# 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 April 30, 2020

[] 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	(IRS Employer
incorporation or organization)	Identification No.)
305 College Road East, Princeton, NJ	08540
(Address of principal executive offices)	(Zip Code)
(609) 45	2-9813
(Registrant's tele	ephone number)
Securities registered pursuant to Section 12(b) of the Act:	

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADXS	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has fled 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 fling requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No []

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

Large Accelerated Filer	[]	Accelerated Filer	[]
Non-accelerated Filer	[X]	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 June 11, 2020 was 61,607,580.

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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 such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "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, our available cash, liquidity, prospects, growth and strategies, impacts of the ongoing COVID-19 pandemic, 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 our 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 forwardlooking 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 or reimbursement of our product candidates for marketing;
- our ability to obtain the appropriate labeling of our products under any regulatory approval;
- our ability to develop and commercialize our products;
- potential effects of the coronavirus (COVID-19) pandemic on our business, financial condition, liquidity and results of operations, and our ability to continue operations in the same manner as previously conducted prior to the macroeconomic effects of the COVID-19 pandemic;
- 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 fiscal year ended October 31, 2019, (as filed with the SEC on December 20, 2019, and amended by Amendment No. 1 thereto on Form 10-K/A filed on January 21, 2020 and by Amendment No. 2 thereto on Form 10-K/A filed on February 28, 2020, as so amended the "2019 Form 10-K/A"), as further supplemented by the factors described in "Item 1A. Risk Factors", beginning on page 26 hereof, 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, we have not independently verified such data.

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# Item 1. Financial Statements

# ADVAXIS, INC. CONDENSED BALANCE SHEETS

(In thousands, except share and per share data)

		April 30, 2020 (Unaudited)		October 31, 2019
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	28,217	\$	32,363
Deferred expenses		1,777		2,353
Prepaid expenses and other current assets		1,774		1,433
Total current assets		31,768		36,149
Property and equipment (net of accumulated depreciation)		3,893		4,350
Intangible assets (net of accumulated amortization)		4,149		4,575
Operating right-of-use asset (net of accumulated amortization)		5,218		-
Other assets		182		183
Total assets	\$	45,210	\$	45,257
	<u> </u>		Ť	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	1,530	\$	976
Accrued expenses	Ψ	1,764	Ψ	3.478
Common stock warrant liability		40		19
Current portion of operating lease liability		891		-
Other current liabilities		-		48
Total current liabilities		4,225		4,521
		7,220		7,021
Operating lease liability, net of current portion		5.548		_
Other liabilities		5,540		1,205
Total liabilities		9,773		5,726
Total habilities		9,775		5,720
Commitments and contingencies – Note 10				
Communents 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 April 30, 2020 and October 31, 2019 Liquidation preference				
of \$0 at April 30, 2020 and October 31, 2019		_		_
Common stock - \$0.001 par value; 170,000,000 shares authorized, 60,252,444 and				
50,201,671 shares issued and outstanding at April 30, 2020 and October 31, 2019,				
respectively		60		50
Additional paid-in capital		433,826		423,750
Accumulated deficit		(398,449)		(384,269)
Total stockholders' equity		35,437	_	39,531
Total liabilities and stockholders' equity	\$	45,210	\$	45,257
	Φ	45,210	Φ	43,237

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 April 30,			Six Mont Apri		ed	
		2020		2019	 2020		2019
Revenue	\$	250	\$	1,188	\$ 253	\$	20,877
Operating expenses:							
Research and development expenses		3,922		5,969	8,781		12,675
General and administrative expenses		2,649		3,092	5,679		5,759
Total operating expenses		6,571	_	9,061	 14,460		18,434
(Loss) income from operations		(6,321)		(7,873)	(14,207)		2,443
Other income (expense):							
Interest income, net		35		113	101		259
Net changes in fair value of derivative liabilities		14		(14)	(23)		2,395
Loss on shares issued in settlement of warrants		-		(1,607)	-		(1,607)
Other expense		(1)		(2)	(1)		(6)
Net (loss) income before benefit for income taxes		(6,273)		(9,383)	(14,130)		3,484
Income tax expense		50		-	 50	. <u></u>	50
Net (loss) income	\$	(6,323)	\$	(9,383)	\$ (14,180)	\$	3,434
Net (loss) income per common share							
Basic	\$	(0.10)	\$	(1.59)	\$ (0.25)	\$	0.65
Diluted	\$	(0.10)	\$	(1.59)	\$ (0.25)	\$	0.20
Weighted average number of common shares outstanding							
Basic		60,572,632		5,900,449	56,107,657		5,259,677
Diluted		60,572,632		5,900,449	 56,107,657		5,282,772

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

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# ADVAXIS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Six Months Ended April 30,			ed
		2020	- <u></u>	2019
OPERATING ACTIVITIES				
Net (loss) income	\$	(14,180)	\$	3,434
Adjustments to reconcile net (loss) income to net cash used in operating activities:	4	(1,100)	Ŷ	5,151
Stock compensation		452		1,101
Employee stock purchase plan expense		1		2
Loss (gain) on change in value of warrants		23		(2,395)
Loss on shares issued in settlement of warrants		-		1,607
Loss on disposal of property and equipment		-		2
Abandonment of intangible assets		603		357
Depreciation expense		457		571
Amortization expense of intangible assets		181		193
Amortization of right-of-use asset		365		-
Change in operating assets and liabilities:				
Accounts receivable		-		1,664
Prepaid expenses and other current assets		235		(994)
Other assets		1		-
Accounts payable and accrued expenses		(1,161)		(6,675)
Deferred revenue		-		(18,665)
Operating lease liabilities		(397)		-
Other liabilities		-		28
Net cash used in operating activities		(13,420)		(19,770)
INVESTING ACTIVITIES				
Purchase of property and equipment		-		(54)
Proceeds from disposal of property and equipment		-		8
Cost of intangible assets		(358)		(663)
Net cash used in investing activities		(358)		(709)
FINANCING ACTIVITIES				
Net proceeds of issuance of common stock		9,628		8,982
Warrant exercise		-		68
Proceeds from employee stock purchase plan		4		17
Employee tax withholdings paid on equity awards		-		(13)
Tax shares sold to pay for employee tax withholdings on equity awards		-		13
Net cash provided by financing activities		9,632		9,067
Net decrease in cash and cash equivalents		(4,146)		(11,412)
Cash and cash equivalents at beginning of period		32,363		45,118
Cash and cash equivalents at end of period	\$	28,217	\$	33,706
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for taxes	\$	50	\$	50
	Ŷ	50	Ŷ	50
SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES				F (00
Shares issued in settlement of warrants		-		5,463
Warrant liability reclassified into equity		2		53

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

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#### ADVAXIS, INC. NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Unaudited)

#### **1. NATURE OF OPERATIONS**

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the 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<sup>TM</sup>. 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, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

#### Liquidity and Financial Condition

The Company has not yet commercialized any products and the products that are being developed have not generated significant revenue. As a result, the Company has experienced recurring losses and requires significant cash resources to execute its business plans. Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its 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 April 30, 2020, the Company raised approximately \$303.8 million in gross proceeds (\$11.6 million in fiscal year 2020) from various public and private offerings of its common stock.

