Advaxis, Inc.
Form 10-Q
March 12, 2019

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 January 31, 2019

[ ] 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	[X]
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 February 28, 2019 was 69,743,547.

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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 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 and to resolve any clinical holds that may occur;

our ability to obtain and maintain approval of our product candidates for trial initiation;

our ability to manufacture and the performance of third-party manufacturers;

our ability to identify license and collaboration partners and to maintain existing relationships;

the performance of our clinical research organizations, clinical trial sponsors, clinical trial investigators and collaboration partners for any clinical trials we conduct; 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, 2018, as filed with the SEC on January 11, 2019, 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)

	January 31, 2019	October 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$32,710	$44,141
Restricted cash	-	977
Accounts receivable	1,521	1,664
Deferred expenses	3,271	2,072
Prepaid expenses and other current assets	1,072	1,611
Total current assets	38,574	50,465
Property and equipment (net of accumulated depreciation)	6,444	6,684
Intangible assets (net of accumulated amortization)	5,005	4,838
Other assets	280	280
Total assets	$50,303	$62,267
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$3,201	$5,646
Accrued expenses	3,928	6,185
Deferred revenue	347	4,476
Common stock warrant liability	4,108	6,517
Other current liabilities	48	48
Total current liabilities	11,632	22,872
Deferred revenue	-	14,189
Other liabilities	1,171	1,155
Total liabilities	12,803	38,216
Commitments and contingencies – Note 10		
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, 2019 and October 31, 2018 Liquidation preference of $0 at January 31, 2019 and October 31, 2018	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 69,734,259 and 69,556,452 shares issued and outstanding at January 31, 2019 and October 31, 2018, respectively	70	70
Additional paid-in capital	392,270	391,638
Accumulated deficit	(354,840)	(367,657)
Total stockholders' equity	37,500	24,051
Total liabilities and stockholders' equity	$50,303	$62,267

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 January 31,	
	2019	2018
Revenue	$19,689	$2,056
Operating expenses:		
Research and development expenses	6,707	16,751
General and administrative expenses	2,666	5,852
Total operating expenses	9,373	22,603
Income (loss) from operations	10,316	(20,547)
Other income (expense):		
Interest income, net	146	140
Net changes in fair value of derivative liabilities	2,409	-
Other expense	(4)	(35)
Net income (loss) before benefit for income taxes	12,867	(20,442)
Income tax expense	50	50
Net income (loss)	$12,817	$(20,492)
Net income (loss) per common share, basic and diluted	$0.18	$(0.49)
Weighted average number of common shares outstanding, basic	69,640,769	41,428,199
Weighted average number of common shares outstanding, diluted	69,642,251	41,428,199

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

ADVAXIS, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)

	Three Months Ended January 31,	
	2019	2018
OPERATING ACTIVITIES		
Net income (loss)	$12,817	$(20,492)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock compensation	622	2,809
Employee stock purchase plan expense	1	-
Gain on change in value of warrants	(2,409)	-
Loss on disposal of property and equipment	-	27
Write-off of intangible assets	244	143
Depreciation expense	285	265
Amortization expense of intangible assets	96	93
Net amortization of premiums and discounts	-	3
Change in operating assets and liabilities:		
Accounts receivable	143	918
Prepaid expenses and other current assets	(660)	478
Income tax receivable	-	4,453
Other assets	-	(128)
Accounts payable and accrued expenses	(4,707)	550
Deferred revenue	(18,318)	(1,806)
Other liabilities	16	33
Net cash used in operating activities	(11,870)	(12,654)
INVESTING ACTIVITIES		
Purchases of short-term investment securities	-	(12,487)
Proceeds from maturities of short-term investment securities	-	26,441
Purchase of property and equipment	(45)	(1,172)
Cost of intangible assets	(507)	(354)
Net cash (used in) provided by investing activities	(552)	12,428
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock	-	2,659
Proceeds from employee stock purchase plan	14	9
Tax withholdings paid related to net share settlement of equity awards	-	(7)
Employee tax withholdings paid on equity awards	(11)	(209)
Tax shares sold to pay for employee tax withholdings on equity awards	11	197

Net cash provided by financing activities	14	2,649
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,408)	2,423
Cash, cash equivalents and restricted cash at beginning of year	45,118	24,487
Cash, cash equivalents and restricted cash at end of year	$32,710	$26,910
The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed balance sheets that sum to the total of the same such amounts shown in the condensed statements of cash flows:		
Cash and cash equivalents	$32,710	$25,933
Restricted cash	-	977
Total cash, cash equivalents and restricted cash shown in condensed statements of cash flows	$32,710	$26,910
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for taxes	$50	$50
SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES		
Property and equipment included in accounts payable and accrued expenses	$-	$57

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 is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- 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 attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 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 has not yet commercialized any human products and the 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 within one year from the date of filing. The accompanying 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, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its common stock, clinical collaborations, option and warrant exercises, and interest income. From October 2013 through January 2019, the Company raised approximately $265 million in gross proceeds from various public and private offerings of our common stock.

As of January 31, 2019, the Company had approximately $32.7 million in cash and cash equivalents. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. 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 Securities and Exchange Commission ("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 January 31, 2019 has been derived from the Company's October 31, 2018 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.

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, fair value and recoverability of the carrying value of property and equipment and intangible assets, fair value of warrant liability, 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 as of and for the year ended October 31, 2018 and notes thereto contained in the Company's annual report on Form 10-K, as filed with the SEC on January 11, 2019.

Reclassification

Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. These reclassifications had no effect on the previously reported net loss.

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 were collateralized by cash which was unavailable for withdrawal or for usage for general obligations. During the three months ended January 31, 2019 the two letters of credit were terminated and as of January 31, 2019 the Company has no restricted cash balance.

