Advaxis, Inc.
Form 10-Q
September 10, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] 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)

Delaware	**02-0563870**
(State or other jurisdiction of incorporation or organization)	(IRS Employer 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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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 [X] No [ ]

Indicate by checkmark 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	[X]
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 [X]

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

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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:		

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 July 31,		Nine Months Ended July 31,	
	2018	2017	2018	2017
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

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.

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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.

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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 Ended July 31,		Nine Months 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/), 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.

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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 L*m* 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)

	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)	4,579	(76)
Total research & development expense	$10,800	$17,794	$(6,994)	(39)%
Stock-based compensation expense included in research and development expense	$543	$1,517	$(974)	(64)%

HPV-associated cancers

HPV-associated research and development costs include clinical trial and other related costs associated with our cervical and head and neck programs. HPV-associated costs for the three months ended July 31, 2018 decreased approximately $1.7 million, or 29%, compared to the same period in 2017. The decrease resulted primarily from lower enrollment activities associated with the Phase 3 AIM2CERV trial as well as the winding down of the GOG-0265 study.

Neoantigen-based therapies

Research and development costs associated with neoantigen-based therapies for the three months ended July 31, 2018 increased approximately $0.1 million, or 15%, compared to the same period in 2017. The increase is attributable to additional manufacturing and certain study management costs in conjunction with the Phase 1 ADXS-NEO study in addition to the costs associated with filing our first IND in ADXS-HOT with the FDA.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the three months ended July 31, 2018 decreased approximately $9.9 million, or 58%, compared to the same period in 2017. The decrease was primarily attributable to a decrease in laboratory costs, drug manufacturing process validation and drug stability studies supporting the MAA, which was filed in February 2018. In addition, there was a decrease in salary-related expenses, including stock compensation, and travel expenses resulting from a reduction in headcount due to the reduction in force that the Company initiated in June 2018.

Partner reimbursements

Partner reimbursements for the three months ended July 31, 2018 decreased approximately $4.6 million, or 76%, compared to the same period in 2017. The decrease is attributable to reimbursements from Amgen supporting ADXS-NEO covering three months during the three months ended July 31, 2018 as compared to reimbursements from Amgen covering one year during the same period in 2017.

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 for the three months ended July 31, 2018 and 2017 were as follows (in thousands):

	Three Months Ended July 31,		Increase (Decrease)	
	2018	2017	$	%
General and administrative expense	$4,495	$17,995	$(13,500)	(75)%
Stock-based compensation expense included in general and administrative expense	$1,409	$12,853	$(11,444)	(89)%

General and administrative expenses for the three months ended July 31, 2018 decreased approximately $13.5 million, or 75%, compared to the same period in 2017. The decrease is primarily attributable to a decrease in stock-based compensation of approximately $11.4 million 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, a reduction in headcount and the elimination of stock-based compensation paid to consultants. In addition, there was a decrease to legal costs on general corporate matters.

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

Revenue

Revenue decreased $5.4 million to $4.9 million for the nine months ended July 31, 2018 compared to $10.3 million for the nine 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 L*m* technology through our pre-clinical and clinical development programs. Research and development expenses for the nine months ended July 31, 2018 and 2017 were categorized as follows (in thousands):

	Nine Months Ended July 31,		Increase (Decrease)	
	2018	2017	$	%
HPV-associated cancers	$14,224	$14,962	$(738)	(5)%
Neoantigen-based therapies (ADXS-NEO and ADXS-HOT)	1,753	1,597	156	10
Other expenses	27,241	40,191	(12,950)	(32)
Partner reimbursements	(4,515)	(9,000)	4,485	(50)
Total research & development expense	$38,703	$47,750	$(9,047)	(19)%
Stock-based compensation expense included in research and development expense	$2,342	$4,271	$(1,929)	(45)%

HPV-associated cancers

HPV-associated research and development costs include clinical trial and other related costs associated with our cervical and head and neck programs. HPV-associated costs for the nine months ended July 31, 2018 decreased approximately $0.7 million, or 5%, compared to the same period in 2017. The decrease resulted from the winding down of the GOG-0265 study and was partially offset by the expansion of the Phase 3 AIM2CERV trial into additional countries in early 2018.