In Note 2 of the notes to the Company's audited financial statements as of and for the year ended October 31, 2019, management stated that the Company had incurred significant losses, negative operating cash flows and as of those dates needed to raise additional funds to meet its obligations and sustain its operations. As a result, the Company concluded that there was substantial doubt as to the Company's ability to continue as a going concern. As of April 30, 2020, the Company had approximately \$28 million in cash and cash equivalents. The Company significantly reduced its operating expenses to \$38.9 million for the fiscal year ended October 31, 2019 as compared to \$76.4 million during the fiscal year ended October 31, 2018. The Company believes to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least August 2021.

Given its cash balances including funds raised in fiscal 2020 of \$11.6 million (which yielded net proceeds of \$10.6 million) and based on its budgeted, reduced cash flow requirements for the next twelve months from the date of filing, the Company believes such funds are sufficient to support ongoing operations at least one year after the issuance of these financial statements.

#### 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 interim condensed balance sheet as of April 30, 2020 has been derived from the Company's October 31, 2019 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 fiscal year ended October 31, 2019 and notes thereto contained in the Company's annual report on Form 10-K, as filed with the SEC on December 20, 2019, as amended by Amendment No. 1 thereto on Form 10-K/A filed on January 21, 2020 and by Amendment No. 2 thereto on Form 10-K/A filed on February 28, 2020.

#### Leases

Effective November 1, 2019, the Company adopted ASC Topic 842, Leases ("ASC 842") using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, Leases.

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

#### Recent Accounting Standards

#### Recently Adopted Accounting Standards

On November 1, 2019, the Company adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), as amended, which establishes ASC 842 and supersedes the lease accounting guidance under ASC 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less.

As of the November 1, 2019 effective date, the Company had identified one operating lease arrangement and one short-term lease in which it is a lessee. The adoption of ASC 842 resulted in the recognition of an operating lease liability and a right-of-use asset of approximately \$6.8 million and \$5.6 million, respectively, on the Company's balance sheet relating to its leases, with the difference relating to reclassifications of the current accrued rent liability and the current lease incentive obligation of approximately \$0.9 million and \$0.3 million, respectively, as reductions to the right-of-use-asset for its operating lease. The adoption of the standard did not have a material effect on the Company's condensed statements of operations or condensed statements of cash flows.

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):

April 30, 2020		October 31, 2019	
\$	2,335	\$	2,335
	3,405		3,405
	744		744
	409		409
	83		83
	6,976		6,976
	(3,083)		(2,626)
\$	3,893	\$	4,350
	April \$ 	\$ 2,335 3,405 744 409 83 6,976 (3,083)	\$ 2,335 \$ 3,405 744 409 83 6,976 (3,083)

Depreciation expense for the three months ended April 30, 2020 and 2019 was \$0.2 million and \$0.3 million, respectively. Depreciation expense for the six months ended April 30, 2020 and 2019 was \$0.5 million and \$0.6 million, respectively.

### 4. INTANGIBLE ASSETS

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

	April 30, 2020		October 31, 2019	
Patents	\$	5,520	\$	5,833
Licenses		777		777
Software		117		117
Total intangibles		6,414		6,727
Accumulated amortization		(2,265)		(2,152)
Intangible assets	\$	4,149	\$	4,575

The expirations of the existing patents range from 2020 to 2040 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 \$0.4 million and \$0.1 million were abandoned and were charged to research and development expenses in the statement of operations for the three months ended April 30, 2020 and 2019, respectively. Patent applications for the six months ended April 30, 2020 and 2019, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the statement of operations aggregated \$0.1 million for each of the three months ended April 30, 2020 and 2019, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the statement of operations aggregated \$0.1 million for each of the six months ended April 30, 2020 and 2019, respectively.

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-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 its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

At April 30, 2020, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

Fiscal year ending October 31,

2020 (Remaining)	\$ 1	167
2021	3	325
2022	3	324
2023	3	324
2024	3	324
Thereafter	2,6	685
Total	\$ 11	1/19

# 5. ACCRUED EXPENSES:

	April	30, 2020	 October 31, 2019
Salaries and other compensation	\$	852	\$ 158
Vendors		562	3,194
Professional fees		350	126
Total accrued expenses	\$	1,764	\$ 3,478

# 6. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

#### Warrants

As of April 30, 2020, there were outstanding warrants to purchase 5,398,226 shares of our common stock with exercise prices ranging from \$0 to \$281.25 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Type of Financing
\$ -	327,338	July 2024	July 2019 Public Offering
\$ 281.25	25	N/A	Other warrants
\$ 0.372	70,863	September 2024	September 2018 Public Offering
\$ 1.25	5,000,000	July 2025	January 2020 Public Offering
Grand Total	5,398,226		

As of October 31, 2019, there were outstanding warrants to purchase 432,142 shares of our common stock with exercise prices ranging from \$0 to \$281.25 per share. Information on the outstanding warrants is as follows:

Exercise	Number of Shares	Enginetien Dete	The of Financia a
Price	Underlying Warrants	Expiration Date	Type of Financing
\$ -	359,838	July 2024	July 2019 Public Offering
\$ 281.25	25	N/A	Other Warrants
\$ 0.372	72,279	September 2024	September 2018 Public Offering
Grand Total	432,142		

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

		W	Veighted	Weighted Average Remaining		
		A	Average	Contractual Life		Aggregate
	Shares	Exe	rcise Price	In Years	In	trinsic Value
Outstanding and exercisable warrants at October 31,						
2019	432,142	\$	0.08	4.76	\$	114,069
Issued	5,000,000		1.25			
Exercised *	(33,916)		0.02			
Outstanding and exercisable warrants at April 30, 2020	5,398,226	\$	1.16	5.16	\$	240,832

\* Includes the cashless exercise of 32,500 warrants that resulted in the issuance of 32,500 shares of common stock.

As of April 30, 2020, the Company had 5,327,363 of its total 5,398,226 outstanding warrants classified as equity (equity warrants). At October 31, 2019, the Company had 359,863 of its total 432,142 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 April 30, 2020, the Company had 70,863 of its total 5,398,226 outstanding warrants classified as liabilities (liability warrants). At October 31, 2019, the Company had 72,279 of its total 432,142 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 April 30, 2020, the down round feature was triggered three times and the exercise price of the warrants were reduced from \$22.50 to \$0.372. 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 settlement in other than cash 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.