Revenue Recognition

Effective November 1, 2018, the Company adopted ASC Topic 606, Revenue form Contracts with Customers (ASC 606), using the modified retrospective transition method. Under this method, results for reporting periods beginning on November 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605, *Revenue Recognition* (ASC 605). The Company only applied the modified retrospective transition method to contracts that were not completed as of November 1, 2018, the effective date of adoption for ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Research and Development Services. The promises under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenue as such amounts are incurred by the collaboration partner. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

Recent Accounting Standards

In February 2016, the Financial Accounting Standards Board, (“FASB”), issued Accounting Standards Update, (“ASU”), No. 2016-02, Leases (Topic 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, including a number of optional practical expedients that entities may elect to apply. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, an update which provides another transition method, in addition to the existing modified retrospective transition method, by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company’s financial statements.

Recently Adopted Accounting Standards

In May 2014, FASB issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. ASU No. 2014-09 superseded the revenue recognition requirements in ASC 605 and created ASC 606 described above. In 2015 and 2016, the FASB issued additional ASUs related to ASC 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent

considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. Effective November 1, 2018, the Company adopted ASC 606 using the modified retrospective transition method.

As a result of adopting ASC 606, the Company made reclassifications to the balance sheet and income statement. Net income (loss) was not impacted by the adoption of ASC 606. A summary of the amount by which each financial statement line item was affected by the impact of the cumulative adjustment is set forth in the table below (in thousands):

	Impact of ASC 606 Adoption on Condensed Balance Sheet as of November 1, 2018		
(in thousands)	As reported under ASC 606	Adjustments	Balances without adoption of ASC 606
Accounts receivable	$1,664	$ 1,664	$ -
Prepaid expenses and other current assets	$1,611	$ (1,664)	$ 3,275

A summary of the amount by which each financial statement line item was affected in the current reporting period by ASC 606 as compared with the guidance that was in effect prior to the adoption of ASC 606 is set forth in the tables below.

	Impact of ASC 606 Adoption on Condensed Balance Sheet as of January 31, 2019		
(in thousands)	As reported under ASC 606	Adjustments	Balances without adoption of ASC 606
Accounts receivable	$1,521	$ 1,521	$ -
Prepaid expenses and other current assets	$1,072	$ (1,521)	$ 2,593

(in thousands)	Impact of ASC 606 Adoption on Condensed Statement of Operations for the Three Months Ended January 31, 2019		
	As reported under ASC 606	Adjustments	Balances without adoption of ASC 606
Revenue	$19,689	$ 1,119	$18,570
Research and Development Expenses	$6,707	$ 1,119	$7,826

(in thousands)	Impact of ASC 606 Adoption on Condensed Statement of Cash Flows for the Three Months Ended January 31, 2019		
	As reported under ASC 606	Adjustments	Balances without adoption of ASC 606
Accounts receivable	$143	$ (143)	$ -
Prepaid expenses and other current assets	$(660)	$ 1,342	$ 682

The most significant change to the Company's accounting for revenue as a result of the adoption of ASC 606 relates to its treatment of clinical development payments it receives in its collaboration and licensing agreement with Amgen, Inc. ("Amgen"). Under ASC 605, the Company accounted for the clinical development payments as a reduction of research and development expenses in the statement of operations. Under ASC 606, the Company accounted for the reimbursements for research and development costs as revenue. For further discussion of the adoption of this standard, see Note 9.

In November 2018, the FASB issued ASU No. 2018-18, "Collaborative Arrangements (Topic 808)—Clarifying the Interaction between Topic 808 and Topic 606" ("ASU 2018-18"). The amendments in ASU 2018-18 make targeted improvements to generally accepted accounting principles (GAAP) for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and

disclosure requirements. In addition, unit-of-account guidance in Topic 808 was aligned with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The amendments should be applied retrospectively to the date of initial application of Topic 606. The Company adopted this guidance effective November 1, 2018 using the modified retrospective approach. There was no impact on the Company's financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash* (ASU No. 2016-18). The amendments in ASU No. 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU No. 2016-18 was effective for the Company on November 1, 2018. The Company adopted ASU No. 2016-18 using a full retrospective approach and it did not have a significant impact on its financial statements and related disclosures.

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. PROPERTY AND EQUIPMENT

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

	January 31, 2019	October 31, 2018
Leasehold improvements	$2,335	$2,321
Laboratory equipment	5,541	5,510
Furniture and fixtures	746	746
Computer equipment	409	409
Construction in progress	17	17
Total property and equipment	9,048	9,003
Accumulated depreciation and amortization	(2,604)	(2,319)
Net property and equipment	$6,444	$6,684

Depreciation expense for each of the three months ended January 31, 2019 and 2018 was approximately $0.3 million.

4. INTANGIBLE ASSETS

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

	January 31, 2019	October 31, 2018
Patents	$6,211	$5,970
Licenses	777	777
Software	117	117
Total intangibles	7,105	6,864
Accumulated amortization	(2,100)	(2,026)
Intangible assets	$5,005	$4,838

The expirations of the existing patents range from 2019 to 2039 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 $0.2 million and $0.1 million were abandoned and were charged to general and administrative expenses in the statement of operations for the three months ended January 31, 2019 and 2018, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the statement of operations aggregated approximately $0.1 million for each of the three months ended January 31, 2019 and 2018.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents and licenses related to axalimogene filolisbac (AXAL), ADXS-NEO, ADXS-HOT, ADXS-PSA and ADXS-HER2 and other products that are in development. However, if a competitor were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value. Lastly, if the Company is unable to raise enough capital to continue funding our studies and developing our intellectual property, the Company would likely record an impairment to these assets.