Neoantigen-based therapies

Research and development costs associated with neoantigen-based therapies for the three months ended July 31, 2018 increased approximately $0.2 million, or 10%, compared to the same period in 2017. The increase is attributable to additional manufacturing and certain study management costs in conjunction with the Phase 1 ADXS-NEO study and the filing of our first IND in ADXS-HOT.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the nine months ended July 31, 2018 decreased approximately $13.0 million, or 32%, compared to the same period in 2017. The decrease was primarily attributable to a decrease in laboratory costs, drug manufacturing process validation and drug stability studies supporting the MAA, which was filed in February 2018. In addition, there was a decrease in salary-related expenses, including stock compensation, and travel expenses resulting from a reduction in headcount due to the reduction in force that the Company initiated in June 2018.

Partner reimbursements

Partner reimbursements decreased approximately $4.5 million, or 50%, for the nine months ended July 31, 2018 compared to the same period in 2017. The decrease relates to $3.0 million from Stendhal for partner reimbursements supporting AIM2CERV in the prior period. In addition, reimbursements from Amgen supporting ADXS-NEO decreased to $4.5 million for the nine months ended July 31, 2018 compared to $9.0 million for the nine months ended July 31, 2018, as the Company received reimbursements from Amgen covering nine months during the nine months ended July 31, 2018 as compared to reimbursements covering one year during the same period in 2017.

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 for the nine months ended July 31, 2018 and 2017 were as follows (in thousands):

	Three Months Ended July 31,		Increase (Decrease)	
	2018	2017	$	%
General and administrative expense	$14,495	$33,101	$(18,606)	(56)%
Stock-based compensation expense included in general and administrative expense	$3,645	$20,423	$(16,778)	(82)%

General and administrative expenses for the nine months ended July 31, 2018 decreased approximately $18.6 million, or 56%, compared to the same period in 2017. The decrease is primarily attributable to a decrease in stock-based compensation of approximately $16.8 million 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, a reduction in headcount and the elimination of stock-based compensation paid to consultants. In addition, there was a decrease to legal costs on general corporate matters and litigation settlements. 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

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.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $48.9 million for the nine months ended July 31, 2018 compared to net cash used in investment activities of approximately $58.7 million for the nine months ended July 31, 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 $43.5 million for the nine months ended July 31, 2018 compared to net cash used in investing activities of approximately $39.6 million for the nine months ended July 31, 2017. During the nine months ended July 31, 2018, all of the Company's remaining short-term investment securities matured and some of the proceeds were used to fund operating activities, while in the prior year, some of the matured short-term investment securities were re-invested. In addition, there was a reduction in property and equipment purchases of approximately $2.0 million as compared to the prior year and during the nine months ended July 31, 2018, approximately $390,000 of restricted cash was established with a letter of credit. During both periods, there were legal costs associated with supporting of our intellectual property.

Financing Activities

Net cash provided by financing activities was approximately $21.0 million for the nine months ended July 31, 2018 as compared to approximately $0.5 million for the nine months ended July 31, 2017. The increase resulted primarily from net proceeds of approximately $18.4 million from the sale of 10,000,000 shares of our common stock in a public offering and approximately $2.7 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. As of July 31, 2018, and October 31, 2017, we had an accumulated deficit of approximately $349.1 million and $301.1 million, respectively, and stockholders' equity of approximately $33.3 million and $54.3 million, 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 July 31, 2018, the Company's total future minimum lease payments under noncancelable operating leases was $9.7 million.

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 July 31, 2018, the Company had approximately $40.4 million in cash and cash equivalents, which consisted primarily of bank deposits and money market funds. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

In June 2018, the Company announced that Molly Henderson was named Chief Financial Officer. During the quarter ended July 31,2018, 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 Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. Refer to Footnote 9: Commitments and Contingencies for more information on legal proceedings.

Item 1A. Risk Factors

You should carefully consider the risks described below as well as other information provided to you in this Quarterly Report on Form 10-Q, including information in the section of this document entitled "Cautionary Note Regarding Forward Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our Common Stock could decline, and you may lose all or part of your investment.

Risks Related to our Business and Industry

We are a clinical stage company.

We are a clinical stage biotechnology company with a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout our clinical stage, we may exhaust our financial resources and be unable to complete the development of our products. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period.

