

Advaxis, Inc.
Form 10-Q
September 10, 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 July 31, 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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of August 31, 2018 was 52,828,483.

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>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
Item 4. <u>Controls and Procedures</u>	21
PART II <u>OTHER INFORMATION</u>	21
Item 1. <u>Legal Proceedings</u>	21
Item 1A. <u>Risk Factors</u>	21
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 3. <u>Defaults Upon Senior Securities</u>	35
Item 4. <u>Mine Safety Disclosures</u>	35
Item 5. <u>Other Information</u>	35
Item 6. <u>Exhibits</u>	35
<u>SIGNATURES</u>	36

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 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 raise additional capital to fund our growth and to support our operations;

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 establish and manage strategic collaborations;

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)**

(In thousands, except share and per share data)

	July 31, 2018	October 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	\$39,434	\$23,900
Restricted cash	977	587
Short-term investment securities	-	46,398
Income tax receivable	-	4,453
Deferred expenses	5,046	2,986
Prepaid expenses and other current assets	2,323	2,919
Total current assets	47,780	81,243
Property and equipment (net of accumulated depreciation)	7,513	7,111
Intangible assets (net of accumulated amortization)	5,277	4,857
Other assets	489	431
Total assets	\$61,059	\$93,642
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,842	\$5,121
Accrued expenses	3,918	8,700
Deferred revenue	4,476	6,995
Other current liabilities	874	48
Total current liabilities	12,110	20,864
Deferred revenue	15,317	17,479
Other liabilities	301	1,039
Total liabilities	27,728	39,382

Commitments and contingencies – Note 9

Stockholders' equity:

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

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at July 31, 2018 and October 31, 2017 Liquidation preference of \$0 at July 31, 2018 and October 31, 2017	-	-
Common stock - \$0.001 par value; 95,000,000 shares authorized, 52,802,360 and 41,206,538 shares issued and outstanding at July 31, 2018 and October 31, 2017	53	41
Additional paid-in capital	382,337	355,361
Accumulated deficit	(349,059)	(301,142)
Total stockholders' equity	33,331	54,260
Total liabilities and stockholders' equity	\$61,059	\$93,642

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

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

(In thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	July 31,	2017	July 31,	2017
	2018		2018	
Revenue	\$ 1,131	\$3,052	\$4,934	\$ 10,268
Operating expenses:				
Research and development expenses	10,800	17,794	38,703	47,750
General and administrative expenses	4,495	17,995	14,495	33,101
Total operating expenses	15,295	35,789	53,198	80,851
Loss from operations	(14,164)	(32,737)	(48,264)	(70,583)
Other income (expense):				
Interest income, net	149	184	439	514
Net changes in fair value of derivative liabilities	-	-	-	20
Other expense	(2)	(72)	(42)	(75)
Net loss before benefit for income taxes	(14,017)	(32,625)	(47,867)	(70,124)
Income tax expense	-	-	50	50
Net loss	\$(14,017)	\$(32,625)	\$(47,917)	\$(70,174)
Net loss per common share, basic and diluted	\$(0.27)	\$(0.80)	\$(1.00)	\$(1.74)
Weighted average number of common shares outstanding, basic and diluted	52,668,919	40,609,794	47,966,672	40,315,356

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

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

(in thousands)

	Nine Months Ended July 31,	
	2018	2017
OPERATING ACTIVITIES		
Net loss	\$(47,917)	\$(70,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	5,987	24,694
Employee stock purchase plan expense	13	82
Gain on change in value of warrants and embedded derivative	-	(20)
Loss on disposal of property and equipment	27	3
Write-off of intangible assets	424	108
Depreciation expense	827	554
Amortization expense of intangible assets	288	239
Net (accretion) amortization of premiums and discounts	(6)	150
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,339)	(3,299)
Income tax receivable	4,453	2,550
Other assets	(58)	(49)
Accounts payable and accrued expenses	(7,030)	(3,634)
Deferred revenue	(4,681)	(10,018)
Other liabilities	88	140
Net cash used in operating activities	(48,924)	(58,674)
INVESTING ACTIVITIES		
Restricted cash established with letter of credit agreements	(390)	-
Purchases of short-term investment securities	(12,487)	(73,426)
Proceeds from maturities of short-term investment securities	58,891	38,220
Purchase of property and equipment	(1,381)	(3,419)
Cost of intangible assets	(1,132)	(960)
Net cash provided by (used in) investing activities	43,501	(39,585)
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock	21,042	706
Proceeds from exercise of warrants	-	1
Proceeds from employee stock purchase plan	22	141
Tax withholdings paid related to net share settlement of equity awards	(87)	(354)
Employee tax withholdings paid on equity awards	(458)	(1,548)
Tax shares sold to pay for employee tax withholdings on equity awards	438	1,575
Net cash provided by financing activities	20,957	521

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

Net increase (decrease) in cash and cash equivalents	15,534	(97,738)
Cash and cash equivalents at beginning of period	23,900	112,751
Cash and cash equivalents at end of period	\$39,434	\$ 15,013

SUPPLEMENTAL CASH FLOW INFORMATION

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

SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES

Accounts payable and accrued expenses settled with common stock	\$-	\$75
Property and equipment included in accounts payable and accrued expenses	-	86

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 redirects the immune system to attack cancer in three distinct ways by:

Alerting and training 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 500 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.