5. ACCRUED EXPENSES

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

	January 31, 2019	October 31, 2018
Salaries and other compensation	$1,259	$2,035
Vendors	2,116	3,660
Professional fees	553	490
Total accrued expenses	$3,928	$6,185

6. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

A summary of warrant activity was as follows (In thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding and exercisable warrants at October 31, 2018	14,169,542	$ 1.50	5.87	$ -
Exercised	-	-		
Expired	-	-		
Outstanding and exercisable warrants at January 31, 2019	14,169,542	$ 1.50	5.62	$ -

As of January 31, 2019 and October 31, 2018, the Company had 2,876 of its total 14,169,542 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the relative fair value method, in the stockholders' equity section of the balance sheet.

Warrant Liability

As of January 31, 2019 and October 31, 2018, the Company had 14,166,666 of its total 14,169,542 outstanding warrants classified as liabilities (liability warrants). These warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of January 31, 2019, the down round feature was not triggered. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which net cash settlement would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo Simulation Model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

As of January 31, 2019 and October 31, 2018, the fair value of the warrant liability was approximately $4.1 million and $6.5 million, respectively. For the three months ended January 31, 2019 and 2018, Company reported income of approximately $2.4 million and $0, respectively, due to changes in the fair value of the warrant liability.

In measuring the warrant liability at January 31, 2019 and October 31, 2018, the Company used the following inputs in its Monte Carlo Simulation Model:

	January 31, 2019	October 31, 2018
Exercise Price	$1.50	$1.50
Stock Price	$0.38	$0.56
Expected Term	5.62 years	5.87 years
Volatility %	95.93 %	97.47 %
Risk Free Rate	2.43 %	3.03 %

7. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the condensed statement of operations (in thousands):

	Three Months Ended January 31,	
	2019	2018
Research and development	$323	$1,273
General and administrative	299	1,536
Total	$622	$2,809

Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the three months ended January 31, 2019 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Non-vested balance at October 31, 2018	489,270	$ 4.69
Vested	(147,701)	4.52
Cancelled	(37,696)	7.33
Non-vested balance at January 31, 2019	303,873	$ 4.45

As of January 31, 2019, there was approximately $1.1 million of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of 1.3 years.

As of January 31, 2019, the aggregate fair value of non-vested RSUs was approximately $0.1 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 147,701 shares and 195,167 shares (195,046 shares on a net basis after employee taxes) during the three months ended January 31, 2019 and 2018, respectively. Total stock compensation expense associated with employee awards for the three months ended January 31, 2019 and 2018 was approximately $0.3 and $1.4 million, respectively.

Director Stock Awards

During the three months ended January 31, 2019 and 2018, total stock compensation expense associated with unvested Director awards was approximately $0 and $0.1 million, respectively.

Stock Options

A summary of changes in the stock option plan for the three months ended January 31, 2019 is as follows:

	Number of Options	Weighted-Average Exercise Price
Outstanding at October 31, 2018:	4,951,049	$ 8.19
Granted	1,174,550	0.45
Canceled or Expired	(93,867)	1.81
Outstanding at January 31, 2019	6,031,732	6.78
Vested and Exercisable at January 31, 2019	3,442,050	$ 10.89

Total compensation cost related to the Company’s outstanding stock options, recognized in the condensed statement of operations for the three months ended January 31, 2019 and 2018 was approximately $0.3 million and $1.4 million, respectively.

As of January 31, 2019, there was approximately $2.3 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 2.1 years.

As of January 31, 2019, 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, 2019 and 2018, the Company used the following inputs in its Black-Scholes Merton ("BSM") model:

	Three Months Ended January 31,			
	2019		2018	
Expected Term	5.50-6.51 years		5.50-6.50 years	
Expected Volatility	90.29%-99.32	%	95.11%-100.34	%
Expected Dividends	0	%	0	%
Risk Free Interest Rate	2.65%-3.15	%	2.00%-2.66	%

2018 Employee Stock Purchase Plan

During the three months ended January 31, 2019, the Company issued 30,106 shares that were purchased under the 2018 Employee Stock Purchase Plan ("ESPP").

8. NET INCOME (LOSS) PER SHARE

Basic and diluted earnings per share is calculated as follows (in thousands, except share and per share data):

	Three Months Ended January 31,	
	2019	2018
Numerator:		
Net Income (loss)	$12,817	$(20,492)
Earnings attributable to common stockholders – basic and diluted	12,817	(20,492)
Denominator:		
Weighted-average number of common shares used in earnings per share - basic	69,640,769	41,428,199
Effect of dilutive stock options	1,483	-
Weighted-average number of common shares used in earnings per share - diluted	69,642,251	41,428,199
Earnings per share – basic and diluted	$0.18	$(.49)

The following potentially dilutive securities, prior to the use of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive:

	As of January 31,	
	2019	2018
Warrants	14,169,542	3,092,395
Stock Options	5,749,382	4,442,558
Restricted Stock Units	303,873	1,257,526
Total	20,222,797	8,792,479

