

Advaxis, Inc.  
Form 10-Q  
March 12, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended January 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 000-28489

**ADVAXIS, INC.**

(Exact name of registrant as specified in its charter)



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

The number of shares of the registrant's Common Stock, \$0.001 par value, outstanding as of March 8, 2018 was 52,313,849.

**TABLE OF CONTENTS**

	Page No.
<b><u>PART I FINANCIAL INFORMATION</u></b>	4
Item 1. <u>Financial Statements (unaudited)</u>	4
<u>Condensed Balance Sheets at January 31, 2018 and October 31, 2017</u>	4
<u>Condensed Statements of Operations for the Three Months Ended January 31, 2018 and 2017</u>	5
<u>Condensed Statements of Cash Flows for the Three Months Ended January 31, 2018 and 2017</u>	6
<u>Notes to the Condensed Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	19
<b><u>PART II OTHER INFORMATION</u></b>	20
Item 1. <u>Legal Proceedings</u>	20
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 6. <u>Exhibits</u>	20
<b><u>SIGNATURES</u></b>	21

## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

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

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

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

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

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

Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the “Risk Factors” section of the Company’s annual report on Form 10-K for the year ended October 31, 2017, as filed with the SEC on December 21, 2017, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate.

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

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

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

(Unaudited)

	January 31, 2018	October 31, 2017
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$25,932,403	\$23,899,809
Restricted cash	977,000	587,000
Short-term investment securities	32,441,933	46,398,304
Income tax receivable	-	4,452,682
Deferred expenses	2,535,883	2,986,385
Prepaid expenses and other current assets	2,097,834	2,918,644
Total current assets	63,985,053	81,242,824
Property and equipment (net of accumulated depreciation)	\$7,923,612	7,111,081
Intangible assets (net of accumulated amortization)	4,974,995	4,856,775
Other assets	558,870	431,098
Total assets	\$77,442,530	\$93,641,778
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$7,088,469	\$5,121,406
Accrued expenses	7,295,575	8,700,036
Deferred revenue	7,163,628	6,995,336
Other current liabilities	47,520	47,520
Total current liabilities	21,595,192	20,864,298
Deferred revenue	\$15,504,839	17,478,758
Other liabilities	1,071,694	1,038,555
Total liabilities	38,171,725	39,381,611

Commitments and contingencies – Note 9

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

Stockholders' equity:

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at January 31, 2018 and October 31, 2017.	-	-
Liquidation preference of \$0 at January 31, 2018 and October 31, 2017.		
Common stock - \$0.001 par value; 65,000,000 shares authorized, 42,283,221 shares issued and outstanding at January 31, 2018 and 41,206,538 shares issued and outstanding at October 31, 2017.	42,283	41,207
Additional paid-in capital	360,863,215	355,361,187
Accumulated deficit	(321,634,693)	(301,142,227)
Total stockholders' equity	39,270,805	54,260,167
Total liabilities and stockholders' equity	\$77,442,530	\$93,641,778

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



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

(Unaudited)

	Three Months Ended January 31,	
	2018	2017
Revenue	\$2,055,627	\$3,790,842
Operating expenses:		
Research and development expenses	17,070,266	13,648,554
General and administrative expenses	5,532,832	7,327,809
Total operating expenses	22,603,098	20,976,363
Loss from operations	(20,547,471)	(17,185,521)
Other income (expense):		
Interest income, net	139,522	145,014
Net changes in fair value of derivative liabilities	-	9,504
Other expense	(34,517 )	-
Net loss before income tax benefit	(20,442,466)	(17,031,003)
Income tax benefit	50,000	50,000
Net loss	\$(20,492,466)	\$(17,081,003)
Net loss per common share, basic and diluted	\$(0.49 )	\$(0.43 )
Weighted average number of common shares outstanding, basic and diluted	41,428,199	40,115,178

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

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

(Unaudited)

