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): December 15, 2021

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)

Not Applicable
(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 December 15, 2021, Aerovate Therapeutics, Inc. announced the initiation of the IMPAHCT Phase 2b/Phase 3 trial of AV-101 in 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 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 December 15, 2021, 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: December 15, 2021

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

Exhibit 99.1

Aerovate Therapeutics Announces Initiation of IMPAHCT Phase 2b/Phase 3 Trial of AV-101 In Pulmonary Arterial Hypertension

WALTHAM, Mass. – December 15, 2021 – Aerovate Therapeutics, Inc. (Nasdaq: AVTE), a clinical-stage biopharmaceutical company focused on developing drugs that meaningfully improve the lives of patients with rare cardiopulmonary diseases, today announced the initiation of its **I**nhaled I**m**atinib **P**ulmonary **A**rterial **H**ypertension **C**linical **T**rial (IMPAHCT) Phase 2b/Phase 3 trial to evaluate the safety and efficacy of AV-101 (dry powder inhaled imatinib) in adult patients with Pulmonary Arterial Hypertension (PAH).

"There is a real need for new treatment options for PAH patients that work differently from our currently approved therapies," said Dr. Nicholas Hill, Chief, Pulmonary, Critical Care and Sleep Division, Tufts Medical Center and Chair of the IMPAHCT clinical advisory board. "Imatinib has shown promise as a therapy for PAH and if AV-101 can deliver improvements for patients with fewer of the systemic adverse events associated with oral imatinib in PAH, it could represent a real advancement for patients."

"We are excited and humbled to initiate this Phase 2b/Phase 3 trial of AV-101," said Tim Noyes, Chief Executive Officer at Aerovate. "Starting enrollment represents an important milestone for Aerovate Therapeutics and advances our goal of improving the lives of patients suffering from rare cardiovascular diseases."

Aerovate expects to report top-line results from the Phase 2b portion of IMPAHCT in mid-2023.

More information about this trial is available at
https://clinicaltrials.gov/ct2/show/NCT05036135.

About the IMPAHCT Trial

IMPAHCT is a multi-national, placebo-controlled Phase 2b/Phase 3 trial in adults with pulmonary arterial hypertension (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 6-minute walk distance (6MWD) over 24 weeks versus placebo.

About Pulmonary Arterial Hypertension (PAH)

Pulmonary arterial hypertension (PAH) is a rare, progressive disease characterized by cellular hyperproliferation of the pulmonary vasculature that affects approximately 70,000 people in the United States and Europe. The disease process involves remodeling, constriction and occlusion of the small pulmonary arteries resulting in elevated blood pressure in the pulmonary circulation. PAH can cause strain on the heart, leading to limitation of physical activity, heart failure and reduced life expectancy. Existing vasodilator drugs fail to treat the underlying cellular proliferation causing the disease.

About AV-101

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

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 diseases. 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 regarding patient enrollment for the Phase 2b portion of our Phase 2b/Phase 3 trial of AV-101 in PAH; our business plans and objectives for AV-101, including expectations regarding timing and success of the our Phase 2b/Phase 3 clinical trial, including the timing of top-line results, 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 patient recruitment, initiation and continuation of our Phase 2b/Phase 3 trial of AV-101 in PAH patients and timing of top-line results, 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.

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