9. COLLABORATION AND LICENSING AGREEMENTS

Amgen

On August 1, 2016, the Company entered into a global agreement (the "Amgen Agreement") with Amgen for the development and commercialization of the Company's ADXS-NEO, a novel, preclinical investigational immunotherapy, using the Company's proprietary Listeria monocytogenes attenuated bacterial vector which activates a patient's immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient's tumor. Under the terms of the Amgen Agreement, Amgen received an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of $40 million and purchased directly from Advaxis 3,047,446 shares of the Company's common stock, at approximately $8.20 per share (representing a purchase at market using a 20 day VWAP methodology) for a total of $25 million. Amgen funded the clinical development and commercialization of ADXS-NEO and Advaxis retained manufacturing responsibilities. Advaxis and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO. Advaxis received reimbursements for research and development costs and Advaxis was eligible to receive future contingent payments based on development, regulatory and sales milestone payments of up to $475 million and high single digit to double digit royalty payments based on worldwide sales by Amgen.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Amgen, is a customer. The Company identified the following material promises under the arrangement: (1) licenses, (2) research and development activities, (3) clinical supplies, (4) regulatory responsibilities and (5) participation on a Joint Steering Committee (JSC). The Company determined that the licenses and research and development activities were not distinct from another, as the licenses had limited value without the performance of the research and development activities. Participation on the JSC to oversee the research and development activities was determined to be quantitatively and qualitatively immaterial and therefore was excluded from performance obligations. The clinical supply and regulatory responsibilities did not represent separate performance obligations based on their dependence on the research and development efforts. Based on this assessment, the Company identified one performance obligation at the outset of the Amgen Agreement, which consists of: (1) licenses, (2) research and development activities, (3) clinical supplies and (4) regulatory responsibilities.

Under the Amgen Agreement, in order to evaluate the appropriate transaction price, the Company determined that the upfront amount of $40 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which is allocated to the single performance obligation. Company has concluded that a time-based method was most appropriate to measuring progress toward completion given that the research and development services are satisfied reasonably evenly over the agreement and the Company has a stand-ready obligation to perform over such time. Accordingly, progress toward completion and related revenue recognition is measured using the input method of time elapsed relative to the estimated timeline for Advaxis to submit the Phase 2 package to Amgen, or perform the contractual research and development services, which is the predominant promise in the Company's combined performance obligation to Amgen.

The reimbursement for the research and development costs is variable consideration that is included in the transaction price at the outset, subject to the constraint. The Company estimated the consideration from the reimbursement of the research and development costs using the most-likely amount. When the research and development costs are no longer constrained, they are added to the transaction price for the single, combined performance obligation and recognized over the same recognition period as the rest of the performance obligation's allocated revenue. The potential milestone and sales-based royalty payments that the Company is eligible to receive were excluded from the transaction price, as all milestone and sales royalty amounts were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

On December 10, 2018, the Company received a written notice of termination from Amgen with respect to the Amgen Agreement. The termination became effective as of February 8, 2019. The Company is currently enrolling patients in its ADXS-NEO program and evaluating its options for partnering the program. Pursuant to the terms of the Amgen Agreement, upon Amgen's termination, the license to Amgen terminated and the Company regained worldwide rights for the development and commercialization of its ADXS-NEO program. In addition, Amgen has certain obligations as set forth in the Amgen Agreement, including promptly deleting or destroying any materials related to the development or manufacturing of the ADXS-NEO program.

The remaining deferred revenue of approximately $18.2 million on December 10, 2018 related to the $40 million non-refundable, up-front payment received from Amgen was accounted for as of the modification date. As of that notification date, the Company adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019. Advaxis is required to continue to provide the R&D services and Amgen continues to have rights to the intellectual property covered under the R&D license through the effective date of the termination (i.e. the parties have enforceable rights and obligations through the 60-day period following the notification).

The Company recognized cumulative catch-up revenue of approximately $15.6 million on December 10, 2018. The remaining $2.6 million will be recognized over the subsequent 60 days until the performance obligation is satisfied on February 8, 2019.

During the three months ended January 31, 2019 and 2018, the Company recognized revenue from the Amgen Agreement of approximately $19.4 million and $1.8 million, respectively. During the three months ended January 31, 2018, Company recorded reductions in research and development expenses of approximately $1.5 million pertaining to the reimbursement of research and development costs. During the three months ended January 31, 2019, the reimbursement of research and development costs of approximately $1.1 was included in revenue. Deferred revenue related to the Amgen Agreement amounted to approximately $0.3 million and $18.7 million as of January 31, 2019 and October 31, 2018, respectively.

Aratana Therapeutics

On March 19, 2014, the Company and Aratana entered into a definitive Exclusive License Agreement (the "Aratana Agreement"). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Aratana Agreement, Aratana paid an upfront payment to the Company, of $1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana, upon execution of the Aratana Agreement, the Company recorded the $1 million payment as licensing

revenue during the year ended October 31, 2014. Aratana will also pay the Company up to an additional $36.5 million based on the achievement of certain milestones with respect to the advancement of products pursuant to the terms of the Aratana Agreement. In addition, Aratana may pay the Company an additional $15 million in cumulative sales milestones pursuant to the terms of the Aratana Agreement.

Advaxis (i) issued and sold 306,122 shares of Advaxis' common stock to Aratana at a price of $4.90 per share, which was equal to the closing price of the common stock on the NASDAQ Capital Market on March 19, 2014, and (ii) issued a ten-year warrant to Aratana giving Aratana the right to purchase up to 153,061 additional shares of Advaxis' common stock at an exercise price of $4.90 per share. In connection with the sale of the common stock and warrants, Advaxis received aggregate net proceeds of $1.5 million. Aratana exercised all of its 153,061 warrants. As a result, no warrants remain outstanding under this agreement.

During the year ended October 31, 2018, the USDA's Center for Veterinary Biologics granted Aratana conditional approval for its canine osteosarcoma vaccine using Advaxis' technology. During the three months ended January 31, 2019 and 2018, Advaxis recognized royalty revenue totaling approximately $2,000 and $0, respectively, from Aratana's sales of the canine osteosarcoma vaccine.

Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. ("GBP"), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC).

GBP is planning to conduct a randomized Phase 2, open-label, controlled trial in HPV-associated NSCLC in patients following first-line induction chemotherapy. GBP has obtained Taiwanese regulatory approval for this trial and plans to initiate this trial in 2019. This trial will be fully funded exclusively by GBP and GBP will be responsible for all clinical development and commercialization costs in the GBP territory and GBP is committed to establishing manufacturing capabilities for its own. Under the terms of the agreement, the Company will exclusively license the rights of axalimogene filolisbac to GBP for the Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. Advaxis will retain exclusive rights to axalimogene filolisbac for the rest of the world.