	Three Months Ended	
	January 31,	2017
	2018	2017
<b>OPERATING ACTIVITIES</b>		
Net loss	\$(20,492,466)	\$(17,081,003)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	2,809,118	5,110,425
Gain on change in value of warrants and embedded derivative	-	(9,504)
Loss on disposal of property and equipment	27,361	-
Write-off of intangible assets	143,115	-
Depreciation expense	264,989	157,580
Amortization expense of intangible assets	92,525	74,410
Amortization of premium on held to maturity investments	2,545	44,005
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	1,396,312	(88,748)
Income tax receivable	4,452,682	2,549,862
Other assets	(127,772)	24,380
Accounts payable and accrued expenses	550,157	(1,454,011)
Deferred revenue	(1,805,627)	(3,540,842)
Other liabilities	33,139	48,355
Net cash used in operating activities	(12,653,922)	(14,165,091)
<b>INVESTING ACTIVITIES</b>		
Restricted cash established with letter of credit agreement	(390,000)	-
Purchases of short-term investment securities	(12,487,174)	(46,525,169)
Sales of short-term investment securities	26,441,000	6,522,333
Purchase of property and equipment	(1,172,436)	(1,127,000)
Cost of intangible assets	(353,860)	(81,432)
Net cash provided by (used in) investing activities	12,037,530	(41,211,268)
<b>FINANCING ACTIVITIES</b>		
Net proceeds of issuance of common stock	2,658,749	-
Proceeds from employee stock purchase plan	9,482	67,923
Tax withholdings paid related to net share settlement of equity awards	(7,168)	(9,810)
Employee tax withholdings paid on equity awards	(208,892)	(204,614)
Tax shares sold to pay for employee tax withholdings on equity awards	196,815	338,486
Net cash provided by financing activities	2,648,986	191,985

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

Net increase (decrease) in cash and cash equivalents	2,032,594	(55,184,374 )
Cash and cash equivalents at beginning of period	23,899,809	112,750,980
Cash and cash equivalents at end of period	\$25,932,403	\$57,566,606

SUPPLEMENTAL CASH FLOW INFORMATION

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

SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES

Accounts payable and accrued expenses settled with common stock	\$-	\$75,000
Property and equipment included in accounts payable and accrued expenses	57,445	115,637

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 *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*”) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains could be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment (“TME”) to enable the T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile, and most product candidates are immediately available for treatment with a low cost of goods. The Company’s passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline and driven towards increasing stockholder value.

Advaxis is focused on four franchises in various stages of clinical and pre-clinical development, which they believe will provide the greatest opportunity to have a significant impact on patients and their families:

- Human Papilloma Virus (“HPV”)-associated cancers
- Individualized neoantigen therapy
- Disease focused hotspot / cancer antigen therapies
- Prostate cancer

All four clinical franchises are anchored in the Company’s *Lm* Technology, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex (“MHC”) I and II pathways, due to its active phagocytosis by Antigen Presenting Cells (“APCs”). Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potent stimulation of the immune system.

*Liquidity and Financial Condition*

The Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through February 2018, we raised approximately \$245.2 million in gross proceeds from various public and private offerings of our common stock.

As of January 31, 2018, the Company had approximately \$59.4 million in cash, restricted cash, cash equivalents and short-term investment securities on its balance sheet. The Company has plans to continue to be disciplined in regard to its utilization of its capital and anticipates its cash burn will decrease from fiscal 2017. This decrease will largely be due to several one-time items in fiscal 2017 related to the preparation of our Marketing Authorization Application ("MAA") filing in Europe of axalimogene filolisbac and other one-time costs that the Company does not anticipate to recur. Additionally, during February 2018 the Company entered into an underwritten public offering of its Common Stock, raising gross proceeds of \$20 million. We believe our current cash position as of January 31, 2018 along with the net proceeds received from the Company's underwritten public offering that closed on February 26, 2018 is sufficient to fund our business plan approximately into second calendar quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors.

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

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

*Basis of Presentation/Estimates*

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information, and in accordance with the rules and regulations of the SEC with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and the accompanying unaudited condensed balance sheet as of October 31, 2017 has been derived from the Company's October 31, 2017 audited financial statements. In the opinion of management, the unaudited interim condensed financial statements furnished include all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods presented. Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year.



Operating results for interim periods are not necessarily indicative of the results to be expected for the full year. The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates include the fair value and recoverability of the carrying value of property and equipment and intangible assets (patents and licenses), the fair value of investments, the fair value of options and warrants, 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*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$25.6 million is subject to credit risk at January 31, 2018. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

#### *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 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 January 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, convertible debt and other potential Common Stock outstanding during

the period. In the case of a net loss the impact of the potential Common Stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential Common Stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of Common Stock that have been excluded from diluted net loss per share.

