERV in the prior year compared to \$1,593,557 from Amgen for partner reimbursements supporting ADXS-NEO in the current year.

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses decreased \$3,311,086 to \$4,467,142 for the three months ended April 30, 2018, compared with \$7,778,228 for the three months ended April 30, 2017. The decrease is primarily attributable to a decrease in stock based compensation related to the resignation of the Company's Chief Financial Officer and Chief Executive Officer in April 2018 and July 2017, respectively, two Board members who did not seek re-election in March 2018 and the elimination of stock based compensation paid to consultants. In addition, litigation settlements declined year over year. These decreases were offset by an increase in severance associated with the resignation of the Interim Chief Executive Officer and Chief Financial Officer.

Results of Operations for the Six Months Ended April 30, 2018 and 2017*Revenue*

Revenue decreased \$3,413,115 to \$3,803,107 for the six months ended April 30, 2018 compared to \$7,216,222 for the six months ended April 30, 2017. The decrease was due to a change in the estimated performance period associated with upfront fees received from Amgen in conjunction with the collaboration agreement signed in August 2016.

Research and Development Expenses

We make significant investments in research and development to support our pre-clinical and clinical development programs. Research and development expenses for the six months ended April 30, 2018 and 2017 were categorized as follows:

	Six months Ended April 30,	
	2018	2017
HPV-associated cancers	\$9,937,495	\$8,965,813
Prostate cancer	1,383,152	1,649,280
Neoantigen therapy	902,437	1,043,852
Other clinical trial expenses	226,517	990,546
Other external research & development expenses	6,683,799	8,799,470
All other expenses	11,863,115	11,506,453
Partner reimbursements	(3,093,557)	(3,000,000)
Total research & development expense	\$27,902,958	\$29,955,414

Axalimogene Filolisbac

HPV-associated expenses increased \$971,682 to \$9,937,495 for the six months ended April 30, 2018 compared to \$8,965,813 for the six months ended April 30, 2017. The increase resulted primarily from startup activities for additional countries in the Phase 3 AIM2CERV trial.

Other Clinical Trial Expenses

Other clinical trial expenses decreased \$764,029 to \$226,517 for the six months ended April 30, 2018 compared to \$990,546 for the six months ended April 30, 2017. The decrease relates to the dose findings of a HER2 Phase 1b trial being completed in fiscal 2017 and the Company's decision not to proceed to the expansion phase of the trial.

Other External Research & Development Expenses

Other external research & development expenses consist primarily of professional fees and laboratory costs that have not been specifically allocated to one of our franchises. The decrease of \$2,115,671 to \$6,683,799 for the six months ended April 30, 2018 compared to \$8,799,470 for the six months ended April 30, 2017 is primarily attributable to a decrease in laboratory costs and drug manufacturing process validation and drug stability studies supporting the MAA which was filed in February 2018.

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses decreased \$5,106,063 to \$9,999,974 for the six months ended April 30, 2018, compared with \$15,106,037 for the six months ended April 30, 2017. The decrease is primarily attributable to a decrease in stock based compensation related to the resignation of the Company's Chief Financial Officer and Chief Executive Officer in April 2018 and July 2017, respectively, two Board members who did not seek re-election in March 2018 and the elimination of stock based compensation paid to consultants. In addition, litigation settlements declined year over year. These decreases were offset by an increase in severance associated with the resignation of the Interim Chief Executive Officer and Chief Financial Officer.

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 May 2018, we raised approximately \$245.2 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 April 30, 2018, the Company had approximately \$58.8 million in cash, restricted cash, cash equivalents and short-term investment securities on its balance sheet and working capital of \$46.6 million. The Company has completed a thorough analysis of operating expenses, as well as research and development (“R&D”) programs. Accordingly, Management’s plans to mitigate such shortfall of cashflows include the approval of a work force reduction effective June 7, 2018, and also cost reductions regarding select ongoing programs for clinical trials. Based upon these actions, we believe our current working capital position as of April 30, 2018 and cashflows expected to be generated from future operations is sufficient to enable the Company to meet its obligations as they become due in the ordinary course of business for a period of at least one year from the issuance of these financial statements. Had these actions not been taken, the Company’s future cashflows may not have been sufficient for the Company to meet its obligations as they become due. The actual amount of cash that we will need to operate is subject to many factors, and the Company has the ability to further reduce other variable costs if needed. Should further financing be needed, the Company could access additional capital through the equity capital or debt markets although no assurance can be provided that the Company would be successful in any capital raising efforts.

