Advaxis Reports Fiscal Year 2020 Financial Results and Provides a Business Update

January 25, 2021

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

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

Continued durable tumor control with two patients on treatment beyond 12 months

Strengthened balance sheet through $9.2M public offering and utilization of common stock purchase agreement and at-the-market facility

PRINCETON, N.J., Jan. 25, 2021 (GLOBE NEWSWIRE) -- 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 fiscal year ended October 31, 2020 and provides a business update.

Fiscal Year 2020 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
  - In the Part B combination arm, reported disease control rate of 67% and overall response rate of 17% in first six evaluable patients with immediate prior progression on KEYTRUDA®
  - Reported durable and sustained tumor control, with confirmed stable disease and a partial response lasting out to 10 months
  - Biomarker data across 9 patients across trial arms confirmed on-mechanism activation of innate and adaptive immune responses to ADXS-503 with 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
- 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 metastatic NSCLC that would receive KEYTRUDA® alone as per label indication with PD-L1 expression ≥ 1% or who are unfit to receive the standard of care regimen of KEYTRUDA® in combination with platinum based-chemotherapy
- Announced FDA Clearance of new Investigational New Drug (IND) application for ADXS-504 for the treatment of prostate cancer at a leading medical institution
- Announced common stock purchase agreement for up to $20 million of common stock with Lincoln Park Capital
- Announced an at-the-market offering program for up to $40 million of common stock with A.G.P./Alliance Global Partners, as sales agent
- 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, including investment in our ADXS-HOT program and for general corporate purposes
- Cash runway currently anticipated to take the Company into fiscal second quarter of 2022

Management Commentary

"Fiscal year 2020 was transformative for Advaxis, with important clinical and biomarker data from the ongoing Phase 1/2 study of ADXS-503 in NSCLC which now consistently show 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. "Based on these encouraging results, we have prioritized this study, beginning enrollment in the expansion of Part B to further evaluate the promising signals of sustained clinical benefit observed in Part B in NSCLC patients with immediate prior progression on KEYTRUDA®, as well as Part C, which will evaluate ADXS-503 in combination with KEYTRUDA® in the first line setting. We remain confident that our clinical strategy will explore the full potential of ADXS-503 to improve responses to checkpoint inhibitors across diverse clinical settings and patient populations, and are highly enthusiastic about the on-mechanism innate and adaptive immune stimulation seen in our broadly accessible, off-the-shelf neoantigen immunotherapy. In addition to these encouraging data, our strengthened balance sheet ensures our

continued momentum with the ADXS-HOT program as we advance our *Lm*-technology to expand the reach of checkpoint inhibitors."

Balance Sheet Highlights

As of October 31, 2020, Advaxis had cash and cash equivalents of $25.2 million. The Company used $21.9 million in cash to fund operations during fiscal year 2020, mainly attributed to funding research and development and general and administrative activities. Throughout fiscal year 2020, the Company continued to prioritize its strategic pipeline across all programs and reduced its annual operating expenses by approximately $12.2 million, or nearly 31%.

Fiscal Year 2020 Financial Information
Research and development expenses for fiscal year 2020 were $15.6 million, compared with $26.7 million for fiscal year 2019. The $11.1 million decrease was primarily attributable to decreases in clinical trial costs, laboratory costs, drug manufacturing process validation and drug stability studies.

General and administrative expenses for fiscal year 2020 were $11.1 million, compared to $12.2 million for fiscal year 2019.

The net loss for the fiscal year ended October 31, 2020 was $26.5 million or $0.43 per share based on about 61 million weighted average shares outstanding. This compares with a net loss for fiscal year 2019 of $16.6 million or $1.09 per share based on 15.2 million weighted average shares outstanding.

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

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

	October 31, 2020	October 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,178	$ 32,363
Deferred expenses	1,808	2,353
Prepaid expenses and other current assets	865	1,433
Total current assets	27,851	36,149
Property and equipment (net of accumulated depreciation)	2,393	4,350
Intangible assets (net of accumulated amortization)	3,261	4,575
Operating right-of-use asset (net of accumulated amortization)	4,839	-
Other assets	182	183
Total assets	$ 38,526	$ 45,257
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	$ 410	$ 976
Accrued expenses	1,737	3,478
Current portion of operating lease liability	962	-
Deferred revenue	165	-
Common stock warrant liability	17	19
Other current liabilities	-	48
Total current liabilities	3,291	4,521
Operating lease liability, net of current portion	5,055	-
Other liabilities	-	1,205
Total liabilities	8,346	5,726
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 October 31, 2020 and 2019. Liquidation preference of $0 at October 31, 2020 and 2019.	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 78,074,023 and 50,201,671 shares issued and outstanding at October 31, 2020 and 2019.	78	50
Additional paid-in capital	440,840	423,750
Accumulated deficit	(410,738)	(384,269)
Total stockholders' equity	30,180	39,531
Total liabilities and stockholders' equity	$ 38,526	$ 45,257

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

	Year Ended October 31,	
	2020	2019
Revenue	$ 253	$ 20,884
Operating expenses:		
Research and development expenses	15,612	26,677
General and administrative expenses	11,090	12,179
Total operating expenses	26,702	38,856
Loss from operations	(26,449)	(17,972)
Other income (expense):		
Interest income	110	435
Net changes in fair value of derivative liabilities	-	2,589
Loss on shares issued in settlement of warrants	(77)	(1,607)
Other expense	(3)	(7)
Net loss before income tax benefit	(26,419)	(16,562)
Income tax expense	50	50
Net loss	$ (26,469)	$ (16,612)
Net loss per common share, basic and diluted	$ (0.43)	$ (1.09)
Weighted average number of common shares outstanding, basic, and diluted	61,003,839	15,207,637

Source: Advaxis, Inc.