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): September 10, 2020

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36138	02-0563870
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

305 College Road East Princeton, New Jersey	08540
(Address of principal executive offices)	(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 Global Select 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 8.01 Other Events

On September 10, 2020, Advaxis, Inc. (the "Company") issued a press release announcing third quarter ended July 31, 2020 financial results and provided a pipeline update. The Company's press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

The following exhibits are filed as part of this report:

Exhibit No.	Exhibit Name
99.1	Press Release of Advaxis, Inc., dated September 10, 2020

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.

September 10, 2020

ADVAXIS, INC.

By: */s/ Molly Henderson*
Name: Molly Henderson
Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

Advaxis Reports Third Quarter Ended July 31, 2020 Financial Results and Provides a Business Update

Strategic expansion of ADXS-503 HOT program in NSCLC to explore potential to enhance and or restore sensitivity to checkpoint inhibitors

Enrolling in Phase 1/2 Study efficacy expansion of ADXS-503 in NSCLC based on sustained and durable clinical responses in first two of three evaluable patients from Part B combination arm with KEYTRUDA®

Enrolling in Part C for first-line regimen with KEYTRUDA® in NSCLC patients with PD-L1 expression ≥ 1% and patients who are unfit for standard of care combination therapy with KEYTRUDA® and platinum-based chemotherapy

PRINCETON, N.J.– September 10, 2020 – Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced an update on its clinical pipeline and financial results for the third quarter ended July 31, 2020.

Key recent corporate and clinical pipeline updates:

- Presented updated clinical data from the ongoing Phase 1/2 trial of ADXS-503 in non-small cell lung cancer (NSCLC) demonstrating durable clinical benefit in two out of 3 evaluable patients with immediate prior progression on KEYTRUDA® including one durable response now out to 34 weeks with 25% reduction in target lesion and another sustained response now out to 33 weeks with a 60% reduction in site lesions. Both patients remain on treatment in Part B, the combination arm with KEYTRUDA®
    - Clinical benefit achieved after immediate prior progression on KEYTRUDA® with previous best responses of stable disease suggest ADXS-503 may re-sensitize or enhance response to KEYTRUDA®
- Initiated ADXS-503 Part B combination arm efficacy expansion which will enroll up to 15 patients to evaluate the potential of ADXS-503 in combination with KEYTRUDA® to restore and/or enhance responsiveness to checkpoint inhibitors in PD-1/L-1 refractory NSCLC patients
- Initiated ADXS-503 Part C combination arm to evaluate ADXS-503 in combination with KEYTRUDA® as a first line treatment in patients with NSCLC with PD-L1 expression ≥ 1% or who are unfit for chemotherapy
- ADXS-503 monotherapy and in combination with KEYTRUDA® appeared safe and well tolerated with no dose limiting toxicities or added toxicity in the combination setting
- Announced common stock purchase agreement for up to $20 million with Lincoln Park Capital

Management Commentary

“We are highly encouraged by the clinical and on-mechanism biomarker data from our ongoing Phase 1/2 study of ADXS-503 in NSCLC and have continued to execute on our expansion of the evaluation of the potential of ADXS-503 to synergistically enhance and/or restore sensitivity to checkpoint inhibitors,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “This quarter, we have begun enrollment in the expansion of Part B to further evaluate the promising signals of sustained clinical benefit observed in the first dose cohort of Part B in NSCLC patients with immediate prior progression on KEYTRUDA®. This could yet be another strategy to rechallenge the tumor with a checkpoint inhibitor without having to stop the drug at progression. In addition, we have started enrollment in Part C which will evaluate ADXS-503 in combination with KEYTRUDA®, moving our HOT program to a first line treatment for patients with metastatic NSCLC that would receive KEYTRUDA® alone as per label indication (i.e., PD-L1 expression ≥ 1%) and patients who are unfit to receive the standard of care regimen of KEYTRUDA® in combination with platinum based-chemotherapy. We believe these two clinical evaluations in Part B and Part C of this study will elucidate the potential of ADXS-503 to improve responses to checkpoint inhibitors in diverse clinical settings and for patients who have limited treatment options. We anticipate having additional data on this program by the end of the year.”

Mr. Berlin continued, “We are particularly encouraged by the safety and tolerability profile of ADXS-503 as a monotherapy and in combination KEYTRUDA®, and with no dose limiting toxicities observed, we believe this can be an important addition to standard of care for those patients whose illness makes them ineligible for other forms of chemotherapy. Our recently announced common stock purchase agreement allows us to continue the prioritization of our HOT program with the ongoing expansions in NSCLC as well as the initiation of a Phase 1 study of ADXS-504 in prostate cancer patients with biochemical recurrence before year end.”

Third Quarter Ended July 31, 2020 Financial Results

Research and development expenses for the third quarter of fiscal year 2020 were $3.5 million, compared with $7.1 million for the third quarter of fiscal year 2019. The decrease is largely attributable to the winding down of the Phase 3 AIM2CERV and Phase 1 ADXS-NEO studies as announced in June 2019 and October 2019, respectively.

General and administrative expenses for the three months ended July 31, 2020 were approximately $2.4 million compared to $3.1 million in the same three-month period in 2019. The decrease in expenses is mainly attributable to lower legal fees and business development costs.

As of July 31, 2020, the Company had approximately $23.8 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 July 2021.

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.

To learn more about Advaxis, visit 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. 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 December 20, 2019 and Form 10-K/A on February 28, 2020, 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® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

Advaxis, Inc.
Selected Balance Sheet Data
(In thousands)

	July 31, 2020 (Unaudited)	October 31, 2019
Cash and cash equivalents	$ 23,846	$ 32,363
Total assets	$ 40,019	$ 45,257
Total stockholders' equity	$ 31,466	$ 39,531

STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share and per share data)

	Three Months Ended July 31,		Nine months ended July 31,	
	2020	2019	2020	2019
Revenue	$ -	$ 6	$ 253	$ 20,883
Operating expenses:				
Research and development expenses	3,458	7,060	12,239	19,735
General and administrative expenses	2,384	3,076	8,063	8,834
Total operating expenses	5,842	10,136	20,302	28,569
Loss from operations	(5,842)	(10,130)	(20,049)	(7,686)
Other income	13	272	90	1,312
Net loss before benefit for income taxes	(5,829)	(9,858)	(19,959)	(6,374)
Income tax expense	-	-	50	50
Net loss	$ (5,829)	$ (9,858)	$ (20,009)	$ (6,424)
Net loss per common share, basic and diluted	$ (0.09)	$ (1.00)	$ (0.35)	$ (0.94)
Weighted average number of common shares outstanding, basic and diluted	61,634,031	9,870,461	57,963,228	6,813,494
* Includes stock-based compensation as follows:				
Research and development	$ 79	$ 241	$ 233	$ 822
General and administrative	176	223	475	743
	$ 255	$ 464	$ 708	$ 1,565

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