Since our inception through April 30, 2018, we reported accumulated net losses of approximately \$335.0 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately \$30.8 million for the six months ended April 30, 2018 compared to \$33.7 million for the six months ended April 30, 2017. Net cash used in operating activities includes spending associated with our clinical trial programs and general and administrative activities as well as an increase in proceeds received from the sale of our state NOLs and R&D tax credits of approximately \$1.9 million.

Investing Activities

Net cash provided by investing activities was approximately \$34.8 million for the six months ended April 30, 2018 compared to \$49.0 million for the six months ended April 30, 2017. The change was primarily due to higher level of the use of proceeds from matured short-term investment securities to fund operating activities and fewer purchases of held-to-maturity investments. The change was also impacted by restricted cash established with a letter of credit, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Financing Activities

Net Cash provided by financing activities was approximately \$21.0 million for the six months ended April 30, 2018 as compared to net cash used in financing activities of \$26,000 for the six months ended April 30, 2017. The increase resulted primarily from net proceeds of approximately \$18,383,000 from the sales of 10,000,000 shares of our common stock in a public offering and approximately \$2,659,000 million from the sale of 881,629 shares of our Common Stock at-the-market transactions.

Our capital resources and operations to date have been funded primarily with the proceeds from both public and 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 April 30, 2018, and October 31, 2017, we had an accumulated deficit of \$335,041,765 and \$301,142,227, respectively, and stockholders' equity of \$45,455,318 and \$54,260,167, respectively.

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, 2017 filed on December 21, 2017. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report on Form 10-K other than the changes described in Note 10, "Commitments and Contingencies" in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of April 30, 2018, 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 Standards

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

At April 30, 2018, the Company had approximately \$58.8 million in cash, cash equivalents and short-term investment securities, which consisted primarily of bank deposits, money market funds and short-term investment securities 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 principal 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 principal 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, 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

As previously disclosed, on April 23, 2018, Anthony Lombardo resigned from his position as Interim Chief Executive Officer and Sara Bonstein resigned as Chief Financial Officer, effective as of April 30, 2018. Mr. Lombardo remained with the Company in a non-executive role until his resignation on May 31, 2018. Also, on April 23, 2018, Ken Berlin was named as President and Chief Executive Officer (and was also appointed to the Board of Directors). On June 6, 2018, the Company announced that Molly Henderson was named Chief Financial Officer. During the quarter ended April 30, 2018, there were no other 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 Principal Executive, Financial and Accounting 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 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 March 7, 2018, the registrant issued 8,648 shares of Common Stock to an employee.

On March 29, 2018, the registrant issued 2,889 shares of common stock to its Executive Officers, pursuant to their Employment Agreements

On April 17, 2018, the registrant issued 13,949 shares of Common Stock to an employee.

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

On April 30, 2018, the registrant issued 2,902 shares of common stock to its Executive Officers, pursuant to their Employment Agreements.

On May 31, 2018, the registrant issued 2,707 shares of common stock to its Executive Officers, pursuant to their Employment Agreements.

On May 31, 2018, the registrant issued 26,112 shares of Common Stock to an employee.

Item 6. Exhibits

10.1 Employment Agreement by and between Advaxis, Inc. and Kenneth A. Berlin, dated April 23, 2018, filed as Exhibit 10.1 with our Form 8-K filed on April 23, 2018, and incorporated herein by reference.

10.2 Separation Agreement by and between Advaxis, Inc. and Anthony Lombardo, dated April 23, 2018, as Exhibit 10.2 with our Form 8-K filed on April 23, 2018, and incorporated herein by reference.

10.3 Separation Agreement by and between Advaxis, Inc. and Sara Bonstein, dated April 23, 2018, filed as Exhibit 10.3 with our Form 8-K filed on April 23, 2018, and incorporated herein by reference.

31.1* Certification of Principal Executive, Financial and Accounting Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002

32.1* Certification of Principal Executive, Financial and Accounting Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002

101.INS XBRL INSTANCE DOCUMENT

101.SCH XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

101.CAL XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

101.DEF XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

101.LAB XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

* Filed herewith.

SIGNATURES

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

ADVAXIS, INC.
Registrant

Date: June 7, 2018 By: */s/ Kenneth A. Berlin*
Kenneth A. Berlin
Principal Executive, Financial and Accounting
Officer