During the each of the quarters ended January 31, 2019 and 2018, the Company recorded $0.25 million in revenue for the annual license fee renewal. Since Advaxis has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied at a point in time. In addition, GBP has paid $2.25 million to the contract research organization that manages the Company's AIM2CERV clinical trial.

10. COMMITMENTS AND CONTINGENCIES:

Legal Proceedings

Stendhal

On September 19, 2018, Stendhal filed a Demand for Arbitration before the International Centre for Dispute Resolution (Case No. 01-18-0003-5013) relating to the Co-development and Commercialization Agreement with Especificos Stendhal SA de CV (the "Stendhal Agreement"). In the demand, Stendhal alleged that (i) the Company breached the Stendhal Agreement when it made certain statements regarding its AIM2CERV program, (ii) that Stendhal was subsequently entitled to terminate the Agreement for cause, which it did so at the time and (iii) that the Company owes Stendhal damages pursuant to the terms of the Stendhal Agreement. Stendhal is seeking to recover $3 million paid to the Company in 2017 as support payments for the AIM2CERV clinical trial along with approximately $0.3 million in expenses incurred. Stendhal is also seeking fees associated with the arbitration and interest. The Company has answered Stendhal's Demand for Arbitration and denied that it breached the Stendhal Agreement. The Company also alleges that Stendhal breached its obligations to the Company by, among other things, failing to make support payments that became due in 2018 and that Stendhal therefore owes the Company $3 million. While the arbitration is still in its early stages the Company intends to continue to vigorously defend itself against this matter. At this time, we are unable to predict the likelihood of an unfavorable outcome.

11. INCOME TAXES

The Company did not record any income tax expense associated with its net income for the three months ended January 31, 2019, as the Company expects to incur a net loss for the 2019 fiscal year.

12. FAIR VALUE

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

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

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

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

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of January 31, 2019 and October 31, 2018:

January 31, 2019	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at $1.50 through September 2024	-	-	$ 4,108	$ 4,108

October 31, 2018	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at $1.50 through September 2024	-	-	$ 6,517	$ 6,517

The following table sets forth a summary of the changes in the fair value of the Company's warrant liabilities:

	January 31, 2019
Beginning balance	$6,517
Change in fair value	(2,409)
Ending Balance	$4,108

13. SUBSEQUENT EVENTS

On February 21, 2019, the Company's stockholders voted to approve an amendment to increase the number of authorized shares of common stock from 95,000,000 to 170,000,000 and also voted to approve an amendment to allow the Company to execute a reverse stock split of common stock at the discretion of the Board of Directors. The amendment to increase the number of authorized shares of common stock became effective upon filing of the amendment with the Secretary of State of the State of Delaware on February 28, 2019.

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, 2018. In addition, we intend to use our media and investor relations website (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. ("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. We are using our *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, we have exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Our proprietary approach is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- 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 attack the tumor cells.

Our proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. We believe 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.

The Advaxis Corporate Strategy

Our strategy is to advance the *Lm* Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. We are currently conducting or planning clinical studies of *Lm* Technology immunotherapies in HPV-associated cancers (including cervical and head and neck), prostate cancer, non-small cell lung cancer and other solid tumor types. We are working with, or are in the process of identifying, collaborators for many of these programs.

Moving forward, we expect that we will continue to invest in our core clinical program areas and will also remain opportunistic in evaluating Investigator Sponsored Trials ("ISTs") as well as licensing opportunities. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

Clinical Pipeline

HPV-Related Cancers: Proof of Concept of* Lm *Technology

We are developing therapies for HPV-related cancers using axalimogene filolisbac (AXAL). Axalimogene filolisbac is an *Lm*–based antigen delivery product directed against HPV and designed to target cells expressing HPV. Our HPV-related products are currently under investigation, or being considered, in two HPV-associated cancers: cervical cancer and head and neck cancer, either as a monotherapy or in combination. We have also completed clinical studies of axalimogene filolisbac for the treatment of anal cancer, non-squamous carcinoma of the cervix and metastatic HPV-associated, squamous cell carcinoma of the head and neck.

Cervical Cancer: Axalimogene Filolisbac

HPV is the most common viral infection of the reproductive tract and is the cause of a range of conditions in both females and males. In women, persistent infection with specific oncogenic types of HPV (most frequently alpha7 and alpha9 families) may lead to precancerous lesions which, if untreated, may progress to cervical cancer. There are approximately 527,000 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the World Health Organization ("WHO") Human Papillomavirus and Related Cancers in the World Summary Report 2017. There are approximately 4,250 deaths from cervical cancer each year according to the National Institutes of Health. 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 2017. Vaccination rates are even lower in other countries around the world.

Ongoing Registrational and Phase 3 Study: Axalimogene Filolisbac

Women who are diagnosed with high risk, locally-advanced carcinoma of the cervix ("HRLACC") face a higher chance that their cancer may recur following initial treatment when compared to earlier stages of the disease. When cervical cancer recurs, there are very few treatment options and the prognosis is dire. To address this unmet need, in 2016 we reached an agreement with the FDA, under its Special Protocol Assessment ("SPA") process, for a Phase 3 trial evaluating axalimogene filolisbac in patients with HRLACC ("AIM2CERV" or "Advaxis Immunotherapy 2 Prevent

Cervical Recurrence") to be conducted in collaboration with the GOG/NRG Oncology.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 trial of adjuvant axalimogene filolisbac following primary chemoradiation treatment of women with 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 current trial design has a planned sample size of 450 subjects to maintain adequate statistical power over a broader range of survival outcomes. In late 2018, we submitted a request to FDA to accelerate the IA timeline and establish a more stringent futility and efficacy boundary. In January 2019, we announced that we received notice from FDA that they were placing a partial clinical hold on AIM2CERV. FDA's communication stated that the partial hold relates to their requests for additional information pertaining to certain AXAL chemistry, manufacturing and controls (CMC) matters. The Agency did not cite any safety issues related to the trial and all currently enrolled patients will continue to receive treatment, per the trial protocol. However, no new patients can enroll in AIM2CERV until resolution of this partial hold. We have submitted our response to their requests for additional CMC data and are currently in discussions with the Agency. In parallel, we are also in discussions with the Agency regarding our earlier IA request. We are working diligently to come to a resolution on both of these items.