In measuring the warrant liability at April 30, 2020 and October 31, 2019, the Company used the following inputs in its Monte Carlo simulation model:

	April 30, 2020	October 31, 2019
Exercise Price	\$ 0.372	\$ 0.372
Stock Price	\$ 0.67	\$ 0.32
Expected Term	4.37 years	4.87 years
Volatility %	103.81%	100.99%
Risk Free Rate	0.36%	1.51%

# 7. SHARE BASED COMPENSATION

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

	Three Months Ended April 30,			Six Months Ended April 30,				
		2020		2019		2020		2019
Research and development	\$	62	\$	258	\$	153	\$	581
General and administrative		148		221		299		520
Total	\$	210	\$	479	\$	452	\$	1,101

#### Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the six months ended April 30, 2020 is as follows:

-	Number of RSUs	 Weighted-Average Grant Date Fair Value
Balance at October 31, 2019	14,706	\$ 47.62
Vested	(8,608)	59.61
Cancelled	(280)	98.80
Balance at April 30, 2020	5,818	\$ 27.40

As of April 30, 2020, there was approximately \$0.1 million of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 0.94 years.

As of April 30, 2020, the aggregate intrinsic value of non-vested RSU's was approximately \$4,000.

#### Employee Stock Awards

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 5,651 shares and 692 shares during the three months ended April 30, 2020 and 2019, respectively. Total stock compensation expense associated with employee awards for the three months ended April 30, 2020 and 2019 was approximately \$40,000 and \$0.2 million, respectively

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 8,608 shares and 10,539 shares during the six months ended April 30, 2020 and 2019, respectively. Total stock compensation expense associated with employee awards for the six months ended April 30, 2020 and 2019 was approximately \$0.1 million and \$0.5 million, respectively.

# Stock Options

A summary of changes in the stock option plan for the six months ended April 30, 2020 is as follows:

	Number of	Weighted-Average
	Options	 Exercise Price
Outstanding at October 31, 2019:	560,490	\$ 71.56
Canceled or expired	(18,212)	13.77
Outstanding at April 30, 2020	542,278	73.50
Vested and Exercisable at April 30, 2020	289,982	\$ 132.62

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended April 30, 2020 and 2019 was approximately \$0.2 million and \$0.3 million, respectively. For the six months ended April 30, 2020 and 2019, compensation cost related to the Company's outstanding stock options was approximately \$0.4 million and \$0.6 million, respectively.

As of April 30, 2020, there was approximately \$0.8 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 approximately 1.17 years.

As of April 30, 2020, the aggregate intrinsic value of vested and exercisable options was \$0.

In determining the fair value of the stock options granted during the six months ended April 30, 2019, the Company used the following inputs in its Black Scholes Merton model:

	Six Months Ended April 30,
	2019
Expected Term	5.50 – 6.51 years
Expected Volatility	90.29 - 104.20%
Expected Dividends	0%
Risk Free Interest Rate	2.39 – 3.15%

Employee Stock Purchase Plan

During the six months ended April 30, 2020 and 2019, the Company issued 8,249 and 3,512 shares, respectively, 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 April 30,			April 30,
		2020		2019
Numerator:				
Net loss	\$	(6,323)	\$	(9,383)
Loss attributable to common stockholders – basic and diluted		(6,323)		(9,383)
Denominator:				
Weighted-average number of common shares used in earnings per share – basic and diluted		60,572,632		5,900,449
	<i>.</i>	(0, 4, 0)		(1 = 2)
Loss per share – basic and diluted	\$	(0.10)	\$	(1.59)
		Circ Months Er	۸ <b>۲</b> - ۲	
		Six Months Er	ided A	-
		2020		2019
Numerator:				
Net (loss) income	\$	(14,180)	\$	3,434
(Loss) income attributable to common stockholders – basic		(14,180)		3,434
Effect of liability classified warrants		-		(2,395)
(Loss) income attributable to common stockholders – diluted		(14,180)		1,039
Denominator:				
Weighted-average number of common shares used in earnings per share - basic		56,107,657		5,259,677
Effect of dilutive stock options		-		61
Effect of dilutive warrants		-		23,034
Weighted-average number of common shares used in earnings per share - diluted				5,282,772
		56,107,657		
(Loss) income per share – basic	\$	(0.25)	\$	0.65
(Loss) income per share – diluted	\$	(0.25)	\$	0.20

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 A	pril 30,
	2020	2019
Warrants	5,398,226	72,304
Stock options	252,296	235,097
Restricted stock units	5,818	17,063
Total	5,946,322	324,464

# 9. COLLABORATION AND LICENSING AGREEMENTS

#### Elanco Animal Health (formerly Aratana Therapeutics)

During the year fiscal 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 each of three months ended April 30, 2020 and 2019, Advaxis recognized royalty revenue totaling \$0, respectively, from Aratana's sales of the canine osteosarcoma vaccine. During the six months ended April 30, 2020 and 2019, Advaxis recognized royalty revenue totaling approximately \$3,000 and \$2,000, respectively, from Aratana's sales of the canine osteosarcoma vaccine. During the six months ended April 30, 2020 and 2019, Advaxis recognized royalty revenue totaling approximately \$3,000 and \$2,000, respectively, from Aratana's sales of the canine osteosarcoma vaccine. On July 16, 2019, Aratana announced their shareholders approved a merger agreement with Elanco Animal Health ("Elanco") whereby Elanco will be the majority shareholder of Aratana. All of the terms of the Aratana Agreement remain in effect.

#### 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). During each of the six months ended April 30, 2020 and 2019, the Company recorded \$0.3 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 when the license renews.

# **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. Advaxis is also seeking fees associated with the arbitration and interest.

From October 21-23, 2019, an evidentiary hearing for the arbitration was conducted. On April 1, 2020, the Arbitrator issued a final award denying Stendhal's claim in full. The Arbitrator found that the Company had not repudiated the Agreement and did not owe Stendhal damages, fees, or interest associated with the arbitration. The Arbitrator also denied the Company's claim that Stendhal breached its obligations to the Company. The parties were ordered to bear their own attorneys' fees and evenly split administrative fees and expenses for the arbitration.

#### 11. LEASES

#### **Operating Leases**

The Company leases its corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that expires in November 2025. The Company has the option to renew the lease term for two additional five-year terms. The renewal periods were not included the lease term for purposes of determining the lease liability or right-of-use asset. The Company has provided a security deposit of approximately \$182,000, which is recorded as Other Assets in the condensed balance sheet.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company does not have sufficient insight to determine an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized a synthetic credit rating model to determine a benchmark for its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for the lease.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.
- Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.
- Variable lease payments, such as common area maintenance, real estate taxes, and property insurance are not included in the determination of the lease's right-of-use asset or lease liability.

