Advaxis Reports Second Quarter Ended April 30, 2021 Financial Results and Provides a Business Update

June 14, 2021

ADXS-503 Phase 1/2 trial data presented at ASCO demonstrate disease control rate of 44% with durable clinical benefit observed beyond one year in patients with disease progression on KEYTRUDA®

Expansion of off-the-shelf ADXS-HOT program with planned Phase 1 study in early prostate cancer with biochemical recurrence

Cash runway anticipated into fiscal 3rd quarter of 2023

PRINCETON, N.J., June 14, 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 second quarter ended April 30, 2021 and provides a business update.

Second Quarter Ended April 30, 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 American Society of Clinical Oncology (ASCO) 2021 Annual Meeting
  - 10 patients have been treated with ADXS-503 as an add on therapy in patients failing pembrolizumab as last therapy with 10 patients evaluable for safety and 9 patients evaluable for efficacy
  - Combination therapy was well tolerated with no dose-limiting toxicities (DLTs) or added toxicity of the two drugs
  - The disease control rate (DCR) was 44% (4/9) with durable clinical benefit observed including a partial response (PR) and stable disease (SD) sustained for over a year, and another observed SD lasting over 6 months. An additional PR was maintained for approximately 4 months
  - Biomarker data demonstrate that patients who seem to achieve clinical benefit include those with PD-L1 expression ≥50%, secondary resistance disease to pembrolizumab and those who show proliferation and/or activation of NK and CD8+ T cells within the first weeks of therapy
  - Translational studies show antitumoral T-cell responses elicited against hot-spot mutation antigens and/or tumor associated antigens (TAAs), induction of proliferation and/or activation of pre-existing CD8+ T-cell clones, emergence of naive CD8+ T cell clones, and PD-1 and CD38 upregulation
  - Continuing to enroll patients for treatment with ADXS-503 in combination with KEYTRUDA® (pembrolizumab) as first line therapy as well
- Presented data 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 agreement with Columbia University Irving Medical Center to fund Phase 1 Study of ADXS-504 for the treatment of early prostate cancer with biochemical recurrence
- Achieved second milestone under ADXS-HER2 licensing agreement with OS Therapies
- Announced $20 million registered direct offering and concurrent private placement priced at-the-market with two healthcare-focused institutional investors to fund continued development and expansion of the Company's product pipeline
- Cash balance at April 30, 2021 of $48.1 million providing the Company with an anticipated cash runaway into fiscal 3rd quarter of 2023.

Management Commentary

"Our recent presentation at ASCO adds to the strong foundation of data which suggest treatment with ADXS-503 has the potential provide durable clinical benefit in patients with certain clinical characteristics and early T cell responses," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Achieving clinical benefit in patients with immediate prior progression on KEYTRUDA® is particularly meaningful, suggesting that ADXS-503 has the potential to enhance and/or restore sensitivity to checkpoint inhibitors. These encouraging data, combined with our expanded set of translational data which show on-mechanism innate and adaptive immune stimulation, leave us confident that our off-the-shelf neoantigen immunotherapy may be an important new treatment option to expand the reach of immunotherapies in diverse treatment settings and indications. We will continue our progress with ADXS-503 in NSCLC and will expand our ADXS-HOT program to additional indications, with our planned study of ADXS-504 in early stage prostate cancer, and look forward to providing additional study updates in the coming months."

Second Quarter Ended April 30, 2021 Financial Results

Research and development expenses for the second quarter of fiscal year 2021 were $4.34 million, compared with $3.92 for the second quarter of fiscal year 2020. The increase of $0.42 million was primarily attributable to winding down some legacy studies and losses on disposal of research-related property and equipment in connection with the termination of the office lease at the Company's former location.

General and administrative expenses for the three months ended April 30, 2021 were at $3.35 million, compared to $2.65 million in the same three-month period in fiscal 2020. The increase of $0.7 million primarily relates to increases in sub-license fees and legal fees, amounts paid in settlement of shareholder demand letters and losses on disposal of other property and equipment in connection with the termination of the Company's office lease at its former location.