Head and Neck Cancer

Squamous Cell Carcinoma of the Head and Neck ("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. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. But while the Pap smear and other HPV tests have reduced rates of cervical cancer, rates of oral cavity and pharynx cancer are growing, with 51,540 new cases projected to be diagnosed in the United Stated in 2018 according to the Surveillance, Epidemiology, and End Results ("SEER") database.

A study published in the Annals of Internal Medicine found that approximately 12% of U.S. men and 3% of women were actively infected with oral HPV between 2011 and 2014. That totals 11 million men and 3 million women who are at risk for developing SCCHN. SCCHN is typically asymptomatic until it has metastasized, and screening options do not exist. The only way to prevent infection is the HPV vaccine, but compliance has been low to date. Another challenge is that preventative vaccines cannot protect those already infected or older than 26, leaving several generations of Americans vulnerable to SCCHN with no way of knowing if cancer is silently growing.

We conducted a clinical trial in collaboration 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 and MedImmune have decided to not continue further enrollment into the expansion phases of this study.

We plan to initiate an investigator-sponsored trial with a major research center in head and neck cancer in 2019. Axalimogene filolisbac has received FDA orphan drug designation for HPV-associated head and neck cancer.

Prostate Cancer (ADXS-PSA)

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 160,000 men are estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 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. Data from the Keynote-199 trial in bone predominant-mCRCP patients treated with KEYTRUDA® ("pembrolizumab") was presented at the 2018 ASCO Annual Meeting. In this trial, only 4 out of 60 patients (7%) had decrease PSA post-baseline, with only 1 case that was ≥50%. The total SD/disease stabilization rate was 37%.

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 in the TME as soon as five 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. We feel 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.

We have entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® ("pembrolizumab"), Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (Keynote-046). 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. For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of 1 x 10^9 cfu (n=7) and successfully escalated to higher dose levels of 5x10^9 cfu (n=3) and 1x10^{10} cfu (n=3) without achieving a maximum tolerated dose. Treatment emergent adverse events noted at these higher dose levels were generally consistent with those observed at the lower dose level (1 x 10^9 cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The ADXS-PSA monotherapy dose-determination phase of the trial has been completed. The Recommended Phase II Dose (RP2D) of ADXS-PSA monotherapy was determined to be 1x 10^9 cfu based on a review of the totality of the clinical data. This dose was used in combination with 200mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in this phase of the trial (n = 37) was completed in January 2017.

Data of this study in mCRPC patients treated with ADXS-PSA monotherapy (Part A) and in combination with pembrolizumab (Part B) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018. At entry, Part A and Part B patients were similar in age (~70 yrs), Gleason score (~8.3), absence of visceral metastases (71% vs. 70%) and prior abiraterone use. Part B patients had higher median baseline PSA values (40.6 vs. 20.8 ng/ml), and more prior enzalutamide (53% vs. 26%) and chemotherapy (49% vs. 36%) use versus Part A patients. A total of 49 patients (98%) experienced treatment-related adverse events (TRAE), mainly chills, fever, nausea and hypotension. Five Part A and 13 Part B patients had grade 3-4 events: fatigue, hypotension, hypertension, anemia. 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. One patient in the monotherapy arm was discontinued from the study due to a grade 4 TRAE related to cytokine release, which resolved within 24 hours using medical management. Overall, two Part A (14%) v 16 Part B patients (43%) had a decreased PSA post-baseline. Of these, seven Part B (22%) versus 0 Part A patients achieved a PSA reduction ≥50% from baseline. Part B patients had higher rates (56.8%) of stable disease/disease stabilization than Part A patients (38.5%). Part B patients had higher rates (27%) of stable disease than monotherapy patients (7.7%). In all treated patients, an improvement in survival was observed in Part B patients with ≥ 50% PSA declines from baseline versus those with < 50% PSA declines. In this population of heavily pretreated mCRPC patients, ADXS-PSA + pembrolizumab had a manageable safety profile (mostly grade 1-2 TRAEs) and showed a greater level of activity compared to monotherapy. We anticipate reporting updated data on this program at the end of March 2019.

Personalized Neoantigen-Directed Therapies (ADXS-NEO)

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO 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.

The FDA has allowed the IND application of ADXS-NEO and in June 2018, we announced the commencement of a Phase 1 trial with the dosing of the first patient with ADXS-NEO. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer. The study had been in development in collaboration with Amgen until December 2018, when Amgen provided us with a notice of termination of their existing collaboration. We anticipate providing additional data from this study in the first half of 2019 including safety, tolerability and immune correlative data from the first two cohorts.

Disease Focused Hotspot/Off-the-Shelf Neoantigen Therapies (ADXS-HOT)

We have created a new group 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 program is a series of novel cancer immunotherapies that 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 are designed to be more capable of generating potent, tumor specific, and high strength killer T cells, versus more traditional 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 products combine many of the potential high avidity targets that are expressed in all patients with the target disease into one “off-the-shelf”, ready to administer treatment. 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.