Supplemental balance sheet information related to leases as of April 30, 2020 was as follows (in thousands):

Operating Leases:	
Operating lease right-of-use assets	\$ 5,218
Operating lease liability	\$ 891
Operating lease liability, net of current portion	5,548
Total operating lease liabilities	\$ 6,439

Supplemental lease expense related to leases was as follows (in thousands):

Lease Cost (in thousands)	Statements of Operations Classification		For the Three Months Ended April 30, 2020		For the Six Months Ended April 30, 2020	
Operating lease cost	General and administrative	_		289		579
Short-term lease cost	General and administrative			85		169
Variable lease cost	General and administrative	\$		129	\$	270
Total lease expense		\$		503	\$	1,018

Other information related to leases where the Company is the lessee is as follows:

	For the Six
	Months Ended
	April 30, 2020
Weighted-average remaining lease term	5.6 years
Weighted-average discount rate	6.5%

Supplemental cash flow information related to operating leases was as follows:

	For the	Three	For the Six	
	Months	Ended	Months Ended	
	April 30	), 2020	April 30, 2020	
Cash paid for operating lease liabilities	\$	311	\$	611

Future minimum lease payments under non-cancellable leases as of April 30, 2020 were as follows:

Fiscal Year ending October 31,	
2020 (Remaining)	\$ 622
2021	1,318
2022	1,369
2023	1,395
2024	1,419
Thereafter	1,564
Total minimum lease payments	 7,687
Less: Imputed interest	(1,248)
Total	\$ 6,439

Under ASC 840, future minimum payments under the Company's operating lease were as follows (in thousands):

Fiscal Year ending October 31,	
2020	\$ 1,233
2021	1,318
2022	1,369
2023	1,395
2024	1,419
Thereafter	1,564
Total	\$ 8,298

Under ASC 840, rent expense for each of the years ended October 31, 2019 and 2018 was approximately \$1.2 million.

# 12. STOCKHOLDERS' EQUITY

A summary of the changes in stockholders' equity for the three and six months ended April 30, 2020 and 2019 is presented below (in thousands, except share data):

				Additional					
	Preferre	ed Stock	Commo	n Stock		Paid-In	Accumulated		areholders'
	Shares	Amount	Shares	Amour	ıt	Capital	Deficit		Equity
Balance at November 1, 2018	-	\$ -	4,634,189	\$	5	\$ 391,703	\$ (367,657)	\$	24,051
Stock based compensation	-	-	9,811		-	622	-		622
Tax withholdings paid on equity awards	-	-	-		-	(11)	-		(11)
Tax shares sold to pay for tax withholdings									
on equity awards	-	-	-		-	11	-		11
Issuance of shares to employees under									
ESPP Plan	-	-	2,007		-	9	-		9
ESPP Expense	-	-	-		-	1			1
Net Income	-	-	-			-	12,817		12,817
Balance at January 31, 2019	-	\$ -	4,646,007	\$	5	\$ 392,335	\$ (354,840)	\$	37,500
Stock based compensation	-	-	693		-	479	-		479
Tax withholdings paid on equity awards	-	-	-		-	(3)	-		(3)
Tax shares sold to pay for tax withholdings									
on equity awards	-	-	-		-	3	-		3
Issuance of shares to employees under									
ESPP Plan	-	-	1,505		-	7	-		7
Warrant exercises	-	-	15,300		-	68	-		68
Warrant liability reclassified into equity	-	-	-		-	53	-		53
ESPP Expense	-	-	-		-	1			1
Shares issued in settlement of warrants	-	-	856,865		1	5,462	-		5,463
Advaxis public offerings	-	-	2,500,000		2	8,980	-		8,982
Net Loss	-	-	-		-	-	(9,383)		(9,383)
Balance at April 30, 2019	-	\$	8,020,370	\$	8	\$ 407,385	\$ (364,223)	\$	43,170

							Additional				Total
	Preferre	ed Sto	ck	Common Stock			Paid-In		Accumulated		areholders'
	Shares	Ar	nount	Shares	A	mount	Capital	Deficit			Equity
Balance at November 1, 2019	-	\$	-	50,201,671	\$	50	\$ 423,750	\$	(384,269)	\$	39,531
Stock based compensation	-		-	2,957		-	242		-		242
Advaxis public offerings	-		-	10,000,000		10	9,618		-		9,628
Warrant exercises	-		-	26,416		-	2		-		2
Issuance of shares to employees under											
ESPP Plan	-		-	5,555		-	2		-		2
Net Income	-		-	-		-	-		(7,857)		(7,857)
Balance at January 31, 2020	-	\$	-	60,236,599	\$	60	\$ 433,614	\$	(392,126)	\$	41,548
Stock based compensation	-		-	5,651		-	210		-		210
Warrant exercises	-		-	7,500		-	-		-		-
Issuance of shares to employees under											
ESPP Plan	-		-	2,694		-	2		-		2
Net Income	-		-	-		-	-		(6,323)		(6,323)
Balance at April 30, 2020		\$	_	60,252,444	\$	60	\$ 433,826	\$	(398,449)	\$	35,437
				16							

On February 21, 2019, the Company's stockholders voted to approve an amendment to the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") 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 the Certificate of Incorporation 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. Additionally, on March 29, 2019, the Company executed a 1 for 15 reverse stock split.

During April 2019, the Company issued 2,500,000 shares of the Company's common stock in a public offering at \$4.00 per share, less underwriting discounts and commissions. The net proceeds to the Company from the transaction was approximately \$9 million.

In January 2020, the Company closed on a public offering of 10,000,000 shares of its common stock at a public offering price of \$1.05, for gross proceeds of \$10.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 5,000,000 shares of common stock. The warrants have an exercise price per share of \$1.25, are exercisable during the period beginning on the six-month anniversary of the date of its issuance (the "Initial Exercise Date") and will expire on the fifth anniversary of the Initial Exercise Date. The warrants haves, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately \$9.6 million.

# **13. 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 April 30, 2019 and October 31, 2019 (in thousands):

April 30, 2020	Level 1	Level 2	Level 3	 Total	
Common stock warrant liability, warrants exercisable at					
\$0.372 through September 2024	-	-	\$ 40	\$	40
October 31, 2019	Level 1	Level 2	Level 3	Total	
Common stock warrant liability, warrants exercisable at					
\$0.372 through September 2024	-	-	\$ 19	\$	19

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

	For the Six Months End April 30, 2020	
Beginning balance	\$	19
Warrant exercises		(2)
Change in fair value		23
Ending Balance	\$	40

#### 14. Subsequent Events

At the Annual Meeting of Stockholders of the Company held on May 4, 2020, the stockholders ratified and approved an amendment to the Company's 2015 Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under such Plan from 877,744 shares to 6,000,000 shares.

On May 4, 2020, the Company granted to directors, officers and employees options to purchase 450,000 shares of common stock. The options are priced at \$0.66, vest annually in equal installments such that 100% of the options will by the third anniversary of the grant date. The stock options vest one-third after the one year anniversary, one-third after the two year anniversary and one-third after the three year anniversary.

