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): November 20, 2023

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 November 20, 2023, Aerovate Therapeutics, Inc. (the "Company") issued a press release titled "Aerovate Therapeutics Announces Simultaneous Completion of Enrollment in Phase 2b Portion and Enrollment of First Patient into Phase 3 in the IMPAHCT Trial Evaluating AV-101 for 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 November 20, 2023, the Company announced the Phase 2b portion of the Inhaled Imatinib Pulmonary Arterial Hypertension Clinical Trial (IMPAHCT) Phase 2b/Phase 3 study evaluating AV-101, a novel dry powder inhaled formulation of imatinib for the treatment of pulmonary arterial hypertension (PAH), completed enrollment of 202 adult patients. In addition, the first patient has been enrolled in the Phase 3 portion of IMPAHCT. The Company expects to report topline data from the Phase 2b portion of the trial in June 2024. Currently, more than 120 sites are open and actively recruiting patients in the Phase 3 portion of the trial.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release of Aerovate Therapeutics, Inc., dated November 20, 2023
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: November 20, 2023

By: */s/ Timothy P. Noyes*
Timothy P Noyes
Chief Executive Officer

Aerovate Therapeutics Announces Simultaneous Completion of Enrollment in Phase 2b Portion and Enrollment of First Patient into Phase 3 in the IMPAHCT Trial Evaluating AV-101 for the Treatment of Pulmonary Arterial Hypertension

Topline Phase 2b data expected in June 2024

More than 120 sites around the world actively recruiting in the Phase 3 portion of the IMPAHCT trial

WALTHAM, Mass. – November 20, 2023 – 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 the Phase 2b portion of the **I**nhaled I**m**atinib **P**ulmonary **A**rterial **H**ypertension **C**linical **T**rial (IMPAHCT) Phase 2b/Phase 3 study evaluating AV-101, a novel dry powder inhaled formulation of imatinib for the treatment of pulmonary arterial hypertension (PAH), has completed enrollment at 202 adult patients. Aerovate expects to report topline data from the Phase 2b portion of the trial in June 2024. In addition, the first patient has been enrolled in the Phase 3 portion of IMPAHCT.

“The completion of enrollment in the Phase 2b portion of the trial marks an exciting milestone for Aerovate and for people living with PAH,” said Tim Noyes, Chief Executive Officer at Aerovate Therapeutics. “Because of our innovative adaptive Phase 2b/Phase 3 trial design for IMPAHCT, we were also able to rapidly enroll our first patient in the Phase 3 portion of the study evaluating our novel investigational antiproliferative drug candidate, AV-101, for the treatment of PAH. I am extremely grateful for the commitment of our clinical investigators and their patients, and proud of the Aerovate team’s dedication and ongoing execution of the trial, as this furthers our goal of developing meaningful therapeutic options for PAH patients as quickly as possible.”

IMPAHCT is a Phase 2b/Phase 3, randomized, double-blind, placebo-controlled multi-national trial evaluating the safety, efficacy, tolerability, pharmacokinetics (PK) and pharmacodynamics of AV-101 in adults with PAH. The IMPAHCT trial was structured with a seamless adaptive Phase 2b/Phase 3 design to allow for an efficient development timeline, thus enabling the immediate enrollment of patients in the Phase 3 portion of the study upon the completion of enrollment in the Phase 2b portion. Currently, more than 120 sites are open and actively recruiting patients in the Phase 3 portion of the trial.

The Phase 2b primary endpoint of IMPAHCT is the placebo corrected change from baseline in pulmonary vascular resistance (PVR). Following the results of the Phase 2b portion of the study, an optimal dose will be selected and all subsequent patients enrolled in IMPAHCT will be randomized to either placebo or the optimal dose. The Phase 3 primary endpoint will be the placebo corrected change in 6-minute walk distance (6MWD) after 24 weeks of treatment with the optimal dose.

AV-101, an investigational, proprietary dry powder inhaled formulation of imatinib, is being developed by Aerovate for the treatment of PAH, a rare, progressive disease which involves abnormal cellular proliferation and resistance to apoptosis in the pulmonary vasculature. AV-101 has been formulated for self-administration in which patients will perform two inhalations twice daily with a discreet, pocket-sized device designed for easy use.

About PAH
PAH is a rare, progressive orphan disease with unmet medical need that affects approximately 70,000 people in the United States and Europe. PAH can cause strain on the heart, leading to limitation of physical activity, heart failure and reduced life expectancy.

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/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 therapeutic potential and clinical benefits of AV-101; our expectations regarding clinical sites and continuing patient enrollment for the Phase 3 portion of our Phase 2b/Phase 3 trial; our anticipated timing for the release of topline data from the Phase 2b portion of our clinical trial; and 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.

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.

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