In July 2018, we announced that the U.S. Food and Drug Administration (FDA) allowed our IND application for our ADXS-HOT drug candidate for non-small cell lung cancer (NSCLC). In February 2019, we announced that the first patient has been enrolled into the study. We anticipate an early readout of safety, tolerability and immune correlative data from the first cohort in the first half of 2019. In addition, we plan to file additional ADXS-HOT INDs in 2019, in prostate and bladder cancers.

Other Lm Technology Products

HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to published literature, up to 60% of osteosarcomas are HER2 positive, and this overexpression is associated with poor outcomes for patients. ADXS-HER2 is an *Lm* Technology antigen delivery product candidate designed to target HER2 expressing solid tumors including human and canine osteosarcoma. ADXS-HER2 has received FDA and EMA orphan drug designation for osteosarcoma and has received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

In September 2018, we announced that we had granted a license to OS Therapies, LLC ("OS Therapies") 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, in collaboration with the Children's Oncology Group (COG), will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Pursuant to the agreement, we are to receive an upfront payment, reimbursement for product supply and other support, clinical, regulatory, and sales-based milestone payments, and royalties on future product sales. Additional details of the financial terms have not been disclosed.

Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement (the "Aratana Agreement") with Aratana Therapeutics, Inc. ("Aratana"), where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture ("USDA"). Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana is currently conducting an extended field study which is a requirement for full USDA licensure.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to us in the amount of $1,000,000 upon signing of the Aratana Agreement. Aratana will also pay us: (a) up to $36.5 million based on the achievement of milestone relating to the advancement of products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union ("E.U.") in all four therapeutic areas and up to an

additional $15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all products for use in non-human animal health applications (the "Aratana Field") (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a product-by-product and country-by-country basis from first commercial sale of a product in a country until the later of (a) the 10th anniversary of first commercial sale of such product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates. In fiscal year 2018, we received approximately $3,000 in royalty revenue from Aratana.

Results of Operations for the Three Months Ended January 31, 2019 and 2018

Revenue

Revenue increased $17.6 million to approximately $19.7 million for the three months ended January 31, 2019 compared to $2.1 million for the three months ended January 31, 2018. On December 10, 2018, we received a written notice of termination from Amgen with respect to the Amgen Agreement. The termination was effective as of February 8, 2019. As of the notification date, our adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019 resulting in additional revenue of $15.6 million. In addition, during the three months ended January 31, 2019, the reimbursement of research and development costs of approximately $1.1 million was included in revenue as a result of adoption of ASC 606, whereas during the three months ended January 31, 2018, we recorded reductions in research and development expenses of approximately $1.5 million pertaining to the reimbursement of research and development costs.

Research and Development Expenses

We invest in research and development to advance our *Lm* technology through our pre-clinical and clinical development programs. Research and development expenses for the three months ended January 31, 2019 and January 31, 2018 were categorized as follows (in thousands):

Research and Development (in thousands)

	Three Months Ended January 31,		Increase (Decrease)	
	2019	2018	$	%
HPV-associated cancers	$1,211	$5,551	$(4,340)	(78)%
Personalized neoantigen-directed therapies	1,206	372	834	224
Hotspot mutation-based 'off the shelf' therapies	717	179	538	301
Prostate cancer	578	537	41	8
Other expenses	2,995	11,612	(8,617)	(74)
Partner reimbursements	-	(1,500)	1,500	(100)
Total research & development expense	$6,707	$16,751	$(10,044)	(60)%
Stock-based compensation expense included in research and development expense	$323	$1,273	$(950)	(75)%

HPV-Associated Cancers

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our axalimogene filolisbac (AXAL) programs in cervical and head and neck cancers. HPV-associated costs for the three months ended January 31, 2019 decreased approximately $4.3 million, or 78%, compared to the same period in 2018. The decrease resulted from the partial hold by the FDA during the current period, as there was a decrease in investigator payments and the closing of several sites that did not have patients. In addition, there was a winding down of several studies including our Fawcett study in anal cancer and our MEDI4736 study in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab.

Personalized Neoantigen-Directed Therapies

Research and development costs associated with personalized neoantigen-directed therapies for the three months ended January 31, 2019 increased approximately $0.8 million, or 224%, compared to the same period in 2018. The increase is attributable to the opening of new clinical sites, the enrollment of new patients and manufacturing costs for the clinical supply. In June 2018, we announced the commencement of a Phase 1 trial with the dosing of the first patient with ADXS-NEO. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer and was being developed in

collaboration with Amgen, who provided reimbursement for certain research and development costs associated with conducting the clinical trial. In August 2016, we entered into a License and Collaboration Agreement, with Amgen (“Amgen Agreement”) pertaining to the development and commercialization of our ADXS-NEO program, whereby Amgen received an exclusive worldwide license to develop and commercialize the ADXS-NEO program and we and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO and Amgen reimbursed us for certain research and development costs in support of the ADXS-NEO program. On December 10, 2018, we received a written termination notice from Amgen with respect to the Amgen Agreement. We are continuing to enroll patients into this study and reported early immune response data in February 2019. We anticipate having early biomarker, immunological and correlative data from the first cohort of the study during the first half of 2019.

Hotspot Mutation-Based Off-the-Shelf Therapies

Research and development costs associated with our hotspot mutation-based therapies for the three months ended January 31, 2019 increased approximately $0.5 million to $0.7 million compared to the same period in 2018. The increase is attributable to the startup costs associated with the initiation of the Phase 1/2 clinical trial. This is the first study initiated using our ADXS-HOT construct which we believe is applicable across several tumor types. On February 14, 2019, we announced that the first patient has been enrolled in this study and we anticipate having safety and immune response on the first cohort of our first clinical trial using ADXS-HOT, during the first half of 2019.