#### At-the-Market Transactions

On May 8, 2020, the Company filed a prospectus supplement and associated sales agreement related to an at-the-market ("ATM") equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to \$40 million through A.G.P./Alliance Global Partners, as sales agent, for general corporate purposes. From May 8, 2020 through the date the financial statements were issued, the Company sold 1,353,237 shares of its common stock under the ATM program for \$1.067 million, or an average of \$0.79 per share, and received proceeds of \$1.033 million, net of commissions of \$34,000.



# 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 fiscal year ended October 31, 2019. In addition, we intend to use our media and investor relations website (www.advaxis.com/investor-relations), SEC filings, press releases, public conference calls and webcasts to communicate with the public about Advaxis, its services and other issues.

## Overview

Advaxis, Inc. ("we" or "Advaxis") is a clinical-stage biotechnology company focused on the 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<sup>TM</sup>. 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 our 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.

#### **Recent Developments**

On March 11, 2020, the World Health Organization declared the coronavirus (COVID-19) a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to COVID-19. The pandemic has resulted in government-imposed quarantines, travel restrictions, business and school closures and other public health safety measures. We are monitoring the COVID-19 pandemic and taking steps intended to mitigate the potential risks to our workforce and our operations. The evolving COVID-19 pandemic has, and may continue to, directly or indirectly affect the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Nonetheless, thus far, the COVID-19 pandemic has not had a significant impact on the business. However, we remain be in contact with the clinical sites in our study and we are in discussion with additional sites in order to combat any potential impact in enrollment. We are unable to determine or predict the extent, duration or scope of the overall impact of the COVID-19 pandemic on our business, operations, financial condition or liquidity.

#### Strategic Transactions

As a matter of course, we are reviewing strategic transactions and alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transactions, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business. These transactions could include, but are not limited to, collaboration agreements, co-development agreements, strategic mergers, reverse mergers, the issuance or buyback of public shares, or the purchase or sale of specific assets, in addition to other potential actions aimed at increasing stockholder value. There can be no assurance that the review of strategic transactions will result in the identification or consummation of any transaction. Our Board of Directors may also determine that our most effective strategy is to continue to effectuate our current business plan. Any potential transaction would be dependent upon a number of factors that may be beyond our control, including, but not limited to, market conditions, industry trends, the interest of third parties in our business and the availability of financing to potential buyers on reasonable terms. No decision has been made with respect to any transaction.

#### 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 have conducted 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 our 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 2040.

# **Advaxis Pipeline of Product Candidates**

IND Cleared Jan 2020		
	*	

#### Disease focused hotspot/ 'off the shelf' neoantigen therapies (ADXS-HOT)

We are creating a new group of immunotherapy constructs for major solid tumor cancers that combines our optimized *Lm* Technology vector with promising targets designed to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that will target somatic mutations, or hotspots, cancer testis antigens, or CTAs, and oncofetal antigens, or 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 tumor associated antigens. 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 will 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. We believe the ADXS-HOT technology has a strong intellectual property, or IP, position, with potential protection into 2040, 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, or FDA, allowed our investigational new drug, or IND, application for our ADXS-HOT drug candidate (ADXS-503) for non-small cell lung cancer, or NSCLC. The Phase 1/2 clinical trial of ADXS-503 is seeking to establish the recommended dose, safety, tolerability and clinical activity of ADXS-503 administered alone and in combination with a KEYTRUDA® in approximately 50 patients with NSCLC, in at least five sites across the U.S. The two dose levels with monotherapy in Part A,  $(1x10^8 \text{ and } 5x10^8 \text{ CFU})$  have been completed and Part B with ADXS-503 ( $1x10^8 \text{ CFU}$ ) in combination with KEYTRUDA® is currently closed to enrollment. Based on the results reported to date, including an observed stable disease and a partial response in the first two patients in Part B who previously progressed on KEYTRUDA®, we are planning to expand Part B to additional patients at dose level 1 ( $1x10^8 \text{ CFU} + \text{KEYTRUDA}$ ®) with the potential to proceed to dose level 2 ( $5x10^8 \text{ CFU} + \text{KEYTRUDA}$ ®) at a later date. In addition, we intend to expand the study to Part C, which will evaluate ADXS-503 in combination with KEYTRUDA® ( $1x10^8 \text{ CFU} + \text{KEYTRUDA}$ ®) as a first line treatment for patients that are medically unfit to receive the standard of care regimen with KEYTRUDA® in combination with chemotherapy.

Additionally, in January 2020, we announced that the FDA has allowed our IND for the initiation for a Phase 1 clinical study of ADXS-504, our ADXS-HOT drug candidate for prostate 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 191,000 men are estimated to be diagnosed with prostate cancer in 2020, with approximately 33,000 deaths each year. Unfortunately, in about 10-20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer, or CRPC, which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC, or 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.

We have entered into a clinical trial collaboration and supply agreement with Merck & Co., or Merck, to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA<sup>®</sup>, 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  $1 \times 10^9$  cfu (n=7) and successfully escalated to higher dose levels of  $5 \times 10^9$  cfu (n=3) and  $1 \times 10^{10}$  cfu (n=3) without achieving a maximum tolerated dose. Treatment-related adverse events, or TRAEs, noted at these higher dose levels were generally consistent with those observed at the lower dose level ( $1 \times 10^9$  cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The Recommended Phase II Dose of ADXS-PSA monotherapy was determined to be  $1 \times 10^9$  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 the study was completed in January 2017.

Data regarding checkpoint inhibitor monotherapy (KEYNOTE-199) has shown some antitumor activity that provides disease control in a subset of patients with bone-predominant mCRPC previously treated with next generation hormonal agents and docetaxel. Data from the KEYNOTE-199 trial in bone-predominant mCRPC patients treated with KEYTRUDA®, or pembrolizumab, was presented at the ASCO GU meeting in 2019. In this trial, the total stable disease/disease stabilization rate was 39% with no responses reported so far, and only one patient with  $\geq$ 50% decrease in the post-baseline PSA value. It is hypothesized that the limited activity in mCRPC may be due to 1) the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment and 2) the presence of an immunosuppressive tumor micro-environment, or TME. The combination therapy with agents—like *Lm* constructs—that induce T cell infiltration within the tumor and decrease negative regulators in the TME may improve performance of checkpoints in prostate cancer.

For KEYNOTE-046, as of the final data cutoff, September 16, 2019, the median overall survival (mOS) for 37 patients in the combination arm was 33.7 months (95% CI, range 15.4-33.7 months) and the median overall survival (95% CI) of 16.4 months (4.0-NR) for patients with prior visceral metastasis (n=11; 10 pts with prior docetaxel). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research Annual Meeting in April 2019, where median overall survival was 21.1 months in the combination arm. The majority of TRAEs consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well-tolerated to date, with no additive toxicity observed. We are in discussions with potential partners regarding opportunities to expand or advance this mCRPC program.

