Aerovate Therapeutics Announces Second Quarter 2022 Financial Results

August 15, 2022

WALTHAM, Mass., Aug. 15, 2022 (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 June 30, 2022, and recent business highlights.

Recent Highlights

- Progress Continued for IMPAHCT Global Phase 2b/Phase 3 Clinical Trial
- Presented Phase 1 Results at ATS
- Expanded Intellectual Property Portfolio
- Management Team Strengthened

Progress Continued for IMPAHCT Global Phase 2b/Phase 3 Clinical Trial. IMPAHCT (Inhaled iMatinib Pulmonary Arterial Hypertension Clinical Trial) is a Phase 2b/Phase 3 trial of AV-101, our dry powder inhaled formulation of the anti-proliferative drug imatinib for the treatment of pulmonary arterial hypertension (PAH), a devastating disease impacting approximately 70,000 people in the United States and Europe. Since the quarter ended March 31, 2022, progress continued for our IMPAHCT trial with additional clinical site activations and patients enrolled. We expect to report topline data from the Phase 2b portion of the trial in the fourth quarter of 2023 or first quarter of 2024.

Presented Phase 1 Results at ATS. The Phase 1 AV-101 results, presented at the American Thoracic Society (ATS) International Conference in May, showed AV-101 delivered by dry powder inhalation to healthy adult volunteers was generally well-tolerated at doses from 10mg twice daily to 90mg twice daily with no serious treatment-emergent adverse events reported and significantly reduced systemic exposure compared with 400mg oral imatinib, the dose used in Novartis' IMPRES trial in PAH.

Expanded Intellectual Property Portfolio. We continued expanding our intellectual property portfolio. The United States Patent and Trademark Office has issued Patents 11,298,355 and 11,229,650 to Aerovate and we have received notices of allowance for two other patents. We continue prosecuting multiple additional applications to cover our product globally.

Management Team Strengthened. Stephen Yu joined our leadership team as Senior Vice President, Quality. Mr. Yu has more than 20 years of regulatory compliance and quality management systems experience in the pharmaceutical and life science industry from early phase development to commercial operations. He previously led Quality teams at Allena Pharmaceuticals Inc., Lyndra Therapeutics, Inc., and Immunogen, Inc.

Second Quarter 2022 Financial Results

Financial guidance: We expect that our cash, cash equivalents and short-term investments will be sufficient to fund our operations into the second half of 2025, based on our current operating plan.

Cash, cash equivalents and short-term investments totaled $152.0 million as of June 30, 2022, compared to $167.4 million as of December 31, 2021. The decrease was primarily driven by operational costs for the six-month period ended June 30, 2022.

R&D expenses: Research and development (R&D) expenses for the second quarter ended June 30, 2022 were $8.4 million as compared to $4.3 million for the second quarter ended June 30, 2021. The increase in R&D expenses was due primarily to clinical trial costs, manufacturing costs, and increased headcount-related costs, offset by lower preclinical costs in 2022 as compared to 2021.

G&A expenses: General and administrative (G&A) expenses for the second quarter ended June 30, 2022 were $3.9 million as compared to $1.4 million for the second quarter ended June 30, 2021. The increase in G&A expenses was due primarily to operating as a public company inclusive of insurance costs, legal fees, accounting fees and consulting expenses as well as increased headcount-related costs in 2022 as compared to 2021.

Net loss: Net loss for the second quarter ended June 30, 2022 was $12.0 million as compared to $5.8 million for the second quarter ended June 30, 2021. Net loss included stock-based compensation expense of $1.2 million and $0.3 million for the second quarter ended June 30, 2022 and June 30, 2021, respectively.

About AV-101

AV-101 is an investigational, proprietary dry powder inhaled formulation of the anti-proliferative drug imatinib. Developed specifically for pulmonary arterial hypertension (PAH), 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 presented at the 2022 American Thoracic Society (ATS) annual meeting 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 different doses of AV-101 in adults with PAH.

A copy of the ATS conference Phase 1 data poster presentation is available in the "Events & Presentations" section of Aerovate's website at ir.AerovateTx.com/events-presentations.

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 selected in Phase 2b of AV-101 with 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," "potential," 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 clinical site activation and patient enrollment for our Phase 2b/Phase 3 trial; our anticipated timing for the completion of enrollment and release of topline data from the Phase 2b portion of our clinical trial; our belief that we will have capital to fund Aerovate into the second half of 2025; our business plans and objectives for AV-101, including expectations regarding timing and success of our Phase 2b/Phase 3 clinical trial, potential regulatory submissions and approvals for AV-101; and our growth and goals as a company.

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 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 the COVID-19 pandemic 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 151,988	$ 167,375
Prepaid expenses and other current assets	1,461	6,958
Total current assets	153,449	174,333
Property and equipment, net	316	186
Operating lease right-of-use asset	1,188	542
Other long-term assets	731	302
Total assets	$ 155,684	$ 175,363
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued and other current liabilities	$ 3,409	$ 2,358
Operating lease liability	347	192
Total current liabilities	3,756	2,550
Operating lease liabilities, net of current portion	862	382
Other liabilities	13	13
Total liabilities	4,631	2,945

Commitments and contingencies:		
Stockholders' equity:		
Total stockholders' equity	151,053	172,418
Total liabilities and stockholders' equity	$ 155,684	$ 175,363

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 8,363	$ 4,327	$ 15,618	$ 6,523
General and administrative	3,852	1,447	7,615	2,031
Total operating expenses	12,215	5,774	23,233	8,554
Loss from operations	(12,215)	(5,774)	(23,233)	(8,554)
Total other income (expense)	224	(1)	332	(2)
Net loss and comprehensive loss	$ (11,991)	$ (5,775)	$ (22,901)	$ (8,556)
Net loss per share, basic and diluted	$ (0.49)	$ (23.80)	$ (0.94)	$ (35.29)
Weighted-average shares of common stock outstanding, basic and diluted	24,410,503	243,076	24,410,448	243,076

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