UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): March 30, 2022

AEROVATE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40544**	**83-1377888**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Aerovate Therapeutics, Inc.
930 Winter Street, Suite M-500, Massachusetts 02451
(Address of principal executive offices, including zip code)

(617) 443-2400
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	AVTE	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition

On March 30, 2022, Aerovate Therapeutics, Inc. announced its financial results for the fourth quarter and year ended December 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Aerovate Therapeutics, Inc. on March 30, 2022, furnished herewith.
104	Cover Page Interactive Data File

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aerovate Therapeutics, Inc.

Date: March 30, 2022

By: */s/ George A. Eldridge*
George A. Eldridge
Chief Financial Officer

Exhibit 99.1

Aerovate Therapeutics Announces
Full-Year 2021 Financial Results

- Initiated IMPAHCT, a global Phase 2b/Phase 3 trial of AV-101 for pulmonary arterial hypertension (PAH) in December 2021
- Received FDA guidance in April 2021 that our Phase 2b/Phase 3 trial could support an NDA submission based on change in six minute walk distance as the primary endpoint for the Phase 3 portion of the trial
- Granted orphan drug designation by the FDA in December 2020 and EMA for AV-101 for the treatment of PAH in June 2021
- Raised $126.9 million in net proceeds from IPO in July 2021

WALTHAM, Mass. – March 30, 2022 – 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 year ended December 31, 2021, and recent business highlights.

"We've built a team with deep experience in pulmonary arterial hypertension and pulmonary drug development," said Timothy Noyes, chief executive officer of Aerovate. "We were excited to initiate our global Phase 2b/Phase 3 trial of AV-101 in PAH last December and are well-positioned to execute our plan. Aerovate was founded to develop AV-101 for PAH and our team is excited to work closely with clinicians, KOLs, clinical sites, and patient groups."

2021 Highlights

Progress Continues 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 PAH, a devastating disease impacting approximately 70,000 people in the United States and Europe. Along with initiating the trial, drug supply has been manufactured and we have been shipping it to clinical sites. We anticipate including experienced PAH centers from more than 20 countries in our Phase 2b/Phase 3 trial. We have obtained orphan drug designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for AV-101 for the treatment of PAH in the United States and the European Union.

FDA Guidance Supports 6MWD as Primary Endpoint for Phase 3. At our April 14, 2021 End-of-Phase 1 meeting with the FDA, we received regulatory guidance that our Phase 2b/Phase 3 trial with AV-101 for the treatment of PAH, if successful, could support a New Drug Application (NDA) submission using the change in six minute walk distance (6MWD) compared to placebo as the primary endpoint in the Phase 3 portion of the trial.

Received Scientific Advice from EMA Regarding Requirements for Approval. In the first half of 2021, we completed the formal process of seeking scientific advice and regulatory guidance from the EMA regarding its requirements for approval. We believe that, if successful, our existing clinical program could support a marketing authorization application submission for regulatory approval in Europe.

Raised $126.9 Million in Net Proceeds from IPO. On July 2, 2021, we closed our initial public offering (IPO) raising gross proceeds of $139.8 million, which included full exercise of the underwriters' option to purchase additional shares of common stock, at a public offering price of $14.00 per share. We received net proceeds of approximately $126.9 million after deducting underwriting discounts and commissions and other offering expenses paid by us.

2021 Financial Results

Cash, cash equivalents and short-term investments totaled $167.4 million as of December 31, 2021, compared to $180.9 million as of September 30, 2021. The decrease was primarily driven by operational costs for the three-month period ended December 31, 2021.

R&D expenses: Research and development (R&D) expenses for the year ended December 31, 2021 were $15.0 million as compared to $7.9 million for the year ended December 31, 2020. The increase in R&D expenses was due primarily to clinical trial costs, manufacturing costs, and increased headcount-related costs in 2021 as compared to 2020.

G&A expenses: General and administrative (G&A) expenses for the year ended December 31, 2021 were $8.0 million as compared to $0.9 million for the year ended December 31, 2020. The increase in G&A expenses was due primarily to increased payroll costs, insurance costs, legal fees, stock-based compensation, accounting fees and consulting expenses in 2021 as compared to 2020.

Net loss: Net loss for the year ended December 31, 2021 was $23.0 million as compared to $9.6 million for the year ended December 31, 2020. Net loss included stock-based compensation expense of $2.0 million and $0.1 million for the years ended December 31, 2021 and December 31, 2020, respectively.

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

About AV-101

AV-101 is a proprietary dry powder inhaled formulation of the anti-proliferative drug imatinib. Dosed 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. In a Phase 1 clinical trial, AV-101 was generally well-tolerated by healthy adult volunteers with no serious adverse events associated with AV-101.

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 compared to placebo to identify an optimal dose based on the primary endpoint, change in pulmonary vascular resistance (PVR) over 24 weeks versus placebo, 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 dry powder inhaled formulation of the drug imatinib for the treatment of PAH.

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 of AV-101; our expectations of identifying clinical site locations and recruitment of patients for our Phase 2b/Phase 3 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, the therapeutic potential and clinical benefits of AV-101 and 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, and the timing associated with the identification of clinical sites, patient recruitment, 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, and other risks identified in our filings with the Securities and Exchange Commission ("SEC"), including our Registration Statement on Form S-1, 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
(in thousands)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 167,375	$ 4,573
Prepaid expenses and other current assets	6,958	103
Total current assets	174,333	4,676
Property and equipment, net	186	39
Operating lease right-of-use asset	542	-
Other long-term assets	302	-
Total assets	$ 175,363	$ 4,715
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued and other current liabilities	$ 2,358	$ 1,774
Operating lease liability	192	-
Total current liabilities	2,550	1,774
Operating lease liabilities, net of current portion	382	-
Other liabilities	13	-
Total liabilities	2,945	1,774
Commitments and contingencies:		
Series A and Series Seed redeemable convertible preferred stock	-	16,285
Stockholders' equity (deficit):		
Total stockholders' equity (deficit)	172,418	(13,344)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 175,363	$ 4,715

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

	Years Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 14,987	$ 7,940
General and administrative	8,035	949
Total operating expenses	23,022	8,889
Loss from operations	(23,022)	(8,889)
Other income (expense)	62	(722)
Net loss before income taxes	(22,960)	(9,611)
Provision for income taxes	3	-
Net loss	$ (22,963)	$ (9,611)
Unrealized loss on securities	(59)	-
Comprehensive loss	$ (23,022)	$ (9,611)
Net loss per share, basic and diluted	$ (1.87)	$ (40.31)
Weighted-average shares of common stock outstanding, basic and diluted	12,293,629	242,232

Media Contact
info@aerovatetx.com

Investor Contact
ir@aerovatetx.com

# # #