#### HPV-Related Cancers

We conducted several studies evaluating axalimogene filolisbac, or AXAL, for HPV-related cancers. Axalimogene filolisbac (AXAL) is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV.

In June 2019, we announced the closing of our AIM2CERV Phase 3 clinical trial with AXAL in high-risk locally advanced cervical cancer. The decision to close the study was based on the estimated remaining cost to complete the AIM2CERV trial of \$80 million to \$90 million, in addition to the timing to complete the study. The initial efficacy data was not anticipated for at least three years. No results from the clinical trial were to be available for at least three more years and therefore, results of the study were not the basis for the decision to close the study, nor was safety as the trial recently underwent its third Independent Data Monitoring Committee (IDMC) review with no safety issues noted. We are in the process of winding down the study and plan to publish the results in a medical journal in the future. We have no plans to further fund studies using AXAL.

In 2014, Advaxis granted Global BioPharma, or GBP, an exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former Soviet Union territory, exclusive of India and certain other countries. GBP is responsible for all development and commercial costs and activities associated with the development in their territories. GBP anticipates initiating its Phase 2, open-label controlled trial in HPV-associated NSCLC in patients following first-line chemotherapy by the end of 2019. The study will be assessing the effects of AXAL when combined with pemetrexed in patients with HPV+ NSCLC, following first line induction therapy.

#### 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. In October 2019, we announced that we dosed our last patient in Part A, in monotherapy, and we do not intend to continue into Part B, in combination with a checkpoint inhibitor. As a result, we are in the process of winding down this study and we intend to publish the final results from Part A of the ADXS-NEO study in a medical journal in the future.

#### 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, or 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 will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Pursuant to the agreement, upon OS Therapies' successful completion of a financing, Advaxis expects 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, or Aratana Agreement, with Aratana Therapeutics, Inc., or 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, or 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.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to Advaxis in the amount of \$1,000,000 upon signing of the Aratana Agreement. Aratana will also pay Advaxis: (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, or 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, or 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 2019, we received approximately \$8,000 in royalty revenue from Aratana. Additionally, in July 2019, Aratana announced that their shareholders approved a merger agreement with Elanco Animal Health, or Elanco, whereby Elanco is now the majority shareholder of Aratana. All of the terms of the Aratana Agreement remain in effect.

# Results of Operations for the Three Months Ended April 30, 2020 and 2019

#### Revenue

Revenue decreased approximately \$0.9 million to \$0.3 million for the three months ended April 30, 2020 compared to \$1.2 million for the three months ended April 30, 2019. The decrease was due to the termination of the collaboration agreement with Amgen effective February 8, 2019. Revenue associated with the performance related to the upfront fees received was approximately \$0.3 million for the three months ended April 30, 2019. In addition, during the three months ended April 30, 2019, the reimbursement of research and development costs by Amgen of approximately \$0.9 million was included in revenue. During the three months ended April 30, 2020, we received the annual licensing fee from GBP.

#### 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 April 30, 2020 and April 30, 2019 were categorized as follows (in thousands):

		Three Moi Apri	nths E il 30,	nded		Increase (Decrease)		
	2020		2019		\$		%	
Hotspot/Off-the-Shelf therapies	\$	909	\$	960	\$	(51)	(5)%	
Prostate cancer		156		(214)		370	(173)	
HPV-associated cancers		789		1,950		(1,161)	(60)	
Personalized neoantigen-directed therapies		558		103		455	442	
Other expenses		1,510		3,170		(1,660)	(52)	
Total research & development expense	\$	3,922	\$	5,969	\$	(2,047)	(34)%	
Stock-based compensation expense included in research and development expense	\$	62	\$	258	\$	(196)	(76)%	
	21							

# Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapies for the three months ended April 30, 2020 decreased approximately \$0.1 million to \$0.9 million compared to the same period in 2019. The decrease is attributable to the startup costs associated with the initiation of the Phase 1/2 clinical trial during the prior period. We have completed enrollment in Part A, in monotherapy, and Part B, in combination with pembrolizumab at five sites across the U.S. In February 2020, and further updated in May 2020, we announced the initial clinical data from the study which showed that ADXS-503 has been safe and tolerable with potential signs of clinical activity in four out of the seven evaluable patients achieving stable disease in the refractory setting. In addition, the first two patients evaluated in Part B who previously progressed on pembrolizumab showed stable disease with a 25% reduction in a site lesion in the first patient and a sustained partial response observed in the second patient. We anticipate reporting additional information from this study as it becomes available throughout 2020.

#### Prostate Cancer Therapy (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the three months ended April 30, 2020 increased approximately \$0.4 million, or 173%, compared to the same period in 2019. The increase is attributable to the receipt of credit memorandums from the contract research organization during the prior period. The Phase 1/2 study of our ADXS-PSA compound is in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody. During 2020, we presented updated data from this study which demonstrated an increase in the median overall survival, or mOS, to 33.7 months for patients in the combination arm of this study and mOS of 16.4 for patients with visceral metasteses (n=11). We are in discussions with potential partners on next steps for this therapy.

#### HPV-Associated Cancers

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the three months ended April 30, 2020 decreased approximately \$1.2 million, or 60%, compared to the same period in 2019. The decrease resulted from the announcement made in June 2019 regarding the closing of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. We anticipate that we will continue to incur costs associated with the wind down of the study until late 2020. Additionally, 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, drove further reduction in costs as compared to the prior period. We anticipate that our costs surrounding HPV-associated studies will continue to decline as we wrap up the remaining clinical and regulatory obligations of the program. We currently do not anticipate funding any new AXAL studies.

#### Personalized Neoantigen-Directed Therapies

Research and development costs associated with personalized neoantigen-directed therapies for the three months ended April 30, 2020 increased approximately \$0.5 million, or 442%, compared to the same period in 2019. The increase is attributable to changes in estimates made by our contract research organization, which reduced the expense in the prior period. In October 2019, we announced that we have enrolled our last patient in the ADXS-NEO program in monotherapy and will not continue into Part B of this study. As a result, the costs incurred for ADXS-NEO during the three months ended April 30, 2020 consisted of wind down costs associated with terminating the study. We anticipate that we will incur wind down costs for this study until late 2020 and plan to publish the results of this program in a future medical journal.

# 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 April 30, 2020 decreased approximately \$1.7 million, or 52%, compared to the same period in 2019. The decrease was primarily attributable to a decrease in salary related expenses, including stock compensation, and travel expenses resulting from cost control measures put in place beginning in June 2018. In addition, there were decreases in laboratory and manufacturing costs, as we are focused on the clinical development of our HOT program and less on early research programs. Additionally, we announced in October 2019 that we are winding down ADXS-NEO and therefore no longer incurring costs to manufacture ADXS-NEO.