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. As of July 31, 2018, and October 31, 2017, we had an accumulated deficit of approximately $349.1 million and $301.1 million, respectively, and stockholders' equity of approximately $33.3 million and $54.3 million, respectively. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. If any of our product candidates fail in clinical trials or does not gain regulatory approval, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our ability to raise additional capital to fund our growth and to support our operations may be uncertain.

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.

Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.

Product candidates are subject to extensive pre-clinical testing and clinical trials to demonstrate their safety and efficacy in humans. Conducting pre-clinical testing and clinical trials is a lengthy, time-consuming and expensive process that takes many years. We cannot be sure that pre-clinical testing or clinical trials of any of our product candidates will demonstrate the safety, efficacy and benefit-to-risk profile necessary to obtain marketing approvals. In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in larger or late-stage clinical trials, which are required for marketing approval.

Even if we are successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, we must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. There are a number of additional factors that may cause our clinical trials to be delayed, prematurely terminated or deemed inadequate to support regulatory approval, such as:

- safety issues up to and including patient death (whether arising with respect to trials by third parties for compounds in a similar class as tour product or product candidate), inadequate efficacy, or an unacceptable risk-benefit profile observed at any point during or after completion of the trials;

slower than expected rates of patient enrollment, which could be due to any number of factors, including failure of our third-party vendors, including our CROs, to effectively perform their obligations to us, a lack of patients who meet the enrollment criteria or competition from clinical trials in similar product classes or patient populations, or onerous treatment administration requirements;

the risk of failure of our clinical investigational sites and related facilities, including our suppliers, to maintain compliance with the FDA's cGMP regulations or similar regulations in countries outside of the U.S., including the risk that these sites fail to pass inspections by the appropriate governmental authority, which could invalidate the data collected at that site or place the entire clinical trial at risk;

any inability to reach agreement or lengthy discussions with the FDA, equivalent regulatory authorities, or ethical review committees on trial design that we are able to execute;

changes in laws, regulations, regulatory policy or clinical practices, especially if they occur during ongoing clinical trials or shortly after completion of such trials.

clinical trial record keeping or data quality and accuracy issues.

Any deficiency in the design, implementation or oversight of our development programs could cause us to incur significant additional costs, conduct additional trials, experience significant delays, prevent us from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm our business and cause our stock price to decline.

Our operating history does not afford investors a sufficient history on which to base an investment decision.

We commenced our *Lm* -LLO based immunotherapy development business in February 2002 and today exist as a clinical stage company. We have no approved products and therefore have not derived any significant revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, there is limited information for investors to use as basis for assessing our future viability. Investors must consider the risks and difficulties we have encountered in the rapidly evolving vaccine and immunotherapy industry. Such risks include the following:

- difficulties, complications, delays and other unanticipated factors in connection with the development of new drugs;
- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our immunotherapies;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- need to rely on outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

We cannot be certain that our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

We expect that we will need to raise additional funding to complete the development and commercialization of our product candidates. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.

We estimate that our current cash, cash equivalents and investments will be sufficient for us to fund our operating expenses and capital expenditure requirements through 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In addition, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed, as a result of insufficient authorized shares or otherwise, could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

We may face legal claims; litigation is expensive and we may not be able to afford the costs.

We may face legal claims involving stockholders, consumers, competitors, regulators and other parties. As described in “Legal Proceedings” in Part I Item 3 of this Form 10-K, we are engaged in a number of legal proceedings. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from engaging in business practices, or requiring other remedies, such as compulsory licensing of patents.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial, even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex litigation. Also, a lawsuit, even if frivolous, will require considerable time commitments on the part of management, our attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

We can provide no assurance of the successful and timely development of new products.

Our immunotherapies are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may invest substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, clinical holds, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any new products which could materially harm our business, results of operations and prospects.

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our immunotherapies;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that our research and development expenses will be consistent from period to period. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource the management of our clinical trials to third parties. Agreements with clinical research organizations, clinical investigators and medical institutions for clinical testing and data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For

example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our agents. We are not certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of future development of our agents.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials, or place our products on temporary or permanent hold, at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for our product candidates, which would materially harm our business, results of operations and prospects.

If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of our clinical product candidates, and we rely on strategic collaborations for research, development, marketing and commercialization for some of our immunotherapies. To date, we have been heavily reliant upon third party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials.

