

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 16, 2021

**ADVAXIS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-36138 (Commission File Number)	02-0563870 (IRS Employer Identification No.)
305 College Road East Princeton, New Jersey (Address of principal executive offices)		08540 (Zip Code)

Registrant's telephone number, including area code: (609) 452-9813

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value \$0.001 per share	ADXS	Nasdaq Capital Market
Preferred Stock Purchase Rights	-	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 2.02 Results of Operations and Financial Condition.**

On March 16, 2021, Advaxis, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended January 31, 2021 and providing a business update. A copy of the press release is furnished herewith as Exhibit 99.1.\*

**Item 9.01 Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	<a href="#">Press Release of the Company, dated March 16, 2021</a>
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\* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

March 16, 2021

**ADVAXIS, INC.**

By: /s/ Kenneth A. Berlin

Name: Kenneth A. Berlin

Title: President and Chief Executive Officer, Interim Chief Financial Officer

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**Advaxis Reports First Quarter Ended January 31, 2021 Financial Results and Provides a Business Update**

*Continued enrollment in expanded ADXS-503 HOT program in NSCLC to explore potential to enhance and/or restore sensitivity to checkpoint inhibitors*

*ADXS-503 Phase 1/2 trial data presented at SITC demonstrated disease control rate of 67% and overall response rate of 17% in first six evaluable patients with immediate prior progression on KEYTRUDA®*

*\$9.2M public offering strengthens balance sheet for continued execution*

**PRINCETON, N.J.– March 16, 2021** – Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announces its financial results for the first quarter ended January 31, 2021 and provides a business update.

**First Quarter Ended January 31, 2021 Financial Results and Recent Key Accomplishments:**

- Presented updated clinical data from the ongoing Phase 1/2 trial of ADXS-503 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy, in non-small cell lung cancer (NSCLC) at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting
    - Disease control rate of 67% and overall response rate of 17% in first six evaluable patients with immediate prior progression on KEYTRUDA®. The first two patients treated in Part B combination arm that had achieved stable disease (SD) and partial response (PR) remain on treatment for 10 and 8 months, respectively
    - Biomarker data across 9 patients across trial arms confirmed on-mechanism activation of innate and adaptive immune responses to ADXS-503 with transient elevation of immune-modulatory cytokines, activation of cytotoxic -and/or memory CD8+ T cells as well as 100% efficient priming by ADXS-503
    - Across trial arms, ADXS-503 appeared safe and well tolerated as a monotherapy and in combination with KEYTRUDA® with no added toxicities from combination therapy
  - Announced upcoming presentation at the American Association for Cancer Research (AACR) 2021 Annual meeting, in collaboration with Precision for Medicine, on the development of a novel immunophenotyping assay to accurately evaluate PD-1 expression as a pharmacodynamic marker during PD-1 blockade treatment with pembrolizumab, and the correlation of changes in T cell populations with observed clinical activity in the ongoing ADXS-503 clinical trial
  - Announced receipt of funding milestone payment under ADXS-HER2 licensing agreement with OS Therapies
  - Announced closing of \$9.2 million public offering of common stock and warrants, with proceeds being used to fund continued development and expansion of our product pipeline
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## Management Commentary

“We are encouraged by the growing body of evidence that suggest ADXS-503 has the potential to synergistically enhance and/or restore sensitivity to checkpoint inhibitors,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “Based on our encouraging data, we are prioritizing the ongoing and recently expanded ADXS-503 trial in diverse treatment settings for NSCLC, and will remain focused on continued clinical execution. We look forward to our presentation at AACR, which will further expand upon the previously reported on-mechanism innate and adaptive immune stimulation which we believe are driving meaningful and durable clinical benefit for patients treated with ADXS-503. Our strengthened balance sheet leaves us well positioned to continue progress with our off-the-shelf neoantigen immunotherapy ADXS-HOT program, including our planned expansion into prostate cancer with ADXS-504, and we look forward to providing study updates in the coming months.”

## First Quarter Ended January 31, 2021 Financial Results

Research and development expenses for the first quarter of fiscal year 2021 were \$2.6 million, compared with \$4.9 for the first quarter of fiscal year 2020. The reduction of \$2.3 was primarily attributable to the substantial reduction in costs associated with the winding down of clinical studies that have been discontinued.

General and administrative expenses for the three months ended January 31, 2021 were approximately unchanged at \$3 million, compared to \$3 million in the same three-month period in 2020.

As of January 31, 2021, the Company had approximately \$33.3 million in cash and cash equivalents. The Company believes this is sufficient capital to fund its obligations, as they become due, in the ordinary course of business until May 2022.