	As of January 31,	
	2018	2017
Warrants	3,092,395	3,110,575
Stock Options	4,442,558	3,897,558
Restricted Stock Units	1,257,526	1,111,059
Total	8,792,479	8,119,192

### *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 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 2019. Early adoption of ASU 2016-02 is permitted. The new leases standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company’s financial statements.



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

**3. SHORT-TERM INVESTMENT SECURITIES**

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

	January 31, 2018			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$2,449,989	\$ -	\$ -	\$2,449,989
U.S Treasury Notes	29,991,944	-	17,809	29,974,135
Total short-term investment securities	\$32,441,933	\$ -	\$ 17,809	\$32,424,124

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

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

**4. PROPERTY AND EQUIPMENT**

Property and equipment, net consists of the following:

January 31, 2018	October 31, 2017
---------------------	---------------------

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

Leasehold improvements	\$2,248,751	\$2,167,990
Laboratory equipment	5,218,172	4,143,106
Furniture and fixtures	728,725	728,725
Computer equipment	394,523	394,523
Construction in progress	805,014	883,322
Total property and equipment	9,395,185	8,317,666
Accumulated depreciation and amortization	(1,471,573)	(1,206,585)
Net property and equipment	\$7,923,612	\$7,111,081

Depreciation expense for the three months ended January 31, 2018 and 2017 was \$264,989 and \$157,580 respectively.

## 5. INTANGIBLE ASSETS

Intangible assets, net consist of the following:

	January 31, 2018	October 31, 2017
Patents	\$5,879,973	\$5,727,298
Licenses	776,992	776,992
Software	117,196	108,604
Total intangibles	6,774,161	6,612,894
Accumulated amortization	(1,799,166)	(1,756,119)
Intangible assets	\$4,974,995	\$4,856,775

The expirations of the existing patents range from 2018 to 2038 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. Patent applications having a net book value of \$143,115 and \$0 were abandoned and were charged to research and development expenses in the Statement of Operations for the three months ended January 31, 2018 and 2017, respectively. Amortization expense for intangible assets aggregated \$92,525 and \$74,410 for the three months ended January 31, 2018 and 2017, respectively.

At January 31, 2018, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows:

Year ended October 31,

2018 (Remaining)	\$286,733
2019	379,911
2020	363,056
2021	343,246
2022	343,246
Thereafter	3,258,803
Total	\$4,974,995

## 6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	January 31, 2018	October 31, 2017
Salaries and other compensation	\$3,576,946	\$2,652,583
Vendors	972,018	2,811,956
Professional fees	2,746,611	3,235,497
Total accrued expenses	\$7,295,575	\$8,700,036

## 7. WARRANTS

At January 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 .92 and .67 years, respectively. At January 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:

	Three Months Ended	
	January 31,	
	2018	2017
Research and development	\$1,272,997	\$1,222,483
General and administrative	1,536,121	3,887,942
Total	\$2,809,118	\$5,110,425

### *Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the three months ended January 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	84,000	3.19
Vested	(186,970 )	8.29
Cancelled	(2,623 )	7.94
Balance at January 31, 2018	1,257,526	\$ 8.22

As of January 31, 2018, there was approximately \$7,988,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.80 years.

As of January 31, 2018, the aggregate intrinsic value of non-vested RSUs was approximately \$3,722,000.

### *Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 197,167 shares (195,046 shares on a net basis after employee taxes) and 93,976 shares (92,731 shares on a net basis after employee taxes) during the three months ended January 31, 2018 and 2017 respectively. Total stock compensation expense associated with these awards for the three months ended January 31, 2018 and 2017 was \$1,354,185 and \$1,356,639, respectively.

### *Director Stock Awards*

During the three months ended January 31, 2018 and 2017, total stock compensation expense to the Directors for amortization of unvested awards was \$101,628 and \$101,628, respectively.

### *Stock Options*

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

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2017:	3,893,558	\$ 12.51
Granted	761,685	3.11
Canceled or Expired	(212,685 )	12.11
Outstanding at January 31, 2018	4,442,558	10.91
Vested and Exercisable at January 31, 2018	3,150,667	\$ 12.80

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

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended January 31, 2018 and 2017 was \$1,398,304 and \$3,183,458, respectively.