We are currently seeking a partner to fund the development and commercialization of axalimogene filolisbac in cervical cancer. If a partner is not found, subject to ongoing discussions with our collaboration partners over our obligations with respect the program, we anticipate winding down the program in a clinically responsible manner. We may incur additional costs in connection with such a wind-down, including in severing our relationship with our collaboration partners. Some of the costs are indeterminable at this time and there is no guarantee that we will be able to wind down the program effectively, which could lead to considerable expense and could negatively affect our financial results.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. Our current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we have entered or will enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- financial funding to support said collaboration;
- coordination of our research and development programs with the research and development priorities of our collaborators; and

effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our immunotherapies. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. If we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements. Additionally, our collaborators may seek to renegotiate agreements we have entered into, or may disagree with us about the terms and implementation of these agreements. If collaborators disagree with us about the terms or implementation of our agreements, we may face legal claims that may involve considerable expense and could negatively affect our financial results.

The successful development of immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;

failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;

manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and

the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding product promotion, the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third party providers) comply with cGMPs, and Good Clinical Practices ("GCP"), for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates' post-market approval could have a material adverse effect on our business, financial condition and results of operations.

We must comply with significant government regulations.

The research and development, manufacturing and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. If we obtain approval for any of our product candidates, our operations will be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for marketing approval of a biologic, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its cGMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The cGMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our immunotherapies through clinical testing and to market.

We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.

We are currently evaluating the safety and efficacy of several of our candidates in a number of ongoing pre-clinical and clinical trials. However, even though the initiation and conduct of the clinical trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an IND in the United States, or the equivalent in countries outside of the United States), we are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining FDA (U.S.) and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not submitted for nor obtained regulatory approval for any product candidate in-humans (US & EU) and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Although we have been granted FDA orphan drug designation for axalimogene filolisbac for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as EMA orphan drug designation for axalimogene filolisbac for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU, and intend to continue to expand our designation for these uses where applicable , we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMEA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The recently enacted tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or the TCJA, which significantly amends the Internal Revenue Code of 1986. The TCJA, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted earnings, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact these changes may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of the TCJA on holders of our common stock is also uncertain and could be adverse. This prospectus supplement and the accompanying prospectus do not discuss the TCJA or the manner in which it might affect us or purchasers of our common stock. We urge our stockholders, including purchasers of common stock in this offering, to consult with their legal and tax advisers with respect to the TCJA and the potential tax consequences of investing in our common stock.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to U.S. export control and economic sanctions laws and regulations and other restrictions on international trade. As such, we are required to export our technology, products, and services in compliance with those laws and regulations. If we export our technology, products, or services, the exports may require authorizations, including a license, a license exception or other appropriate government authorization. In addition, the United States and other governments and their agencies impose sanctions and embargoes on certain countries, their governments and designated parties, which may prohibit the export of certain technology, products, and services to such persons altogether.

We are also subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, third-party intermediaries, and other associated persons from authorizing, promising, offering, providing, soliciting, or accepting directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. We have direct or indirect

interactions with officials and employees of government agencies. We can be held liable for the corrupt or other illegal activities of our employees, representatives, contractors, business partners, and agents, in violation of U.S. and applicable foreign anti-corruption, export, import, sanctions, or anti-money laundering laws and regulations, even if we do not explicitly authorize or have actual knowledge of such activities.

Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the *Lm* -LLO based immunotherapy platform technology, and the proprietary technology of others with whom we have entered into collaboration and licensing agreements.

Currently, we own or have rights to approximately 433 patents and applications, which are owned, licensed from, or co-owned with Penn, Merck, NIH, and/or Augusta University. We have obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel, at the University of Pennsylvania.

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and we cannot guarantee that sufficient funds will be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against

use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented as a result of laws, rules and guidelines that are changed due to legislative, judicial or administrative actions, or review, which render our patents unenforceable or invalid. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack utility, sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of our technologies infringe these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our product candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared valid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We are dependent upon our license agreement with Penn; if we breach the license agreement and/or fail to make payments due and owing to Penn under our license agreement, our business will be materially and adversely affected.

Pursuant to the terms of our license agreement with Penn, which has been amended from time to time, we have acquired exclusive worldwide licenses for patents and patent applications related to our proprietary Listeria vaccine technology. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of July 31, 2018, we had no outstanding payments to Penn. We can provide no assurance that we will be able to make all future payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses from Penn for other rights that may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm our business, financial condition and operating results.

