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): June 17, 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 7.01 Regulation FD Disclosure

On June 17, 2024, Aerovate Therapeutics, Inc. ("Aerovate" or the "Company") issued a press release titled "Aerovate Therapeutics Announces 24-Week Topline Results from the Phase 2b Portion of IMPAHCT Study Evaluating AV-101 for the Treatment of Pulmonary Arterial Hypertension." A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On June 17, 2024, the Company announced topline results from the Phase 2b portion of the Phase 2b/Phase 3 Inhaled Imatinib Pulmonary Arterial Hypertension Clinical Trial ("IMPAHCT"). Results showed that, while AV-101 was well tolerated across all dose groups, the study did not meet its primary endpoint for improvement in pulmonary arterial hypertension ("PVR") compared to placebo for any of the studied doses or show meaningful improvements in the secondary endpoint of change in six minute walk distance ("6MWD").

Primary Endpoint – ITT analysis of PVR *(dynes*sec/cm^5)*

Dose	**Least-squares mean difference as compared with placebo (95% CI)**	**P value**
10mg BID (N=50)	42.8 *(-80.57 to 166.09)*	0.4968
35mg BID (N=49)	-5.5 *(-129.16 to 118.18)*	0.9306
70mg BID (N=51)	-57.0 *(-181.14 to 67.20)*	0.3685

Secondary Endpoint – ITT analysis of 6MWD (meters)

Dose	**Least-squares mean difference as compared with placebo (95% CI)**
10mg BID (N=50)	-11.7 (-34.75 to 11.26)
35mg BID (N=49)	-4.2 (-27.74 to 19.37)
70mg BID (N=51)	+1.3 (-22.09 to 24.60)

The Company has also reviewed data from several additional secondary endpoints of the Phase 2b portion of IMPAHCT, which also failed to show meaningful improvements. Based upon these results, Aerovate, in agreement with the independent study advisory committee, is halting enrollment and shutting down the Phase 3 portion of IMPAHCT as well as the long-term extension study. Aerovate plans to release full data from the Phase 2b portion of IMPAHCT at a later date, the timing of which is to be determined.

As of June 15, 2024, Aerovate has approximately $100 million of cash, cash equivalents and short-term investments.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	**Description**
99.1	Press release issued by Aerovate Therapeutics, Inc. on June 17, 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: June 17, 2024

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

Exhibit 99.1

Aerovate Therapeutics Announces 24-Week Topline Results from the Phase 2b Portion of IMPAHCT Evaluating AV-101 for the Treatment of Pulmonary Arterial Hypertension

AV-101 did not meet the primary endpoint of change in pulmonary vascular resistance (PVR) for any of the studied doses

WALTHAM, Mass., June 17, 2024 -- Aerovate Therapeutics, Inc. (Nasdaq: AVTE) today announced topline results from the Phase 2b portion of the **I**nhaled i**M**atinib **P**ulmonary **A**rterial **H**ypertension **C**linical **T**rial (IMPAHCT), a Phase 2b/Phase 3, randomized, double-blind, placebo-controlled, multi-national trial of AV-101, a novel dry powder inhaled formulation of imatinib, in adults with pulmonary arterial hypertension (PAH).

The objective of the Phase 2b portion of IMPAHCT was to assess the efficacy, safety and tolerability of three different doses of AV-101 compared to placebo. The primary endpoint for the Phase 2b portion of IMPAHCT is change in PVR compared with placebo. Results showed that, while AV-101 was well tolerated across all dose groups, the study did not meet its primary endpoint for improvement in PVR compared to placebo for any of the studied doses or show meaningful improvements in the secondary endpoint of change in six minute walk distance (6MWD).

Primary Endpoint – ITT analysis of PVR *(dynes*sec/cm^5)*

Dose	**Least-squares mean difference as compared with placebo (95% CI)**	**P value**
10mg BID (N=50)	*42.8 (-80.57 to 166.09)*	*0.4968*
35mg BID (N=49)	*-5.5 (-129.16 to 118.18)*	*0.9306*
70mg BID (N=51)	*-57.0 (-181.14 to 67.20)*	*0.3685*

Secondary Endpoint – ITT analysis of 6MWD (*meters*)

Dose	**Least-squares mean difference as compared with placebo (95% CI)**
10mg BID (N=50)	-11.7 (-34.75 to 11.26)
35mg BID (N=49)	-4.2 (-27.74 to 19.37)
70mg BID (N=51)	+1.3 (-22.09 to 24.60)

The Company has also reviewed data from several additional secondary endpoints of the Phase 2b portion of IMPAHCT, which also failed to show meaningful improvements. Based upon these results, Aerovate, in agreement with the independent study advisory committee, is halting enrollment and shutting down the Phase 3 portion of IMPAHCT as well as the long-term extension study.

"The results of the Phase 2b portion of IMPAHCT were unexpected and disappointing. Our immediate focus is on transparently sharing these findings with investigators, patients and the PAH community. In the coming weeks, we will engage closely with the IMPAHCT study advisory committee and the PAH community to thoroughly discuss these data and their implications," said Tim Noyes, Chief Executive Officer of Aerovate. "We extend our heartfelt gratitude to all trial participants, investigators, and site teams for their dedication to advancing therapeutic options for the treatment of pulmonary arterial hypertension."

Aerovate plans to release full data from the Phase 2b portion of IMPAHCT at a later date, the timing of which is to be determined.

As of June 15, 2024, Aerovate has approximately $100 million of cash, cash equivalents and short-term investments.

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. 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.

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 evaluated 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. 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 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," 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 Phase 2b/Phase 3 IMPAHCT, including the future release of full clinical data and the Company's plan to halt the Phase 3 portion of the IMPAHCT 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-Q 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.

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