#### 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 April 30, 2020 and April 30, 2019 were as follows (in thousands):

	Three Months Ended April 30,					Increase (Decrease)		
	2020			2019 \$		%		
General and administrative expense	\$	2,649	\$	3,092	\$	(443)	(14)%	
Stock-based compensation expense included in general and administrative expense	\$	148	\$	221	\$	(73)	(33)%	
	22							

General and administrative expenses for the three months ended April 30, 2020 decreased approximately \$443 million, or 14%, compared to the same period in 2019. The decrease is attributable to lower legal fees, employee bonus accruals and business development costs.

#### Loss on shares issued in settlement of warrants

On March 14, 2019, we entered into private exchange agreements with certain holders of warrants issued in connection with our September 2018 public offering of common stock and warrants. Pursuant to such exchange agreements, we issued 856,865 shares of common stock to the investors in exchange for such warrants on a 1:1 basis. In connection with the warrant exchange, we recorded a loss of approximately \$1.6 million for the three months ended April 30, 2019.

#### Results of Operations for the Six Months Ended April 30, 2020 and 2019

#### Revenue

Revenue decreased approximately \$20.6 million to \$0.3 million for the six months ended April 30, 2020 compared to \$20.9 million for the six months ended April 30, 2019. The decrease was due to a change in the estimated performance period associated with upfront fees received from Amgen in conjunction with the collaboration agreement signed in August 2016. 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, we 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 total revenue of \$18.7 million in the prior period. In addition, the reimbursement of research and development costs of approximately \$2.0 million by Amgen was included in revenue in the prior period.

### 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 six months ended April 30, 2020 and April 30, 2019 were categorized as follows (in thousands):

	 Six months April 3		 Increase (Decrease)			
	 2020	2019	 \$	%		
Hotspot/Off-the-Shelf therapies	\$ 1,462	1,677	\$ (215)	(13)%		
Prostate cancer	534	364	170	47		
HPV-associated cancers	2,524	3,161	(637)	(20)		
Personalized neoantigen-directed therapies	908	1,309	(401)	(31)		
Other expenses	3,353	6,164	(2,811)	(46)		
Total research & development expense	\$ 8,781	12,675	\$ (3,894)	(31)%		
Stock-based compensation expense included in research and development expense	\$ 153	581	\$ (428)	(74)%		

# Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapies for the six months ended April 30, 2020 decreased approximately \$0.2 million to \$1.5 million compared to the same period in 2019. The decrease is attributable to the startup costs associated with the initiation of the Phase 1/2 clinical trial in the prior period.

#### Prostate Cancer Therapy (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the six months ended April 30, 2020 increased approximately \$0.2 million, or 47%, compared to the same period in 2019. The increase is attributable to the receipt of credit memorandums from the contract research organization during the prior period.

#### HPV-Associated Cancers

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXA, programs in cervical and head and neck cancers. HPV-associated costs for the six months ended April 30, 2020 decreased approximately \$0.6 million, or 20%, compared to the same period in 2019. The decrease resulted from the announcement made in June 2019 regarding the closing of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer.

#### Personalized Neoantigen-Directed Therapies

Research and development costs associated with personalized neoantigen-directed therapies for the six months ended April 30, 2020 decreased approximately \$0.4 million, or 31%, compared to the same period in 2019. In October 2019, we announced that we have enrolled our last patient in the ADXS-NEO program in monotherapy and will not continue into Part B of this study. As a result, the costs incurred for ADXS-NEO during the six months ended April 30, 2020 consisted of wind down costs associated with terminating the study. We anticipate that we will incur wind down costs for this study until late 2020 and plan to publish the results of this program in a future medical journal.

#### 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 six months ended April 30, 2020 decreased approximately \$2.8 million, or 46%, compared to the same period in 2019. The decrease was primarily attributable to a decrease in salary related expenses, including stock compensation, and travel expenses resulting from cost control measures put in place beginning in June 2018. In addition, there were decreases in laboratory and manufacturing costs, as we are focused on the clinical development of our HOT program and less on early research programs. Additionally, we announced in October 2019 that we are winding down ADXS-NEO and therefore no longer incurring costs to manufacture ADXS-NEO.

#### 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 six months ended April 30, 2020 and April 30, 2019 were as follows (in thousands):

		Six mon Apri	ths ende il 30,	ed	Increase (Decrease	
	2	2020 2019		 \$	%	
General and administrative expense	\$	5,679	\$	5,759	\$ (80)	(1)%
Stock-based compensation expense included in general and administrative expense	\$	299	\$	520	\$ (221)	(43)%

General and administrative expenses for the six months ended April 30, 2020 decreased approximately \$0.1 million, or 1%, compared to the same period in 2019. General and administrative expenses for the six months ended April 30, 2020 were consistent with general and administrative expenses for the six months ended April 30, 2019.

#### Changes in Fair Values

For the six months ended April 30, 2020, we recorded non-cash expense from changes in the fair value of the warrant liability of approximately \$23,000. The increase in the fair value of liability warrants resulted from an increase in our share price from \$0.32 at October 31, 2019 to \$0.67 at April 30, 2020.

For the six months ended April 30, 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 resulted from a decrease in our share price from \$8.42 at October 31, 2018 to \$3.54 at April 30, 2019.

#### Loss on shares issued in settlement of warrants

On March 14, 2019, we entered into private exchange agreements with certain holders of warrants issued in connection with our September 2018 public offering of common stock and warrants. Pursuant to such exchange agreements, we issued 856,865 shares of common stock to the investors in exchange for such warrants on a 1:1 basis. In connection with the warrant exchange, we recorded a loss of approximately \$1.6 million for the six months ended April 30, 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. 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 April 30, 2020, we raised approximately \$302.7 million in gross proceeds (\$10.5 million in fiscal year 2020) 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 April 30, 2020 and October 31, 2019, we had an accumulated deficit of approximately \$398.4 million and \$384.3 million, respectively, and stockholders' equity of approximately \$35.4 million and \$39.5 million, respectively.

The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect our business, financial condition, and access to sources of liquidity. As of April 30, 2020, we had approximately \$28.2 million in cash and cash equivalents. The actual amount of cash that we will need to continue operating 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. We reduced our operating expenses to \$38.9 million for the fiscal year ended October 31, 2019 as compared to \$76.4 million for the fiscal year ended October 31, 2018. Furthermore, we expect operating expenses to be approximately \$25.1 million for fiscal year 2020, which includes approximately \$6.0 million in non-recurring costs related to programs that are winding down. Based on this, we expect to have sufficient capital to fund our obligations as they become due in the ordinary course of business until at least August 2021. In addition, we expect to adjust spending accordingly based on the budgeted cash flow requirements developed and the excess cash on hand.

On May 8, 2020, the Company entered into a sales agreement related to an at-the-market equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to \$40 million through A.G.P./Alliance Global Partners, as sales agent, for general corporate purposes.

