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): August 14, 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 2.02 Results of Operations and Financial Condition

On August 14, 2023, Aerovate Therapeutics, Inc. announced its second quarter financial results and business highlights for the period ended June 30, 2023. 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 August 14, 2023, 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: August 14, 2023

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

Aerovate Therapeutics Announces Second Quarter Financial Results and Business Highlights

WALTHAM, Mass. – August 14, 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 financial results for the quarter ended June 30, 2023, and recent business highlights.

Recent Highlights

- Progress Continued for IMPAHCT Global Phase 2b/Phase 3 Clinical Trial
- Extended Cash Runway into 2026
- Presented Nonclinical Pharmacokinetic Data at ATS
- Expanded Board of Directors

Progress Continued on the 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 self-administered, twice daily dry powder inhaled formulation of the antiproliferative drug imatinib for the treatment of pulmonary arterial hypertension (PAH), a devastating disease impacting approximately 70,000 people in the United States and Europe. We now have more than 110 clinical sites activated in over 20 countries and continue to activate experienced clinical sites and enroll patients to participate in the Phase 2b portion and Phase 3 portion of IMPAHCT. We expect to report topline data from the Phase 2b portion of IMPAHCT in the second quarter of 2024.

Extended Cash Runway into 2026. We sold an aggregate of $45 million of our common stock under our existing "at-the-market" program (the ATM Program). With the net proceeds from such transaction, we expect to fund our operations into 2026, based on our current operating plan.

Nonclinical Pharmacokinetic Data Presented at ATS 2023 International Conference. We presented at the American Thoracic Society (ATS) 2023 International Conference in Washington, D.C. results in nonclinical species that (i) direct delivery of imatinib to the lungs demonstrated increased lung exposure compared with oral or IV dosing and (ii) the type of formulation impacted lung exposure with dry powder demonstrating greater lung exposure than suspension or solution and greater lung exposure vs oral or intravenous delivery.

Expanded Board of Directors. We appointed Habib Dable to our Board of Directors and our Compensation Committee. Mr. Dable is the former President and Chief Executive Officer of Acceleron Pharma Inc. (Acceleron) where he guided Acceleron to its first blockbuster launch in 2019 and eventual sale to Merck & Co. in 2021 for over $11 billion. Mr. Dable brings nearly three decades of experience working with emerging biotech and big pharma companies.

Second Quarter 2023 Financial Results

Financial guidance: We expect that our cash, cash equivalents and available-for-sale securities will be sufficient to fund our operations into 2026, based on our current operating plan.

Cash, cash equivalents and available-for sale securities totaled $150.1 million as of June 30, 2023, compared to $129.2 million as of December 31, 2022. The increase was primarily driven by net proceeds from our ATM Program, offset by operational costs for the six-month period ended June 30, 2023.

R&D expenses: Research and development (R&D) expenses for the second quarter ended June 30, 2023 were $16.0 million as compared to $8.4 million for the second quarter ended June 30, 2022. The increase in R&D expenses was due

primarily to higher headcount-related costs, contract manufacturing costs, and clinical trial costs in 2023 as compared to 2022.

G&A expenses: General and administrative (G&A) expenses for the second quarter ended June 30, 2023 were $4.3 million as compared to $3.9 million for the second quarter ended June 30, 2022. The increase in G&A expenses was due primarily to higher headcount-related costs in 2023 as compared to 2022.

Net loss: Net loss for the second quarter ended June 30, 2023 was $19.0 million as compared to $12.0 million for the second quarter ended June 30, 2022. Net loss included stock-based compensation expense of $3.0 million and $1.2 million for the second quarter ended June 30, 2023 and June 30, 2022, respectively.

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 is enrolling patients in the IMPAHCT Phase 2b/Phase 3 clinical trial 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 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 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 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 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 site activation and patient enrollment for our Phase 2b/Phase 3

trial; our anticipated timing for the release of topline data from the Phase 2b portion of our clinical 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 our Phase 2b/Phase 3 clinical trial, potential regulatory submissions and approvals for AV-101; the anticipated contributions of the members of our Board of Directors; 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 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, such as 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; 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)

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and available-for-sale securities	$ 150,096	$ 129,220
Other assets	5,659	6,081
Total assets	155,755	135,301
Liabilities and Stockholders' Equity		
Accounts payable and accrued and other current liabilities	$ 12,905	$ 7,397
Other liabilities	924	1,161
Total liabilities	13,829	8,558
Total stockholders' equity	141,926	126,743
Total liabilities and stockholders' equity	$ 155,755	$ 135,301

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 16,034	$ 8,363	$ 29,522	$ 15,618
General and administrative	4,302	3,852	8,453	7,615
Total operating expenses (1)	20,336	12,215	37,975	23,233
Loss from operations	(20,336)	(12,215)	(37,975)	(23,233)
Total other income	1,311	224	2,430	332
Net loss	$ (19,025)	$ (11,991)	$ (35,545)	$ (22,901)
Net loss per share, basic and diluted	$ (0.76)	$ (0.49)	$ (1.42)	$ (0.94)
Weighted-average shares of common stock outstanding, basic and diluted	25,166,505	24,410,503	24,973,250	24,410,448

(1) Non-cash charges were $3.0 million and $1.2 million for the second quarter ended June 30, 2023 and 2022, respectively.

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