Going Concern and Managements Plans

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. The aforementioned factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of

liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, our major sources of cash have comprised proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through August 2018, we raised approximately \$245 million in gross proceeds from various public and private offerings of our common stock.

As of July 31, 2018 and August 31, 2018, the Company had approximately \$40.4 million and \$36.3 million, respectively, in cash, restricted cash and cash equivalents. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. On September 7, 2018 the Company announced the pricing of an underwritten public offering which is expected to gross \$20 million in proceeds. It is the belief of the Company, that should the financing close on September 11, 2018 the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business through September 2019. The actual amount of cash that it will need to operate, is subject to many factors.

The Company also recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. 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 operations.

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 of 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 July 31, 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 July 31,	
	2018	2017
Warrants	3,092,395	3,094,173
Stock Options	5,298,869	3,893,558
Restricted Stock Units	706,507	1,527,693
Total	9,097,771	8,515,424

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 short-term investment securities at amortized cost as of October 31, 2017 (in thousands):

	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	\$ -	\$ -	\$ 11,391
Domestic Governmental Agency Loans	500	-	-	500
U.S Treasury Notes	34,507	-	25	34,482
Total short-term investment securities	\$ 46,398	\$ -	\$ 25	\$ 46,373

As of July 31, 2018, all of the Company's short-term investment securities have matured.

4. PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following (in thousands):

	July 31, 2018	October 31, 2017
Leasehold improvements	\$ 2,255	\$ 2,168
Laboratory equipment	5,510	4,381
Furniture and fixtures	746	729
Computer equipment	409	395
Construction in progress	627	645
Total property and equipment	9,547	8,318

Accumulated depreciation and amortization	(2,034)	(1,207)
Net property and equipment	\$7,513	\$7,111

Depreciation expense for the three and nine months ended July 31, 2018 and 2017 was approximately \$0.3 million, \$0.8 million, \$0.2 million and \$0.6 million, respectively.

5. INTANGIBLE ASSETS

Intangible assets, net consist of the following (in thousands):

	July 31, 2018	October 31, 2017
Patents	\$6,351	\$5,727
Licenses	777	777
Software	117	109
Total intangibles	7,245	6,613
Accumulated amortization	(1,968)	(1,756)
Intangible assets	\$5,277	\$4,857

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 approximately \$0.1 million, \$0.4 million, \$0.02 million and \$0.1 million were abandoned and were charged to research and development expenses in the Statement of Operations for the three and nine months ended July 31, 2018 and 2017, respectively. Amortization expense for intangible assets aggregated approximately \$0.1 million, \$0.3 million, \$0.1 million and \$0.2 million for the three and nine months ended July 31, 2018 and 2017, respectively.

At July 31, 2018, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

Year ended October 31,

2018 (Remaining)	\$99
2019	394
2020	377
2021	357
2022	357
Thereafter	3,693
Total	\$5,277

6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses (in thousands):

	July 31, 2018	October 31, 2017
Salaries and other compensation	\$1,627	\$2,653
Vendors	797	2,812
Professional fees	1,494	3,235
Total accrued expenses	\$3,918	\$8,700

7. WARRANTS

At July 31, 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 0.17 and 0.92 years, respectively. At July 31, 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 (in thousands):

	Three Months		Nine Months	
	Ended July 31,		Ended July 31,	
	2018	2017	2018	2017
Research and development	\$ 543	\$ 1,517	\$ 2,342	\$ 4,271
General and administrative	1,409	12,853	3,645	20,423
Total	\$ 1,952	\$ 14,370	\$ 5,987	\$ 24,694

Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the nine months ended July 31, 2018 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2017	1,363,119	\$ 8.54
Granted	380,424	1.96
Vested	(714,518)	7.82
Cancelled	(322,518)	8.39
Balance at July 31, 2018	706,507	\$ 5.78

As of July 31, 2018, there was approximately \$3.2 million of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of 1.57 years.

As of July 31, 2018, the aggregate intrinsic value of non-vested RSUs was approximately \$1.0 million.