## About Advaxis, Inc.

Advaxis, Inc. is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes (Lm)* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable T cells to eliminate tumors.

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To learn more about Advaxis, visit [www.advaxis.com](http://www.advaxis.com) and connect on Twitter, LinkedIn, Facebook and YouTube.

### **Forward-Looking Statements**

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the expected clinical development of the Company's drug product candidates, statements about the Company's balance sheet position, and statements related to the goals, plans and expectations for the Company's ongoing clinical studies. These and other risks are discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on January 22, 2021, and its periodic reports on Form 10-Q and Form 8-K. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

KEYTRUDA<sup>®</sup> is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

### **Contact:**

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**ADVAXIS, INC.**  
**CONDENSED BALANCE SHEETS**  
(In thousands, except share and per share data)

	<b>January 31, 2021</b>	<b>October 31, 2020</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 33,318	\$ 25,178
Deferred expenses	1,602	1,808
Prepaid expenses and other current assets	608	865
Total current assets	<u>35,528</u>	<u>27,851</u>
Property and equipment (net of accumulated depreciation)	2,189	2,393
Intangible assets (net of accumulated amortization)	3,404	3,261
Operating right-of-use asset (net of accumulated amortization)	4,644	4,839
Other assets	182	182
Total assets	<u>\$ 45,947</u>	<u>\$ 38,526</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 399	\$ 410
Accrued expenses	2,142	1,737
Common stock warrant liability	44	17
Current portion of operating lease liability	992	962
Deferred revenue	-	165
Total current liabilities	<u>3,577</u>	<u>3,291</u>
Operating lease liability, net of current portion	<u>4,795</u>	<u>5,055</u>
Total liabilities	<u>8,372</u>	<u>8,346</u>
Commitments and contingencies – Note 9		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at January 31, 2021 and October 31, 2020; Liquidation preference of \$0 at January 31, 2021 and October 31, 2020	-	-
Common stock - \$0.001 par value; 170,000,000 shares authorized, 116,130,688 and 78,074,023 shares issued and outstanding at January 31, 2021 and October 31, 2020, respectively	116	78
Additional paid-in capital	452,174	440,840
Accumulated deficit	(414,715)	(410,738)
Total stockholders' equity	<u>37,575</u>	<u>30,180</u>
Total liabilities and stockholders' equity	<u>\$ 45,947</u>	<u>\$ 38,526</u>

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

**ADVAXIS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS (Unaudited)**  
(In thousands, except share and per share data)

	Three Months Ended January 31,	
	2021	2020
Revenue	\$ 1,615	\$ 3
Operating expenses:		
Research and development expenses	2,570	4,859
General and administrative expenses	3,008	3,030
Total operating expenses	5,578	7,889
Loss from operations	(3,963)	(7,886)
Other income (expense):		
Interest income, net	1	66
Net changes in fair value of derivative liabilities	(27)	(37)
Other income	12	-
Net loss before benefit for income taxes	(3,977)	(7,857)
Income tax expense	-	-
Net loss	\$ (3,977)	\$ (7,857)
Net loss per common share, basic and diluted	\$ (0.05)	\$ (0.15)
Weighted average number of common shares outstanding, basic and diluted	83,943,982	51,747,246

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

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

	Three Months Ended January 31,	
	2021	2020
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (3,977)	\$ (7,857)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	236	242
Loss on change in value of warrants	27	37
Loss on disposal of property and equipment	12	-
Abandonment of intangible assets	-	232
Depreciation expense	192	229
Amortization expense of intangible assets	67	91
Amortization of right-of-use asset	195	181
<u>Change in operating assets and liabilities:</u>		
Prepaid expenses and other current assets	463	789
Other assets	-	1
Accounts payable and accrued expenses	394	(1,462)
Deferred revenue	(165)	-
Operating lease liabilities	(230)	(191)
Net cash used in operating activities	(2,786)	(7,708)
<b>INVESTING ACTIVITIES</b>		
Cost of intangible assets	(210)	(238)
Net cash used in investing activities	(210)	(238)
<b>FINANCING ACTIVITIES</b>		
Net proceeds of issuance of common stock	8,550	9,737
Warrant exercise	2,586	-
Proceeds from employee stock purchase plan	-	2
Net cash provided by financing activities	11,136	9,739
Net increase in cash and cash equivalents	8,140	1,793
Cash and cash equivalents at beginning of period	25,178	32,363
Cash and cash equivalents at end of period	\$ 33,318	\$ 34,156
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid for taxes	\$ -	\$ -
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES</b>		
Warrant liability reclassified into equity	-	2
Amounts accrued for offering costs	-	109

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