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): May 13, 2024

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, Waltham, 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 May 13, 2024, Aerovate Therapeutics, Inc. announced its first quarter 2024 financial results and business highlights for the period ended March 31, 2024. 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 May 13, 2024, 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: May 13, 2024

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

Aerovate Therapeutics Announces First Quarter Financial Results and Business Highlights

- Topline data expected in June 2024 from Phase 2b portion of the IMPAHCT global Phase 2b/Phase 3 clinical trial of AV-101 for pulmonary arterial hypertension (PAH)
- Enrollment continues into the Phase 3 portion of the IMPAHCT trial of AV-101
- Poster to be presented with baseline characteristics of the Phase 2b portion of the IMPAHCT trial at the ATS 2024 Conference on May 21
- Cash runway into 2026, based on our current operating plan

WALTHAM, Mass. – May 13, 2024 – 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 March 31, 2024, and recent business highlights.

Recent Highlights

Topline Data Expected in June 2024 from the Phase 2b Portion of the IMPAHCT Global Phase 2b/Phase 3 Clinical Trial. IMPAHCT (Inhaled iMatinib Pulmonary Arterial Hypertension Clinical Trial) is a global 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 PAH. PAH is a devastating disease impacting approximately 70,000 people in the United States and Europe. We continue to expect to provide topline data in June 2024.

Enrollment Continues in the Phase 3 Portion of IMPAHCT. Due to the seamless trial design, we were able to enroll our first patient in the Phase 3 portion of the IMPAHCT trial in November 2023, simultaneously with completing enrollment in our Phase 2b portion of the IMPAHCT trial. Enrollment continues with over 120 clinical sites in over 20 countries participating in the Phase 3 portion of the trial. The timing for topline Phase 3 data and the size of the Phase 3 portion of the trial will be determined based upon the results from the Phase 2b portion of the trial.

Poster To Be Presented With Baseline Characteristics of the Phase 2b Portion of IMPAHCT at the ATS 2024 International Conference in May. At a poster presentation at the American Thoracic Society (ATS) 2024 International Conference on May 21, 2024 in San Diego, CA, we will present the baseline characteristics from patients enrolled in the dose-ranging Phase 2b portion of IMPAHCT.

Sold $24 Million in April under the ATM Program. In April 2024, we raised net proceeds of approximately $23.6 million from a single purchaser through Aerovate's existing "at-the-market" (ATM) program.

First Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments totaled $99.3 million as of March 31, 2024 (before factoring in the $23.6 million of net proceeds raised in April under the ATM program), compared to $122.4 million as of December 31, 2023. The decrease was primarily driven by operational costs for the three-month period ended March 31, 2024.

R&D expenses: Research and development (R&D) expenses for the quarter ended March 31, 2024 were $20.1 million as compared to $13.5 million for the quarter ended March 31, 2023. The increase in R&D expenses was due primarily to clinical trial costs, manufacturing costs, and increased headcount-related costs in 2024 as compared to 2023.

G&A expenses: General and administrative (G&A) expenses for the quarter ended March 31, 2024 were $4.5 million as compared to $4.2 million for the quarter ended March 31, 2023. The increase in G&A expenses was due primarily to increased headcount-related costs, travel and other miscellaneous costs in 2024 as compared to 2023.

Net loss: Net loss for the quarter ended March 31, 2024 was $23.2 million as compared to $16.5 million for the quarter ended March 31, 2023. Net loss included stock-based compensation expense of $4.2 million and $2.4 million for the quarters ended March 31, 2024 and March 31, 2023, respectively.

Financial guidance: We expect that our cash, cash equivalents and short-term investments will be sufficient to fund our operations into 2026, based on our current operating plan.

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 has completed enrollment in the Phase 2b portion of the IMPAHCT clinical trial and is currently enrolling patients in the Phase 3 portion 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 continuously enrolled patients 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/NCT05036135https://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 X (formerly known as 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 X (formerly known as 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 in PAH; our anticipated timing for the release of topline data from the Phase 2b portion of the IMPAHCT trial; our expectations regarding continuing patient enrollment for the Phase 3 portion of the IMPAHCT 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 IMPAHCT; 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 and clinical benefits of AV-101; the timing associated with patient enrollment, initiation, delivery of drug supply and continuation of our Phase 2b/Phase 3 trial of AV-101 in PAH patients; 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)

	March 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term investments	$ 99,334	$ 122,439
Other assets	7,487	4,979
Total assets	106,821	127,418
Liabilities and Stockholders' Equity		
Accounts payable and accrued and other current liabilities	$ 15,073	$ 17,217
Other liabilities	844	745
Total liabilities	15,917	17,962
Total stockholders' equity	90,904	109,456
Total liabilities and stockholders' equity	$ 106,821	$ 127,418

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 20,080	$ 13,488
General and administrative	4,538	4,151
Total operating expenses (1)	24,618	17,639
Loss from operations	(24,618)	(17,639)
Total other income	1,432	1,119
Net loss	$ (23,186)	$ (16,520)
Net loss per share, basic and diluted	$ (0.83)	$ (0.67)
Weighted-average shares of common stock outstanding, basic and diluted	27,795,827	24,777,847

(1) Non-cash charges were $4.2 million and $2.4 million for the three months ended March 31, 2024 and 2023, respectively.

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