If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

We have limited to no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.

We currently have agreements with various third party manufacturing facilities for production of many of our immunotherapies for research and development and testing purposes. While we have built our own manufacturing facility onsite in Princeton to manufacture clinical materials for some of our products, included ADXS-NEO, we depend on third-party manufacturers to supply most of our preclinical and clinical materials and will be reliant on a third-party manufacturer to produce axalimogene filolisbac on a commercial scale, should that product receive regulatory approval. Third-party manufacturers must be able to meet our deadlines as well as adhere to quality standards and specifications. Our predominant reliance on third parties for the manufacture of our drug substance, investigational new drugs and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If our own manufacturing operation or any contracted manufacturing operation is unreliable or unavailable, we may not be able to manufacture clinical drug supplies of our immunotherapies, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail. If we are able to commercialize our products in the future, there is no assurance that our own manufacturing operation or any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current GMP.

We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our immunotherapies in human clinical trials, and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against us if one of the immunotherapies causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our immunotherapies;

damage to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues;

the inability to commercialize immunotherapies; and

increased difficulty in raising required additional funds in the private and public capital markets.

We have Product Liability and Clinical Trial Liability insurance coverage for each clinical trial. We do not have product liability insurance for sold commercial products because we do not have products on the market. We currently are in the process of obtaining insurance coverage and plan to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of our immunotherapies. However, insurance coverage is increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

We may incur significant costs complying with environmental laws and regulations.

We and our contracted third parties use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our or our outsourced laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with such laws and regulations may be costly.

If we use biological materials in a manner that causes injury, we may be liable for damages.

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste or pollution liability or remediation insurance coverage, nor do our workers' compensation, general liability, and property and casualty insurance policies provide coverage for damages and fines/penalties arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.

As of December 15, 2017, we had 108 employees, all of which were full time employees. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and other products, unable to commercialize any products, and unable to adequately address our management needs.

We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.

We depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like: Aduro Biotech, Agenus Inc., Celldex Therapeutics, Inovio Pharmaceutical Inc., ISA Pharmaceuticals, MedImmune LLC, Neon Therapeutics, Oncolytics Biotech Inc. and Oncothyreon Inc., each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We may not obtain or maintain the benefits associated with breakthrough therapy designation.

If we apply for Breakthrough Therapy Designation (“BTD”), we may not be granted BTD, or even if granted, we may not receive the benefits associated with BTD. This may result from a failure to maintain breakthrough therapy status if it is no longer considered to be a breakthrough therapy. For example, a drug’s development program may be granted BTD using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where BTD is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When BTD is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a breakthrough therapy development program.

We believe that our immunotherapies under development and in clinical trials will address unmet medical needs in the treatment of cancer. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Approval of our product candidates does not ensure successful commercialization and reimbursement.

We are not currently marketing our product candidates, however we are seeking commercial opportunities for axalimogene filolisbac. We cannot assure you that we will be able to commercialize it or any other candidate ourselves or find a commercialization partner or that we will be able to agree to acceptable terms with any partner to launch and commercialize our products.

The commercial success of our product candidates is subject to risks in both the United States and European countries. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner's ability to successfully commercialize in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling on a profitable basis in a particular country, they could prevent the commercial launch or continued sale in that country and could adversely impact the commercialization market opportunity in other countries.

Moreover, as a condition of approval, the regulatory authorities may require that we conduct post-approval studies. Those studies may reveal new safety or efficacy findings regarding our drug that could adversely impact the continued commercialization or future market opportunity in other countries.

In addition, Advaxis predominantly relies on a network of suppliers and vendors to manufacture its products. Should a regulatory authority make any significant findings on an inspection of Advaxis' own operations or the operations of those companies, the ability of Advaxis to continue producing its products could be adversely impacted and further production could cease. Regulatory GMP requirements are extensive and can present a risk of injury or recall, among other risks, if not manufactured or labeled properly under GMPs.

Our potential revenues from the commercialization of our product candidates are subject to these and other factors, and therefore we may never reach or maintain profitability.

Risks Related to our Securities

The price of our Common Stock and warrants may be volatile.