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 215,267 shares (190,247 shares on a net basis after employee taxes) and 463,985 shares (452,084 shares on a net basis after employee taxes) during the three months ended July 31, 2018 and 2017 respectively. Total stock compensation expense associated with employee awards for the three months ended July 31, 2018 and 2017 was approximately \$0.9 and \$4.3 million, respectively

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 669,044 shares (623,687 shares on a net basis after employee taxes) and 717,505 shares (674,543 shares on a net basis after employee taxes) during the nine months ended July 31, 2018 and 2017 respectively. Total stock compensation expense associated with employee awards for the nine months ended July 31, 2018 and 2017 was approximately \$2.9 million and \$7.3 million, respectively.

Included in compensation expense for the three and nine months ended July 31, 2018 is approximately \$110,000 and \$320,000, respectively, 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 and Chief Operating Officer in June 2018. Pursuant to the separation agreements, the vesting was accelerated on all of the outstanding RSU's.

Director Stock Awards

Common stock issued to Directors for compensation related to board and committee membership totaled 45,000 and 0 shares for the three months ended July 31, 2018 and 2017, respectively. During the three months ended July 31, 2018 and 2017, total stock compensation expense associated with Director awards was approximately \$71,000 and \$102,000, respectively.

Common stock issued to Directors for compensation related to board and committee membership totaled 75,000 and 30,000 shares for the nine months ended July 31, 2018 and 2017, respectively. During the nine months ended July 31, 2018 and 2017, total stock compensation expense associated with Director awards was approximately \$178,000 and \$302,000, respectively.

Stock Options

A summary of changes in the stock option plan for the nine months ended July 31, 2018 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2017:	3,893,558	\$ 12.51
Granted	2,473,460	2.08
Canceled or Expired	(1,068,149)	10.66
Outstanding at July 31, 2018	5,298,869	8.01
Vested and Exercisable at July 31, 2018	2,936,262	\$ 12.22

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended July 31, 2018 and 2017 was approximately \$0.9 million and \$9.7 million, respectively. For the nine months ended July 31, 2018 and 2017, compensation cost related to the Company's outstanding stock options was approximately \$2.9 million and \$15.9 million, respectively. Included in compensation expense for the three and nine months ended July 31, 2018 is approximately \$0 and \$77,000, respectively, 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 nine months ended July 31, 2018, 2,473,460 options were granted with a total grant date fair value of approximately \$4.0 million. During the nine months ended July 31, 2017, 556,952 options were granted with a total grant date fair value of approximately \$3.5 million.

As of July 31, 2018, there was approximately \$3.4 million 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 2.19 years.

As of July 31, 2018, the aggregate intrinsic value of vested and exercisable options was \$0.

In determining the fair value of the stock options granted during the nine months ended July 31, 2018 and 2017, the Company used the following inputs in its BSM:

	Nine Months Ended July 31,	
	2018	2017
Expected Term	5.35 – 6.51 years	5.50-6.50 years
Expected Volatility	94.61% - 100.34 %	107.07%-110.93 %
Expected Dividends	0 %	0 %
Risk Free Interest Rate	1.81 – 2.93 %	1.26%-1.58 %

2018 Employee Stock Purchase Plan – update with '18 Plan

During the nine months ended July 31, 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 (in thousands):

Year ended October 31,

2018 (remaining)	\$262
2019	1,107
2020	1,233
2021	1,318
2022	1,369
Thereafter	4,378
Total	\$9,667

10. 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.

11. STOCKHOLDERS' EQUITY

During the nine months ended July 31, 2018, the Company sold 881,629 shares of its common stock at-the-market transactions resulting in net proceeds of approximately \$2.7 million.

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 \$18.4 million.

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.

12. SUBSEQUENT EVENTS

On September 4, 2018, The Company granted a license to OS Therapies LLC for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, OS Therapies LLC, in collaboration with the Children's Oncology Group, will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. The Company will receive an upfront payment, reimbursement for product supply and other support, clinical, regulatory, and sales-based milestone payments, and royalties on future product sales.

On September 7, 2018, the Company announced the pricing of an underwritten public offering of 16,666,666 shares of its common stock and warrants to purchase up to 14,166,666 shares of common stock. Each share of common stock is being sold together in a fixed combination with a warrant to purchase 0.85 shares of common stock. The warrants will be exercisable immediately, will expire six years from the date of issuance and will have an exercise price of \$1.50 per share, subject to anti-dilution adjustments. The gross proceeds of the offering to the Company are expected to be approximately \$20 million, before deducting the underwriting discounts and commissions and other estimated offering expenses, and excluding the exercise of any warrants. The closing of the offering is expected to occur on or

about September 11, 2018, subject to the satisfaction of customary closing conditions.

