Adverum Reports First Quarter 2021 Results

May 6, 2021

REDWOOD CITY, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Adverum Biotechnologies, Inc. (Nasdaq: ADVM), a clinical-stage gene therapy company targeting unmet medical needs in ocular and rare diseases, today reported financial results for the first quarter ended March 31, 2021.

“Our management team and Board are focused on conducting a thorough review of patient safety data from the ADVM-022 program to inform our next steps,” said Laurent Fischer, M.D., chief executive officer at Adverum Biotechnologies. “At ARVO last weekend, long-term data from the OPTIC trial were presented, demonstrating ADVM-022’s durability in patients with treatment-experienced neovascular or wet age-related macular degeneration. As part of our broader mission to advance the field of gene therapy, we are committed to the work our team is doing on behalf of patients who need new treatment options for ocular diseases.”

Recent Developments

- On April 28, 2021, Adverum announced a Suspected Unexpected Serious Adverse Reaction (SUSAR) of hypotony (clinically-relevant decrease in ocular pressure), with panuveitis and loss of vision in the treated eye, in its INFINITY clinical trial evaluating ADVM-022 for the treatment of diabetic patients with macular edema. The company has unmasked the study and is assessing and monitoring this patient and all patients treated with ADVM-022 and is working closely with investigators, the data monitoring committee (DMC), the scientific advisory board, and healthcare authorities. The patient impacted by the SUSAR event is undergoing in-person assessments with leading retina specialists across the U.S. who are working with Adverum to gain an understanding of the causes of the SUSAR and to develop a treatment plan for the patient. In addition, all patients who have received ADVM-022 have been requested to see their treating physician for an evaluation, including ophthalmic and advanced imaging assessments to collect additional data. Adverum, working with its expert advisors, is conducting a thorough review of data from the ADVM-022 program, taking into account learnings from the SUSAR, and plans to report its findings as the analysis progresses.
- At ARVO in May 2021, long-term OPTIC clinical data were presented (March 10, 2021 cutoff date, n=30) that continue to demonstrate the potential of ADVM-022 to greatly reduce the anti-VEGF injection burden for patients with wet AMD. All ADVM-022-related ocular adverse events (AE) were mild (80%) to moderate (20%) in OPTIC patients with wet AMD. No clinical or fluorescein evidence of posterior inflammation and no vasculitis, retinitis, choroiditis, vascular occlusions, or endophthalmitis were observed. The OPTIC data presentation is available on the Publications section of Adverum’s website.
- In light of the announced SUSAR, the company is evaluating its timelines and capital allocation priorities with an aim to extend its cash runway beyond prior guidance.

Financial Results for the Three Months Ended March 31, 2021

- **Cash, cash equivalents and short-term investments** were $404.0 million as of March 31, 2021, compared to $429.7 million as of December 31, 2020.
- **License revenue** was $7.5 million for the three months ended March 31, 2021, compared to no revenue for the same period in 2020. License revenue for the three months ended March 31, 2021 was due to an upfront payment received on a license agreement.
- **Research and development expenses** were $20.0 million for the three months ended March 31, 2021, compared to $14.8 million for the same period in 2020. Research and development expenses increased primarily due to higher personnel-associated costs, material production costs, and clinical trial expenses. Stock-based compensation expense included in research and development expenses was $2.3 million for the first quarter of 2021.
- **General and administrative expenses** were $16.2 million for the three months ended March 31, 2021, compared to $9.0 million for the same period in 2020. General and administrative expenses increased primarily due to higher personnel-associated costs, professional services costs, and depreciation expense for Adverum’s Redwood City facility. Stock-based compensation expense included in general and administrative expenses was $4.9 million for the first quarter of 2021.
- **Net loss** was $28.4 million, or $0.29 per basic and diluted share, for the three months ended March 31, 2021, compared to $22.9 million, or $0.31 per basic and diluted share, for the same period in 2020.

COVID-19

To date, Adverum has experienced limited impact from COVID-19 on its operations and ongoing clinical programs, including the OPTIC and INFINITY clinical trials. The company is continuing to monitor and attempt to address or limit the potential impacts of COVID-19 on its employees and operations, patient safety, continued participation of patients enrolled in the company’s clinical studies, protocol compliance, data quality, and overall study integrity.

About Adverum Biotechnologies

Adverum Biotechnologies (Nasdaq: ADVM) is a clinical-stage gene therapy company targeting unmet medical needs in serious ocular and rare diseases. Adverum is advancing the clinical development of its novel gene therapy candidate, ADVM-022, as a one-time, intravitreal injection for the treatment of patients with wet age-related macular degeneration and diabetic macular edema. For more information, please visit www.adverum.com.

Forward-looking Statements

Statements contained in this press release regarding the events or results that may occur in the future are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include but are not limited to statements regarding the potential efficacy and safety of ADVM-022 in wet AMD and diabetic macular edema (DME). Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks inherent to, without limitation: Adverum’s novel technology, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the results of early clinical trials not always being predictive of future results; and the potential for Adverum’s recent announcement of a SUSAR of hypotony with panuveitis and loss of vision in the treated eye, in its INFINITY clinical trial evaluating ADVM-022 gene therapy for the treatment of DME and any future complications or side effects in connection with use of ADVM-022 to delay or prevent regulatory advancement or approval for ADVM-022. Risks and uncertainties facing Adverum are described more fully in Adverum’s Annual Report on Form 10-K for the year ended December 31, 2020, Adverum’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and any subsequent filings with the SEC, especially under the heading “Risk Factors.” All forward-looking statements contained in this press release speak only as of the date on which they were made. Adverum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Adverum Biotechnologies, Inc.
Consolidated Balance Sheets
(In thousands)

	March 31 2021	December 31, 2020
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 45,422	$ 62,424
Short-term investments	358,596	367,305
Prepaid expenses and other current assets	5,837	4,709
Total current assets	409,855	434,438
Property and equipment, net	28,379	27,725
Operating lease right-of-use asset	19,044	19,376
Restricted cash	3,780	999
Deposit and other long-term assets	493	29
Total assets	$ 461,551	$ 482,567
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	2,056	2,810
Lease liability, current portion	4,512	4,473
Accrued expenses and other current liabilities	13,355	13,588
Total current liabilities	19,923	20,871
Lease liability, net of current portion	25,694	26,235
Other noncurrent liabilities	1,114	1,114
Total liabilities	46,731	48,220
Stockholders' equity:		
Common stock	10	10
Additional paid-in capital	946,098	937,134
Accumulated other comprehensive loss	(316)	(261)
Accumulated deficit	(530,972)	(502,536)
Total stockholders' equity	414,820	434,347
Total liabilities and stockholders' equity	$ 461,551	$ 482,567

(1) Derived from Adverum’s annual audited consolidated financial statements.

Adverum Biotechnologies, Inc.
Consolidated Statements of Operations
(In thousands except per share data)
(Unaudited)

	Three months ended March 31,	
	2021	2020
License revenue	$ 7,500	$ -

Operating expenses:		
Research and development	19,980	14,751
General and administrative	16,163	9,040
Total operating expenses	36,143	23,791
Operating loss	(28,643)	(23,791)
Other income, net	207	885
Net loss	(28,436)	(22,906)
Net loss per share — basic and diluted	$ (0.29)	$ (0.31)
Weighted-average common shares outstanding - basic and diluted	97,750	73,797

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