Aerovate Therapeutics Announces Third Quarter Financial Results and Business Highlights

November 13, 2023

WALTHAM, Mass., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Aerovate Therapeutics, Inc. (Nasdaq: AVTE), a clinical stage biopharmaceutical company focused on developing drugs that meaningfully improve the lives of patients with rare cardiopulmonary disease, today announced financial results for the quarter ended September 30, 2023, and recent business highlights.

Recent Highlights

IMPAHCT Global Phase 2b/Phase 3 Clinical Trial on Track for Topline Data in the Second Quarter of 2024. IMPAHCT (Inhaled iMatinib Pulmonary Arterial Hypertension Clinical Trial) is a Phase 2b/Phase 3 trial of AV-101, our self-administered, twice daily dry powder inhaled formulation of the antiproliferative drug imatinib for the treatment of pulmonary arterial hypertension (PAH), a devastating disease impacting approximately 70,000 people in the United States and Europe. We now have more than 125 clinical sites activated in over 20 countries and continue to enroll patients to participate in the Phase 2b portion of IMPAHCT. We expect to report topline data from the Phase 2b portion of IMPAHCT in the second quarter of 2024.

Expanded Intellectual Property Portfolio. We continued expanding our intellectual property portfolio in 2023 with the issuance of one patent. Since June 30, 2023, the United States Patent and Trademark Office issued Patent 11,806,349 to us bringing total issued patents to five. We continue prosecuting multiple additional applications to cover our product globally.

Third Quarter 2023 Financial Results

Financial guidance: We expect that our cash, cash equivalents and available-for-sale securities will be sufficient to fund our operations into 2026, based on our current operating plan.

Cash, cash equivalents and available-for sale securities totaled $135.2 million as of September 30, 2023, compared to $129.2 million as of December 31, 2022. The increase was primarily driven by net proceeds from our “at-the-market” program, offset by operational costs for the nine-month period ended September 30, 2023.

R&D expenses: Research and development (R&D) expenses for the third quarter ended September 30, 2023 were $16.9 million as compared to $10.8 million for the third quarter ended September 30, 2022. The increase in R&D expenses was due primarily to higher headcount-related costs, contract manufacturing costs, and clinical trial costs in 2023 as compared to 2022.

G&A expenses: General and administrative (G&A) expenses for the third quarter ended September 30, 2023 were $4.5 million as compared to $3.4 million for the third quarter ended September 30, 2022. The increase in G&A expenses was due primarily to higher headcount-related costs in 2023 as compared to 2022.

Net loss: Net loss for the third quarter ended September 30, 2023 was $19.6 million as compared to $13.6 million for the third quarter ended September 30, 2022. Net loss included stock-based compensation expense of $3.2 million and $1.5 million for the three months ended September 30, 2023 and 2022, respectively.

About AV-101

AV-101 is an investigational, proprietary dry powder inhaled formulation of the antiproliferative drug imatinib. Developed specifically for pulmonary arterial hypertension (PAH), AV-101 targets cellular hyperproliferation and resistance to apoptosis, driven by improper signaling in cells of the distal pulmonary arteries. By targeting the proliferation and accumulation of cells in the arteries of the lungs, we believe AV-101 has the potential to provide meaningful improvements for patients beyond the capabilities of currently approved therapies. AV-101 is designed for delivery by an easy-to-use dry powder inhaler, directly into the lungs to maximize potential clinical benefit and limit systemic adverse effects. Phase 1 results published in *ERJ Open Research* showed that AV-101 delivered by dry powder inhalation was generally well-tolerated by healthy adult volunteers with no serious adverse events reported. Aerovate is enrolling patients in the IMPAHCT Phase 2b/Phase 3 clinical trial to evaluate the safety and efficacy of AV-101 in adults with PAH.

About the IMPAHCT Trial

IMPAHCT (Inhaled iMatinib Pulmonary Arterial Hypertension Clinical Trial) is a multi-national, placebo-controlled Phase 2b/Phase 3 trial in adults with PAH that will continuously enroll patients as the study progresses from Phase 2b to Phase 3. The Phase 2b portion of the trial will evaluate three doses of AV-101 over 24 weeks, compared to placebo, to identify an optimal dose based on the primary endpoint, change in pulmonary vascular resistance (PVR), and safety, tolerability, and other clinical measures. The Phase 3 portion of the trial will compare patients taking the optimal dose of AV-101, selected from the Phase 2b data, to placebo. The primary endpoint of the Phase 3 portion of the trial will be change in six-minute walk distance (6MWD) over 24 weeks versus placebo. More information about this trial is available at https://clinicaltrials.gov/ct2/show/NCT05036135.

About Aerovate Therapeutics, Inc.

Aerovate is a clinical-stage biopharmaceutical company focused on developing drugs that meaningfully improve the lives of patients with rare cardiopulmonary disease. Aerovate’s initial focus is on advancing AV-101, its proprietary dry powder inhaled formulation of the drug imatinib for the treatment of patients with PAH. Learn more at aerovatetx.com or follow the company on Twitter and LinkedIn.

Available Information

Aerovate announces material information to the public about the Company, its products and services, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts, the investor relations section of the Company website at ir.aerovatetx.com, and the Company's Twitter account @AerovateTx in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "future," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," seek," "strategy," "should," "target," "will," "would" and similar expressions regarding future periods. These forward-looking statements include, but are not limited to, statements regarding the therapeutic potential and clinical benefits of AV-101; our expectations regarding patient enrollment for our Phase 2b/Phase 3 trial; our anticipated timing for the release of topline data from the Phase 2b portion of our clinical trial; our belief that we will have capital to fund Aerovate into 2026; our business plans and objectives for AV-101, including expectations regarding timing and success of our Phase 2b/Phase 3 clinical trial.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the therapeutic potential and clinical benefits of AV-101; the timing associated with the identification and activation of clinical sites, patient enrollment, initiation, delivery of drug supply and continuation of our Phase 2b/Phase 3 trial of AV-101 in PAH patients; the impact of public health crises on our business, clinical trials, operations and goals; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in our most recent Annual Report on Form 10-K filed with the SEC and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Aerovate Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands)

	September 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and available-for-sale securities	$ 135,199	$ 129,220
Other assets	5,677	6,081
Total assets	140,876	135,301
Liabilities and Stockholders' Equity		
Accounts payable and accrued and other current liabilities	$ 14,274	$ 7,397
Other liabilities	879	1,161
Total liabilities	15,153	8,558
Total stockholders' equity	125,723	126,743
Total liabilities and stockholders' equity	$ 140,876	$ 135,301

Aerovate Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 16,884	$ 10,783	$ 46,406	$ 26,401
General and administrative	4,484	3,369	12,937	10,984
Total operating expenses (1)	21,368	14,152	59,343	37,385
Loss from operations	(21,368)	(14,152)	(59,343)	(37,385)
Total other income	1,805	564	4,235	896
Net loss	$ (19,563)	$ (13,588)	$ (55,108)	$ (36,489)

Net loss per share, basic and diluted	$ (0.71)	$ (0.56)	$ (2.13)	$ (1.49)
Weighted-average shares of common stock outstanding, basic and diluted	27,640,542	24,454,786	25,872,118	24,425,390

(1) Non-cash charges were $3.2 million and $8.7 million, and $1.5 million and $3.7 million for the three and nine months ended September 30, 2023 and 2022, respectively.

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