As of April 30, 2021, the Company had approximately $48.1 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 into the 3rd fiscal quarter of 2023.

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, including the sufficiency of the Company's cash and cash equivalents to fund its obligations into the future, 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.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

	April 30, 2021 (Unaudited)	October 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 48,110	$ 25,178
Deferred expenses	1,333	1,808
Accounts receivable	1,375	-
Prepaid expenses and other current assets	1,295	865
Total current assets	52,113	27,851
Property and equipment (net of accumulated depreciation)	333	2,393
Intangible assets (net of accumulated amortization)	3,325	3,261
Operating right-of-use asset (net of accumulated amortization)	-	4,839
Other assets	-	182
Total assets	$ 55,771	$ 38,526
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,156	$ 410
Accrued expenses	2,133	1,737

Common stock warrant liability	4,931	17
Current portion of operating lease liability	-	962
Deferred revenue	-	165
Total current liabilities	8,220	3,291
Operating lease liability, net of current portion	-	5,055
Total liabilities	8,220	8,346
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 April 30, 2021 and October 31, 2020; Liquidation preference of $0 at April 30, 2021 and October 31, 2020	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 145,638,459 and 78,074,023 shares issued and outstanding at April 30, 2021 and October 31, 2020, respectively	146	78
Additional paid-in capital	467,227	440,840
Accumulated deficit	(419,822)	(410,738)
Total stockholders' equity	47,551	30,180
Total liabilities and stockholders' equity	$ 55,771	$ 38,526

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

	Three Months Ended April 30,		Six Months Ended April 30,	
	2021	2020	2021	2020
Revenue	$ 1,375	$ 250	$ 2,990	$ 253
Operating expenses:				
Research and development expenses	4,344	3,922	6,914	8,781
General and administrative expenses	3,352	2,649	6,360	5,679
Total operating expenses	7,696	6,571	13,274	14,460
Loss from operations	(6,321)	(6,321)	(10,284)	(14,207)
Other income (expense):				
Interest income, net	2	35	3	101
Net changes in fair value of derivative liabilities	995	14	968	(23)
Other income (expense)	217	(1)	229	(1)
Net loss before income taxes	(5,107)	(6,273)	(9,084)	(14,130)
Income tax expense	-	50	-	50
Net loss	$ (5,107)	$ (6,323)	$ (9,084)	$ (14,180)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.10)	$ (0.08)	$ (0.25)
Weighted average number of common shares, basic and diluted	123,145,051	60,572,632	111,895,403	56,107,657

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

	Six Months Ended

	April 30,	
	2021	2020
OPERATING ACTIVITIES		
Net loss	$ (9,084)	$ (14,180)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	451	452
Employee stock purchase plan expense	-	1
Loss (gain) on change in value of warrants	(968)	23
Loss on disposal of property and equipment	1,530	-
Loss on write-down of intangible assets	69	-
Abandonment of intangible assets	-	603
Depreciation expense	316	457
Amortization expense of intangible assets	135	181
Amortization of right-of-use asset	327	365
Net gain on write off of right-of-use asset and lease liability	(1,116)	-
Change in operating assets and liabilities:		
Accounts receivable	(1,375)	-
Prepaid expenses, other current assets and deferred expenses	45	235
Other assets	182	1
Accounts payable and accrued expenses	1,142	(1,161)
Deferred revenue	(165)	-
Operating lease liabilities	(389)	(397)
Net cash used in operating activities	(8,900)	(13,420)
INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	214	-
Cost of intangible assets	(268)	(358)
Net cash used in investing activities	(54)	(358)
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock and warrants	28,115	9,628
Warrant exercises	3,771	-
Proceeds from employee stock purchase plan	-	4
Net cash provided by financing activities	31,886	9,632
Net increase in cash and cash equivalents	22,932	(4,146)
Cash and cash equivalents at beginning of period	25,178	32,363
Cash and cash equivalents at end of period	$ 48,110	$ 28,217
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for taxes	$ -	$ 50
SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES		
Warrant liability reclassified into equity	-	2

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Source: Advaxis, Inc.