During the three months ended January 31, 2018, 761,685 options were granted with a total grant date fair value of \$1,856,699. During the three months ended January 31, 2017, 556,952 options were granted with a total grant date fair value of \$3,542,215.

As of January 31, 2018, there was approximately \$4,877,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.53 years.

As of January 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 three months ended January 31, 2018 and 2017, the Company used the following inputs in its BSM:

	Three Months Ended January 31,			
	2018		2017	
Expected Term	5.50-6.50 years		5.50-6.50 years	
Expected Volatility	95.11-100.34	%	107.07-110.93	%
Expected Dividends	0	%	0	%
Risk Free Interest Rate	2.00-2.66	%	1.26-1.58	%

### *Shares Issued to Consultants*

During the three months ended January 31, 2017, 32,500 shares of Common Stock valued at \$313,600 were issued to consultants for services, of which \$75,000 represented shares issued for amounts previously accrued. The Company recorded a liability on its balance sheet for \$230,100 for shares earned pursuant to consulting agreements but not delivered. The common stock share values were based on the dates the shares vested.

## 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 is based on general allegations related to certain stock options granted to the individual defendants and generally alleges counts for breaches of fiduciary duty and unjust enrichment. The complaint also alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. The complaint seeks damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief.

Defendants filed a motion to dismiss the Bono Action. On May 23, 2016, the 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.

#### *Corporate Office & Manufacturing Facility Lease*

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

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

Year ended October 31,



2018 (remaining)	\$785,514
2019	1,107,385
2020	1,232,907
2021	1,317,640
2022	1,368,819
Thereafter	4,378,521
Total	\$10,190,786

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

## 12. SUBSEQUENT EVENTS

During February 2018, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC and Guggenheim Securities, LLC (the "Underwriters"). Pursuant to the Underwriting Agreement, the Company sold to the Underwriters, and the Underwriters purchased for resale to the public, in a firm commitment underwritten public offering, 10,000,000 shares (the "Shares") of the Company's common stock, \$0.001 par value per share (the "Common Stock"), at a price to the public of \$2.00 per share, less underwriting discounts and commissions.

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

The net proceeds to the Company from the transaction was \$18.8 million before expenses. In addition, pursuant to the Underwriting Agreement, the Company has granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 807,697 shares of Common Stock (the “Optional Shares” and, together with the Shares, the “Offered Shares”). The sale of the Offered Shares was registered pursuant to a Registration Statement (No. 333-216008) on Form S-3, as amended, which was filed by the Company with the Securities and Exchange Commission on March 17, 2017, and declared effective on March 20, 2017.

## 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.

### Overview

Advaxis is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products with the lead program in Phase 3 development. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* bioengineered to secrete antigen/adjuvant fusion proteins. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as they access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T cells to eliminate tumors.

As the field of immunotherapy continues to evolve, the flexibility of the *Lm* Technology platform has allowed Advaxis to develop highly innovative products. To date, *Lm* Technology has demonstrated preclinical synergy with multiple checkpoint inhibitors, co-stimulatory agents and radiation therapy, with clinical trials currently underway or planned in combination with Merck & Co., Inc. ("Merck"), AstraZeneca PLC ("AstraZeneca"), and Bristol-Myers Squibb Company's ("BMS") PD-1/PDL-1 inhibitors. The safety profile of all of the *Lm* Technology constructs seen to date has been generally predictable and manageable, consisting mostly of mild to moderate flu-like symptoms that have been transient and associated with infusion.

Advaxis will continue to invest in its core clinical franchises and will also remain opportunistic based on Investigator Sponsored Trials (“ISTs”) as well as licensing opportunities. Our proprietary *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2038.

### *HPV Related Cancers*

We have developed a franchise 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.

The Company has decided to align and simplify its strategy by using axalimogene filolisbac exclusively in all ongoing and planned HPV-related cancer clinical trials, including the upcoming ADVANCE trial, previously planned with ADXS-DUAL. The Company believes that harmonizing to a single product candidate for all HPV-related programs will streamline developmental, regulatory and commercialization strategies.