The shares of common stock will be sold pursuant to an effective shelf registration statement on Form S-3 (No. 333-226988) filed with the Securities and Exchange Commission on August 23, 2018 and declared effective on August 30, 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 redirects the immune system to attack cancer in three distinct ways by:

Alerting and training 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, while determining other ways to reduce operating expenses, in order to maximize stockholder value. In particular, we took the following actions:

Expanded our search for a U.S. and/or European partner for the Company's lead HPV program, axalimogene filolisbac, who will need to take on all development and commercialization activities and costs for axalimogene filolisbac in cervical cancer. While the Company's lead HPV program 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. If the Company is unable to secure a partner within a limited period of time, 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 HPV-positive 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 and continue to follow patients for the next six to nine months in order to determine the path forward.

In addition, in June 2018, the Company announced that it implemented a reduction in force to align its staffing needs with its new strategy. The reduction involved the elimination of approximately 24% of the Company's work force. Overall the cost of separation payments were slightly higher than the savings of the work force reduction in the third quarter by approximately \$0.14 million. Beginning with the Company's fourth quarter, results of operations net of quarterly savings will be approximately \$1.2 million, or a total annualized workforce payroll savings of approximately \$4.6 million. 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. As of the end of 2017, over 430 patients have received axalimogene filolisbac, and approximately 1,260 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. On July 13, 2018, the Company announced that it received notification from the FDA that the clinical hold has been lifted. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and have been implemented for this combination study and will be implemented across the portfolio as needed. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold.

ADXS-HOT

Utilizing ADXS-HOT, a program that leverages *Lm* Technology to target hotspot neoantigens and other proprietary tumor associated antigens that commonly occur in specific cancer types, the Company is currently prioritizing product development in the most prevalent cancers, with the first tumor type to be NSCLC. On July 30, 2018, the Company announced FDA's allowance of its ADXS-HOT IND in NSCLC. We plan to commence a first-in-human trial in NSCLC in 2018. Going forward, the Company plans to submit additional INDs for drug candidates from its ADXS-HOT program for prostate cancer by the end of 2018, for bladder cancer by the first quarter of 2019 and for one of breast, colorectal, ovarian or head and neck candidates by the third quarter of 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.

In June 2018, we announced plans to increase our internal investment in the ADXS-HOT program.

ADXS-NEO

Preclinical findings in the ADXS-NEO personalized *Lm* immunotherapy 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, the Company's partner in the development and commercialization of the ADXS-NEO program, 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 open-label, dose-escalation, multicenter Phase 1 trial are microsatellite stable colorectal cancer, head and neck cancer, and NSCLC. The first patient, being treated for NSCLC, was dosed in June 2018. Additionally, in June 2018, we announced plans to increase our internal investment in the ADXS-NEO program.

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 (18%) patients in the combination arm with 50% or greater declines in PSA from baseline, and none in the monotherapy arm.

These data, while early, have proven worthy of further evaluation and the company will continue to follow patients’ survival for the next six to nine months in order to determine the path forward.

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. In July 2018, the Company rescinded its application based on EMA feedback following its initial review indicating the application would likely need additional data to support a conditional approval.

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 the Company is unable to secure a partner within a limited period of time, we will wind down the ongoing AIM2CERV trial in high-risk locally advanced cervical cancer. In the short term, patients participating in the AIM2CERV trial are continuing 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. As of the end of 2017, over 430 patients have received axalimogene filolisbac, and approximately 1,260 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. On July 13, 2018, the Company announced that it received notification from the FDA that the clinical hold has been lifted. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and have been implemented for this combination study and will be implemented across the portfolio as needed. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold.

We 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 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.

The Company is evaluating opportunities to conduct cost effective studies evaluating axalimogene filolisbac in head and neck cancer and are in discussion with third parties about a potential study.

Results of Operations for the Three Months Ended July 31, 2018 and 2017

Revenue

Revenue decreased \$2.0 million to approximately \$1.1 million for the three months ended July 31, 2018 compared to \$3.1 million the three months ended July 31, 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 invest in research and development to advance our *Lm* technology through our pre-clinical and clinical development programs. Research and development expenses for the three months ended July 31, 2018 and 2017 were categorized as follows (in thousands):

Research and Development (in thousands)

Three Months Ended	Increase (Decrease)
-----------------------	------------------------

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

	July 31,			
	2018	2017	\$	%
HPV-associated cancers	\$4,287	\$5,996	\$(1,709)	(29)%
Neoantigen-based therapies (ADXS-NEO and ADXS-HOT)	636	553	83	15
Other expenses	7,298	17,245	(9,947)	(58)
Partner reimbursements	(1,421)	(6,000)		