The trading price of our Common Stock and warrants may fluctuate substantially. The price of our Common Stock and warrants that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our Common Stock and warrants. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of our stock;

significant dilution caused by the anti-dilutive clauses in our financial agreements;

departures of key personnel;

changes in the regulatory status of our immunotherapies, including results of our clinical trials;

events affecting Penn or any current or future collaborators;

announcements of new products or technologies, commercial relationships or other events by us or our competitors;

regulatory developments in the United States and other countries;

failure of our Common Stock or warrants to be listed or quoted on The NASDAQ Stock Market, NYSE Amex Equities or other national market system;

changes in accounting principles; and

discussion of us or our stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A limited public trading market may cause volatility in the price of our Common Stock.

The quotation of our Common Stock on the NASDAQ does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our Common Stock is thus subject to this volatility. Sales of substantial amounts of Common Stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our Common Stock and our stock price may decline substantially in a short time and our shareholders could suffer losses or be unable to liquidate their holdings.

The market prices for our Common Stock may be adversely impacted by future events.

Our Common Stock began trading on the over-the-counter-markets on July 28, 2005 and is currently quoted on the NASDAQ Stock Market under the symbol ADXS. Market prices for our Common Stock and warrants will be influenced by a number of factors, including:

the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;

changes in interest rates;

significant dilution caused by the anti-dilutive clauses in our financial agreements;

competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;

variations in quarterly operating results;

change in financial estimates by securities analysts;

the depth and liquidity of the market for our Common Stock and warrants;

investor perceptions of our company and the pharmaceutical and biotech industries generally; and

general economic and other national conditions.

If we fail to remain current with our listing requirements, we could be removed from the NASDAQ Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Companies trading on the NASDAQ Marketplace, such as our Company, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must meet the listing requirements in order to maintain the listing of our Common Stock on the NASDAQ Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Sales of additional equity securities may adversely affect the market price of our Common Stock and your rights may be reduced.

We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our Common Stock or other equity securities in the public markets may adversely affect the market price of our Common Stock and our stock price may decline substantially. Our shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing Common Stock.

Additional authorized shares of Common Stock available for issuance may adversely affect the market price of our securities.

We are currently authorized to issue 65,000,000 shares of our Common Stock. As of December 15, 2017, we had 41,303,988 shares of our Common Stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options, convertible promissory notes and shares of Common Stock earned but not yet issued under our director compensation program. Under our 2011 Employee Stock Purchase Plan, or ESPP, our employees can buy our Common Stock at a discounted price. To the extent the shares of Common Stock are issued, options and warrants are exercised or convertible promissory notes are converted, holders of our Common Stock will experience dilution. In the event of any future financing of equity securities or securities convertible into or exchangeable for, Common Stock, holders of our Common Stock may experience dilution. In addition, as of December 15, 2017, we had outstanding options to purchase 4,380,557 shares of our Common Stock at a weighted average exercise price of approximately $11.47 per share and outstanding warrants to purchase 3,092,395 shares of our Common Stock (including the above warrants subject to weighted-average anti-dilution protection); and zero shares of our Common Stock are available for grant under the ESPP.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our Common Stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our Common Stock will be at our Board of Directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our Board of Directors considers to be relevant.

Our certificate of incorporation, bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our shareholders. To date, we have not issued shares of preferred stock, however, we are authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our Common Stock, and therefore, reduce the value of our Common Stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our certificate of incorporation, Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the certificate of incorporation, Bylaws and Delaware law, as applicable, among other things; provide the Board of Directors with the ability to alter the Bylaws without shareholder approval, and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

We are also subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits "business combinations" between a publicly-held Delaware corporation and an "interested shareholder," which is generally defined as a shareholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such shareholder became an interested shareholder.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our Common Stock to decline.

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 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.

On June 29, 2018, the registrant issued 1,516 shares of common stock to its Executive Officers, pursuant to their Employment Agreements.

On July 31, 2018, the registrant issued 1,505 shares of common stock to an Executive Officer, pursuant to his Employment Agreement.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

31.2* Certification of Principal Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002

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

32.2* Certification of Principal Executive 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.

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SIGNATURES

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

ADVAXIS, INC.
Registrant

Date: September 10, 2018 By:*/s/ Kenneth A. Berlin*
Kenneth A. Berlin
President and Chief Executive Officer

By:*/s/ Molly Henderson*
Molly Henderson
Executive Vice President, Chief Financial Officer