### Cervical Cancer

There are approximately 530,000 new cases of cervical cancer caused by HPV worldwide every year, and 13,240 new cases in the U.S. alone, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2018 (“WHO”). Current preventative vaccines cannot protect all women who are infected with this very common virus. Current preventative HPV vaccines such as Gardasil® and Cervarix® cannot treat or protect the large population of adults already infected with the virus, leaving several generations of women vulnerable. Furthermore, challenges with acceptance, accessibility, and compliance have resulted in suboptimal vaccination rates, with approximately 50% of young women and 38% of young men being fully vaccinated in the United States, according to statistics published by the Centers for Disease Control in 2018. Vaccination rates are even lower in other countries around the world.

We completed a randomized Phase 2 clinical study (*Lm*-LLO-E7-15), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results showed that 34.9% (38/109) of patients were alive at 12 months, 24.8% (27/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months. Of the 15 patients consenting to further follow-up beyond 18 months, 12 (11%) achieved 24-month OS status (range 24 – 34+ months) at the time of study closure. 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 have been accepted and will be published in the May 2018 edition of the peer-reviewed *International Journal of Gynecological Cancer*.

We are conducting a Phase 3 trial 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 will be 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 thirteen countries with 124 sites open to date, and is currently enrolling patients.

We have a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and efficacy of axalimogene filolisbac in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated squamous cell Carcinoma of the head and neck (“SCCHN”). For the axalimogene filolisbac and durvalumab dose escalation portion of the study, the dose-escalation phase has been completed. 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 (11<sup>th</sup> dose of axalimogene filolisbac, 21<sup>st</sup> dose of durvalumab) in the trial. Over 250 patients have received axalimogene filolisbac, and approximately 700 doses have been delivered across multiple trials in HPV-associated cancers, to date, and this is the first time we have seen this type of event. Enrollment and further dosing are on hold for this trial, and we are working closely with the site investigator and FDA to review this event in detail and to determine a path forward from this clinical hold. At this time, this hold does not affect any other current clinical trials or programs.

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

The first stage of enrollment in GOG-0265 was successfully completed with 26 patients treated and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Stage 2 of the study began enrollment in February 2015, and in October 2016, Advaxis and the GOG Foundation/NRG Oncology examined the 12-month survival rate and safety data obtained from the 24 patients who had previously enrolled in Stage 2. The Stage 2 population demonstrated that treatment with axalimogene filolisbac resulted in a 37.5% (9/24) 12-month survival rate. This data was consistent with the findings in Stage 1 that showed a 38.5% 12-month survival rate, despite a greater proportion of Stage 2 patients having failed bevacizumab treatment. Taken together, the available data from both stages of GOG-0265 comprise a Phase 2 clinical trial in 50 subjects with a 12 month survival rate of 38% (19/50). The protocol defined logistic model-based calculation of the expected 12-month milestone survival rate was calculated to be 24.5% using the key predictors from the patients enrolled in the study. The 12 month survival rate of 38% for patients receiving axalimogene filolisbac in the study represented a 55% improvement over the expected 12-month milestone survival rate of 24.5%.

Overall, 28 out of 50 (56%) patients experienced a Grade 1 or Grade 2 TRAE associated with axalimogene filolisbac infusion. The most common (>30%) Grade 1 or Grade 2 TRAEs were fatigue, chills, anemia, nausea and fever. Eighteen (36%) patients experienced a Grade 3 TRAE and two patients experienced a Grade 4 AE, including a Klebsiella lung infection in one patient, and hypotension/cytokine related symptoms in another patient, which were considered possibly related to treatment. Upon review of these findings, we announced early closure of GOG-0265. Results from the GOG-0265 study were presented as an oral late-breaker presentation at the Society of Gynecologic Oncology (“SGO”) annual meeting on March 14, 2017.

We have 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. We plan to initiate a global, randomized, registrational quality trial, the ADVANCE trial, in 2018 and will evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy. Under the terms of the agreement, each party will bear its own internal costs and provide its immunotherapy agents. Advaxis will sponsor the study and pay third-party costs.

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

On February 13, 2018, the Company issued a press release announcing the submission of a conditional MAA to the EMA for the Company's lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of 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. In parallel with the MAA review process, the Company will continue assessing partnership opportunities for the potential commercialization of axalimogene filolisbac in Europe.

### Head and Neck Cancer

SCCHN is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of SCCHNs originate from the mucosal linings of the oral cavity, pharynx, or larynx and 70% of these cancers are caused by HPV, with the incidence increasing every year. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. According to the 2017 American Cancer Society data report, approximately 30,000 new cases will be diagnosed in the United States in 2017.