Prostate Cancer

Research and development costs associated with our prostate cancer therapy for the three months ended January 31, 2019 increased approximately $41,000, or 8%, compared to the same period in 2018. The Phase 2 study of our ADXS-PSA compound in combination with KEYTRUDA® (pembrolizumab), Merck’s humanized monoclonal antibody against PD-1, and we anticipate providing an update on the clinical survival data of the combination arm of the study in the first calendar quarter of 2019.

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 January 31, 2019 decreased approximately $8.6 million, or 74%, compared to the same period in 2018. The decrease was primarily attributable to a decrease in laboratory costs, drug manufacturing process validation and drug stability studies supporting our Marketing Authorization Application ("MAA") in Europe in fiscal year 2018 in support of the filing, which occurred 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.

Partner Reimbursements

Partner reimbursements for the three months ended January 31, 2019 decreased approximately $1.5 million, or 100%, compared to the same period in 2018. During the three months ended January 31, 2019, the reimbursement of research and development costs of approximately $1.1 million was included in revenue as a result of adoption of ASC 606, while during the three months ended January 31, 2018, Company recorded reductions in research and development expenses of approximately $1.5 million pertaining to the reimbursement of research and development costs.

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 January 31, 2019 and January 31, 2018 were as follows (in thousands):

	Three Months Ended January 31,		Increase (Decrease)	
	2019	2018	$	%
General and administrative expense	$2,666	$5,852	$(3,186)	(54)%
Stock-based compensation expense included in general and administrative expense	$299	$1,536	$(1,237)	(81)%

General and administrative expenses for the three months ended January 31, 2019 decreased approximately $3.2 million, or 54%, compared to the same period in 2018. The decrease is primarily attributable to a reduction in headcount, which resulted in lower salary expense, and stock-based compensation due to forfeitures of awards. In addition, there was a decrease in consulting and professional fees in the first quarter of 2019 compared to the prior year due to external strategy and program assessment worked performed during fiscal year 2018.

Changes in Fair Values

For the three months ended January 31, 2019, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $2.4 million. The decrease in the fair value of liability warrants resulting from a decrease in our share price from $0.56 at October 31, 2018 to $0.38 at January 31, 2019.

Liquidity and Capital Resources

Going Concern and Managements Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have suffered recurring losses and we require significant cash resources to execute our business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about our ability to continue as a going concern. The accompanying condensed 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 condensed 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 we 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, debt financings, clinical collaborations, option and warrant exercises, NOL tax sales, income earned on investments and grants, and interest income. From October 2013 through January 2019, we raised approximately $265 million in gross proceeds from various public and private offerings of our common stock. 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 January 31, 2019 and October 31, 2018, we had an accumulated deficit of approximately $354.8 million and $367.7 million, respectively, and stockholders’ equity of approximately $37.5 million and $24.1 million, respectively.

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As of January 31, 2019, we had approximately $32.7 million in cash and cash equivalents. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. It is our belief that we expect to have sufficient capital to fund our obligations, as they become due, in the ordinary course of business until September 2019. The actual amount of cash that we will need to operate is subject to many factors. We have based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of our current product candidates.

We recognize that we will need to raise additional capital in order to continue to execute our business plan in the future. There is no assurance that additional financing will be available when needed or that we will be able to obtain financing on terms acceptable to us or whether we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $11.9 million for the three months ended January 31, 2019 compared to net cash used in operating activities of approximately $12.7 million for the three months ended January 31, 2018. Net cash used in operating activities includes spending associated with our clinical trial programs and general and administrative activities.

Investing Activities

Net cash used in investing activities was approximately $0.6 million for the three months ended January 31, 2019 compared to net cash provided by investing activities of approximately $12.4 million for the three months ended January 31, 2018. During fiscal year 2018, many of our remaining short-term investment securities matured and a portion of the proceeds were used to fund operating activities. In addition, there was a reduction in property and equipment purchases during the three months ended January 31, 2019 of approximately $1.1 million as compared to the prior year.

Financing Activities

Net cash provided by financing activities was approximately $14,000 for the three months ended January 31, 2019 as compared to approximately $2.6 million for the three months ended January 31, 2018. In the prior year, proceeds of approximately $2.7 million resulted from the sale of 881,629 shares of our Common Stock at-the-market transactions.

Off-Balance Sheet Arrangements

As of January 31, 2019, our total future minimum lease payments under noncancelable operating leases was $9.1 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 condensed financial statements that discusses significant accounting policies.

New Accounting Standards

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

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

At January 31, 2019, we had approximately $32.7 million in cash and cash equivalents, which consisted primarily of bank deposits and money market funds. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements. We use a combination of internal and external management to execute our investment strategy and achieve our investment objectives. We typically invest in highly-rated securities, and our 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). We also engaged the services of third party consulting firms to assist in our remediation. 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 fiscal year 2018, we had a material weakness because we did not maintain effective controls over the accounting for complex and non-routine transactions. Specifically, we did not utilize sufficient technical accounting capabilities

related to complex and non-routine transactions with respect to the accounting for a derivative liability. This material weakness was remediated during fiscal 2019 by modifying and redesigning controls procedures and processes surrounding non-routine and complex financial instruments to include the use of third party consulting firms to assist with areas requiring specialized technical accounting expertise and reviewed by management.

Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, do 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

From time to time, we are involved in legal proceedings in the ordinary course of our business. We do 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 Note 10: Commitments and Contingencies, in the notes to the condensed financial statements, for more information on legal proceedings.

Item 1A. Risk Factors

See the Company's most recent annual report filed on Form 10-K (Part I, Item 1A). There has been no material change in this information. The risks described in the annual report on Form 10-K, and the information in the section of this document entitled "Cautionary Note Regarding Forward Looking Statements" 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 risks described in the annual report on Form 10-K 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.[2]

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

Recent Sales of Unregistered Securities

None.

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.

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, 2019 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