#### **Cash Flows**

#### **Operating Activities**

Net cash used in operating activities was approximately \$13.4 million for the six months ended April 30, 2020 compared to \$19.8 million for the six months ended April 30, 2019. Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. In the third quarter of fiscal 2018, we began instituting measures to control costs for non-essential items in areas that didn't support our strategic direction, and as a result, we have continued to reduce operating expenditures significantly.

#### Investing Activities

Net cash used in investing activities was approximately \$0.4 million for the six months ended April 30, 2020 compared to \$0.7 million for the six months ended April 30, 2019. The reduction is a result of the abandonment of certain non-strategic intellectual property.

#### **Financing** Activities

Net cash provided by financing activities was approximately \$9.6 million for the six months ended April 30, 2020 as compared to \$9.1 million for the six months ended April 30, 2019. We completed a public offering of 10,000,000 shares of our common stock in January 2020, which resulted in net proceeds of approximately \$9.7 million, while in fiscal 2019, we received net proceeds of approximately \$9.0 million from the sales of 2,500,000 shares of our common stock in a public offering in April 2019.

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

As of April 30, 2020, our total future minimum lease payments under noncancelable operating leases was approximately \$7.7 million.

#### **Critical Accounting Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America. 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.

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

At April 30, 2020, we had approximately \$28.2 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 principal financial officer of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 ("the Exchange Act"). Based upon this evaluation, our chief executive officer and principal financial officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is: (1) accumulated and communicated to our management, including our chief executive officer, as appropriate to allow timely decisions regarding required disclosure; and (2) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

#### Changes in Internal Control over Financial Reporting

During the quarter ended April 30, 2020, there were no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

#### Limitations on Effectiveness of Controls

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

#### **PART II - OTHER INFORMATION**

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

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. Refer to Note 10 to our condensed financial statements for more information on legal proceedings.

#### **Item 1A. Risk Factors**

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our annual report on Form 10-K for the fiscal year ended October 31, 2019, (as filed with the SEC on December 20, 2019, and amended by Amendment No. 1 thereto on Form 10-K/A filed on January 21, 2020 and by Amendment No. 2 thereto on Form 10-K/A filed on February 28, 2020, as so amended the "2019 Form 10-K/A") should be carefully considered.

The information presented below updates, and should be read in conjunction with, the risk factors identified in our 2019 Form 10-K/A. The risks described in our 2019 Form 10-K/A, this Quarterly Report on Form 10-Q and the information in the section of this document entitled "Cautionary Note Regarding Forward Looking Statements" are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also affect our business operations. If any of the risks described in our 2019 Form 10-K/A actually occur, our business, financial condition or results of operations could be materially adversely affected.



#### **Risks Related to our Business and Operations**

A global health crisis such as a pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a pandemic. The COVID-19 pandemic is affecting the United States and global economies and has affected, and may continue to affect, our operations and those of third parties on which we rely, including by causing disruptions in our raw material supply and the manufacturing of our product candidates. In addition, the COVID-19 pandemic has affected the operations of the U.S. Food and Drug Administration (the "FDA") and other health authorities, which can result in delays of reviews and approvals, including with respect to our product candidates. The evolving COVID-19 pandemic has, and may continue to, directly or indirectly affect the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Additionally, such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic and the federal, state and local responses to such virus, could materially affect the efficiency and pace with which we work and develop our product candidates and the manufacturing of our product candidates. In addition, COVID-19 infection of our workforce could result in a temporary disruption in our business activities, including manufacturing and other functions. Further, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

As a matter of course, we explore and evaluate strategic transactions for our company. We may not be successful in identifying or completing any strategic transaction and any such strategic transaction completed may not yield additional value for stockholders.

As a matter of course, we are reviewing strategic transactions and alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transactions, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business. These transactions could include, but are not limited to, collaboration agreements, co-development agreements, strategic mergers, reverse mergers, the issuance or buyback of public shares, or the purchase or sale of specific assets, in addition to other potential actions aimed at increasing stockholder value. There can be no assurance that the review of strategic transactions will result in the identification or consummation of any transaction. Our Board of Directors may also determine that our most effective strategy is to continue to effectuate our current business plan. The process of reviewing strategic transactions may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying and evaluating potential strategic alternatives. No decision has been made with respect to any transaction and we cannot assure you that we will be able to identify and undertake any transaction that allows our shareholders to realize an increase in the value of their common stock or provide any guidance on the timing of such action, if any.

We also cannot assure you that any potential strategic transaction or other alternative transaction, if identified, evaluated and consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. Any potential transaction would be dependent upon a number of factors that may be beyond our control, including, but not limited to, market conditions, industry trends, the interest of third parties in our business and the availability of financing to potential buyers on reasonable terms. We do not intend to comment regarding the evaluation of strategic alternatives until such time as our Board of Directors has determined the outcome of the process or otherwise has deemed that disclosure is appropriate or required by applicable law. As a consequence, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

### Item 6. Exhibits

10.1	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on March 20, 2020.
31.1*	Certification of Principal Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial 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 Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL INSTANCE DOCUMENT
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
101.LAB	XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

101.PRE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

\* Filed herewith.



# 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.

Date: June 11, 2020

# ADVAXIS, INC.

# Registrant

By: /s/ Kenneth A. Berlin

Kenneth A. Berlin President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Molly Henderson

Molly Henderson Executive Vice President, Chief Financial Officer (Principal Financial Officer)

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# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Kenneth A. Berlin, certify that:

- 1. I have reviewed this report on Form 10-Q for the quarter ended April 30, 2020 of Advaxis, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

June 11, 2020

By: /s/ Kenneth A. Berlin

Name: Kenneth A. Berlin Title: President and Chief Executive Officer

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Molly Henderson, certify that:

- 1. I have reviewed this report on Form 10-Q for the quarter ended April 30, 2020 of Advaxis, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

June 11, 2020

By: /s/ Molly Henderson

Name: Molly Henderson

Title: Executive Vice President, Chief Financial Officer

# CERTIFICATION-PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

The undersigned as Chief Executive Officer of Advaxis, Inc. (the "Company"), does hereby certify that the foregoing Quarterly Report on Form 10-Q of the Company for the quarter ended April 30, 2020:

- (1) Fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) Fairly presents, in all material respects, the financial condition and result of operations of the Company.

June 11, 2020

/s/ Kenneth A. Berlin

Kenneth A. Berlin President and Chief Executive Officer

# CERTIFICATION-PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

The undersigned as Chief Financial Officer of Advaxis, Inc. (the "Company"), does hereby certify that the foregoing Quarterly Report on Form 10-Q of the Company for the quarter ended April 30, 2020:

- (1) Fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) Fairly presents, in all material respects, the financial condition and result of operations of the Company.

June 11, 2020

/s/ Molly Henderson

Molly Henderson Executive Vice President, Chief Financial Officer