The safety and immunogenicity of axalimogene filolisbac is being evaluated in a Phase 2 IST at Mount Sinai and Baylor College of Medicine in a pre-surgery "window of opportunity" trial in patients with HPV-positive head and neck cancer. This clinical trial is the first to evaluate the immunologic and pathologic effects of axalimogene filolisbac in patients at the time of initial diagnosis of HPV-associated head and neck cancer. The trial met its Stage 1 primary objective which allowed accrual to proceed in the second stage of the trial which is intended. The Stage 2 objective is consistent with Stage 1 and enrollment is ongoing.

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part 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.

We will continue to be opportunistic towards alternative funding approaches for continued development in HPV-positive head and neck cancer, and hope to announce an IST with an academic institution in 2018. Axalimogene filolisbac has received FDA orphan drug designation for HPV-associated head and neck cancer.

### Anal Cancer

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

The safety and efficacy of axalimogene filolisbac was evaluated in a Phase 2 IST by Brown University in patients with high-risk locally advanced anal cancer. As of December 2017, no further enrollment in this trial is planned. 10 patients were treated including one with N2 and four with N3 disease. Two patients had grade 3 acute toxicities following the initial dose of axalimogene filolisbac including chills/rigors (n = 2), back pain (n = 1), and hyponatremia (n = 1). All toxicities occurred within 24 hours of administration. There was no apparent increase in chemoradiation toxicities or myelosuppression. One patient had a Grade 5 cardiopulmonary event shortly after beginning 5-FU treatment. This patient did not receive a dose of axalimogene filolisbac. All 9 assessable patients had complete clinical responses by sigmoidoscopy. Eight of the 9 patients (89%) are progression-free at a median follow-up of 42 months. These data were accepted and published in the International Journal of Radiation Oncology.

We conducted a Phase 2 multi-center, open-label, Simon two-stage trial (“FAWCETT” or “Fighting Anal-Cancer with CTL Enhancing Tumor Therapy”), testing axalimogene filolisbac in patients with persistent or recurrent metastatic anal cancer. FAWCETT is designed to evaluate the efficacy and safety of axalimogene filolisbac as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. The trial met the criteria to proceed to Stage 2 of enrollment, but the Company has decided not to initiate the Stage 2 portion of the trial in order to focus its resources on other clinical priorities at this time. We will continue to evaluate alternative funding sources and collaborations to further develop this program in anal cancer. Axalimogene filolisbac has received FDA and EMA orphan drug designation for anal cancer.

#### *ADXS-NEO Franchise*

The Company made the decision to branch into the growing field of individualized cancer treatments with ADXS-NEO. ADXS-NEO is designed to create individualized therapies by activating the patient’s immune system to respond against multiple mutations, or neoantigens, identified from an individual patient’s tumor through DNA sequencing. In August 2016, Advaxis entered into a global agreement with Amgen Inc. (“Amgen”) for the development and commercialization of ADXS-NEO.

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-genome sequencing of a patient’s tumor to identify neoantigens is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient’s immune system and stimulating a T cell response against cancerous cells.



We have filed an IND amendment and we plan to initiate the trial by June 2018. The initial tumor types for the Phase 1 are microsatellite stable colorectal cancer, head and neck cancer, and non-small cell lung cancer.

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

Advaxis is developing a novel portfolio of immunotherapy constructs for major cancers that combines our optimized *Lm* Technology vector with promising targets to generate potent anti-cancer immunity. The ADXS-HOT franchise is a series of novel cancer immunotherapies that will target somatic mutations (“hotspots”), cancer testis antigens (“CTAs”) and oncofetal antigens (“OFAs”). These three types of targets form the basis of the ADXS-HOT program because they have the potential to generate more potent, tumor specific, and high strength killer T cells, compared with over-expressed native sequence TAAs. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT franchise products will combine many high avidity targets that are expressed in a large portion of patients with the target disease into one “off-the-shelf” treatment, ready to administer for multiple patients. The ADXS-HOT technology has a strong Intellectual Property (“IP”) position, with potential protection into 2038, and an IP filing strategy providing for broad coverage opportunities across multiple disease platforms and combination therapies.

The Company is currently prioritizing product development in the most prevalent cancers, with the first tumor type to be non small cell lung cancer (“NSCLC”). Advaxis plans to file multiple ADXS-HOT INDs in 2018, including NSCLC, with a first-in-human trial in one of the ADXS-HOT products to commence in 2018.

#### *ADXS-PSA Franchise*

##### Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men, and is the second leading cause of cancer death in men, behind only lung cancer. More than 161,000 men are estimated to be diagnosed with prostate cancer in 2017, with over 26,000 deaths each year. Unfortunately, in about 10 – 20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer (“CRPC”), which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC (“mCRPC”) occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen (“PSA”) level. This stage of prostate cancer has an average survival of 9-13 months, is associated with deterioration in quality of life, and has few therapeutic options available.

According to a data review published by MD Anderson Cancer Center in 2016, checkpoint inhibitor monotherapy has not shown significant activity in mCRPC to date. The authors hypothesize that may be due to the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment, and that combination therapy with agents that induce T cell infiltration within the tumor may improve performance of checkpoints in prostate cancer. *Lm* Technology constructs have been shown by multiple labs to reduce number and suppressive function of Tregs and MDSCs in the tumor microenvironment and cause the destruction of Tregs as soon as 5 days after dosing in models. This reduction of immune suppression in the tumors has been attributed to our proprietary *tLLO*-fusion peptides expressed by multiple copies of the plasmids in each bacteria. Advaxis feels that the combination of ADXS-PSA, our immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC. Clinical benefit in prostate cancer could be a significant value creator to expand the *Lm* Technology platform into the prostate cancer market.

Advaxis has entered into a clinical trial collaboration and supply agreement with Merck & Co. (“Merck”) to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (“pembrolizumab”), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (Keynote-046). For the ADXS-PSA monotherapy dose escalation portion of the trial has been completed, the safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in this phase of the trial was completed in January 2017.

Preliminary data identifying potential pharmacodynamics biomarkers of clinical response and preliminary immune correlative data in mCRPC patients treated with ADXS-PSA monotherapy were presented at the third annual CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in September 2017, and at the Society for Immunotherapy of Cancer (“SITC”) in November 2017. Viewed collectively, the data presented at CRI-CIMT-EATI-AACR 2017 and SITC 2017 show signs of activity that ADXS-PSA allows for generation of sustained, strengthened T cells against prostate cancer, while weakening the TME and allowing T cells access to the tumor. The Company has submitted an abstract to ASCO and hopes to be able to present initial data from the combination arm of the trial, if accepted for presentation, at ASCO 2018 or another suitable medical conference.

In addition, the Company is actively developing an additional product candidate for prostate cancer, currently in preclinical testing, which could complement ADXS-PSA.

## Results of Operations

### *Revenue*

Revenue decreased \$1,735,215 to \$2,055,627 for the three months ended January 31, 2018 compared to \$3,790,842 for the three months ended January 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 make significant investments in research and development to support our pre-clinical and clinical development programs. Research and development expenses for the three months ended January 31, 2018 and 2017 were categorized as follows:

	Three Months Ended January 31,	
	2018	2017
HPV-associated cancers	\$5,551,174	\$3,964,585
Prostate cancer	702,151	886,630
Neoantigen therapy	371,807	397,774
Personnel expenses	5,963,156	4,754,838
Professional fees	2,945,699	1,570,729
Laboratory costs	2,050,700	1,269,731
Other clinical trial expenses	218,920	470,964
Other expenses	766,659	333,303
Partner reimbursements	(1,500,000 )	-
Total research & development expense	\$17,070,266	\$13,648,554

### *Axalimogene Filolisbac Franchise*

HPV-associated expenses increased \$1,586,589 to \$5,551,174 for the three months ended January 31, 2018 compared to \$3,964,585 for the three months ended January 31, 2017. The increase resulted primarily from startup activities for

additional countries in the Phase 3 AIM2CERV trial.

*Personnel Expenses*

Personnel expenses increased \$1,208,318 to \$5,963,156 for the three months ended January 31, 2018 compared to \$4,754,838 for the three months ended January 31, 2017. The increase relates primarily to a 33% increase in R&D headcount.

*Professional Fees*

Professional fees increased \$1,374,970 to \$2,945,699 for the three months ended January 31, 2018 compared to \$1,570,729 for the three months ended January 31, 2017. The increase is primarily attributable to an increase in drug manufacturing process validation costs and drug stability studies in support of the MAA.

*Laboratory Costs*

Laboratory costs increased \$780,969 to \$2,050,700 for the three months ended January 31, 2018 compared to \$1,269,731 for the three months ended January 31, 2017. The increase is primarily attributable to an increase in headcount and laboratory space, as well as support of the MAA.

*Partner reimbursements*

During the three months ended January 31, 2018, the Company received \$1,500,000 of clinical development payments from Amgen for ADXS-NEO compared to \$0 for the same period in 2017.

*General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses decreased \$1,794,977 to \$5,532,832 for the three months ended January 31, 2018, compared with \$7,327,809 for the three months ended January 31, 2017. The decrease was primarily attributable to a decrease in

stock compensation due to the resignation of two officers during fiscal 2017.

## **Liquidity and Capital Resources**

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through February 2018, we raised approximately \$245.2 million in gross proceeds from various public and private offerings of our common stock. We have not yet commercialized any drug, and we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approvals for our drug, successfully complete any post-approval regulatory obligations, successfully compete with other available treatment options in the marketplace, overcome any clinical holds that the FDA may impose and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate revenues from our drug candidates.

As of January 31, 2018, the Company had approximately \$59.4 million in cash, restricted cash, cash equivalents and short-term investment securities on its balance sheet. We believe our current cash position as of January 31, 2018 along with the net proceeds received from the Company's underwritten public offering that closed on February 26, 2018 is sufficient to fund our business plan approximately into second calendar quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through January 31, 2018, we reported accumulated net losses of approximately \$321.6 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

## **Cash Flows**

### *Operating Activities*

Net cash used in operating activities for the three months ended January 31, 2018 was approximately \$12.7 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$4.5 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Net cash used in operating activities for the three months ended January 31, 2017 was approximately \$14.2 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$2.5 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

### *Investing Activities*

Net cash provided by investing activities for the three months ended January 31, 2018 was approximately \$12.0 million resulting from the use of proceeds from matured short-term investment securities to fund operating activities. This was partially offset by restricted cash established with a letter of credit, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

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

### *Financing Activities*

Cash provided by financing activities was approximately \$2.6 million and \$192,000 for the three months ended January 31, 2018 and 2017 respectively. The net increase resulted primarily from proceeds of 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 public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of January 31, 2018 and October 31, 2017, we had an accumulated deficit of \$321,634,693 and \$301,142,227, respectively, and stockholders' equity of \$39,270,805 and \$54,260,167, respectively.

### **Contractual Commitments and Obligations**

The disclosure of our contractual obligations and commitments was reported in our Annual Report on Form 10-K for the year ended October 31, 2017 filed on December 21, 2017. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report on Form 10-K other than the changes described in Note 10, "Commitments and Contingencies" in this Quarterly Report on Form 10-Q.

### **Off-Balance Sheet Arrangements**

As of January 31, 2018, we had no off-balance sheet arrangements.

### **Critical Accounting Estimates**

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

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

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

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

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

### **New Accounting Standards**

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**



At January 31, 2018, the Company had approximately \$59.4 million in cash, cash equivalents and short-term investment securities, which consisted primarily of bank deposits, money market funds and short-term investment securities such as certificates of deposit, domestic governmental agency loans and U.S treasury notes. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

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

#### **Item 4. Controls and Procedures**

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

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

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

During the quarter ended January 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

##### *Limitations on Effectiveness of Controls*

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

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

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

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

On November 30, 2017 the registrant issued 2,919 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 29, 2017 the registrant issued 1,968 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On January 31, 2018 the registrant issued 1,839 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On February 28, 2018 the registrant issued 3,340 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

**Item 6. Exhibits**

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

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

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

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

101.INS\*\* XBRL INSTANCE DOCUMENT

101.SCH\*\* XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

101.CAL\*\* XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

101.DEF\*\* XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

101.LAB\*\* XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE\*\* XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith.

\*\* Furnished herewith.

**SIGNATURES**

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

**ADVAXIS, INC.**

Registrant

Date: March 12, 2018 By: */s/ Anthony A. Lombardo*  
Anthony A. Lombardo  
Interim Chief Executive Officer

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

