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 16, 2022

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)

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 16, 2022, Aerovate Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2022. 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 16, 2022, 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 16, 2022

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

Exhibit 99.1

Aerovate Therapeutics Announces First Quarter 2022 Financial Results

WALTHAM, Mass. – May 16, 2022 – 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, 2022, and recent business highlights.

Recent Highlights

- Reiterating strong financial position funding operations into the second half of 2025
- Updating guidance and expect to report topline data from the Phase 2b portion of the IMPAHCT trial in the fourth quarter of 2023 or first quarter of 2024
- Strengthened and expanded management team by hiring Marco Verwijs as SVP, CMC and Susan Fischer as SVP, Development Operations

Update on 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 dry powder inhaled formulation of the anti-proliferative drug imatinib for the treatment of pulmonary arterial hypertension (PAH), a devastating disease impacting approximately 70,000 people in the United States and Europe. With IMPAHCT now active at multiple sites, investigators and key opinion leaders continue to express enthusiasm for our Phase 2b/Phase 3 trial. However, we are experiencing site initiation delays as a result of clinical trial site staff shortages and COVID-related short-term interruptions. Because of these delays, we expect to report topline data from the Phase 2b portion of the trial in the fourth quarter of 2023 or first quarter of 2024. We have obtained orphan drug designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for AV-101 for the treatment of PAH in the United States and the European Union.

Expanded Intellectual Property Portfolio. We continued expanding our intellectual property portfolio with the issuance of Patent 11,298,355 and two additional allowances from the United States Patent and Trademark Office.

Management Team Strengthened. We hired Marco Verwijs as SVP, CMC and Susan Fischer as SVP, Development Operations. Mr. Verwijs has over 15 years of product development and manufacturing experience. He has worked on multiple commercial products, leading them from clinical product development to New Drug Application filing and commercial launch. Ms. Fischer has over 20 years of clinical operations experience in both academic and pharmaceutical industry settings. She previously led clinical operation teams at Syndax Pharmaceuticals Inc., Acetylon Pharmaceuticals, Inc. and EMD Serono, Inc. that included global clinical trial sites.

First Quarter 2022 Financial Results

Financial guidance: We expect that our cash, cash equivalents and short-term investments will be sufficient to fund our operations into the second half of 2025, based on our current operating plan.

Cash, cash equivalents and short-term investments totaled $161.1 million as of March 31, 2022, compared to $167.4 million as of December 31, 2021. The decrease was primarily driven by operational costs for the three-month period ended March 31, 2022.

R&D expenses: Research and development (R&D) expenses for the first quarter ended March 31, 2022 were $7.3 million as compared to $2.2 million for the first quarter ended March 31, 2021. The increase in R&D expenses was due primarily to clinical trial costs, manufacturing costs, lower preclinical costs, and increased headcount-related costs in 2022 as compared to 2021.

G&A expenses: General and administrative (G&A) expenses for the first quarter ended March 31, 2022 were $3.8 million as compared to $0.6 million for the first quarter ended March 31, 2021. The increase in G&A expenses was due primarily to increased payroll costs, insurance costs, legal fees, stock-based compensation, accounting fees and consulting expenses in 2022 as compared to 2021.

Net loss: Net loss for the first quarter ended March 31, 2022 was $10.9 million as compared to $2.8 million for the first quarter ended March 31, 2021. Net loss included stock-based compensation expense of $1.0 million and $23,000 for the first quarter ended March 31, 2022 and March 31, 2021, respectively.

About AV-101

AV-101 is an investigational, proprietary dry powder inhaled formulation of the anti-proliferative drug imatinib. Developed specifically for pulmonary arterial hypertension (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. Aerovate is enrolling patients in the IMPAHCT Phase 2b/Phase 3 clinical trial to evaluate the safety and efficacy of different doses 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 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 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," "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; our expectations regarding clinical site activation and patient enrollment for our Phase 2b/Phase 3 trial; investigators and key opinion leaders' continued enthusiasm for our Phase 2b/Phase 3 trial; our anticipated timing for the completion of enrollment and release of topline data from the Phase 2b portion of our clinical trial; our belief that we will have capital to fund Aerovate into the second half of 2025; 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; 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; 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 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 161,072	$ 167,375
Prepaid expenses and other current assets	4,813	6,958
Total current assets	165,885	174,333
Property and equipment, net	288	186
Operating lease right-of-use asset	499	542
Other long-term assets	327	302
Total assets	$ 166,999	$ 175,363
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued and other current liabilities	$ 4,510	$ 2,358
Operating lease liability	193	192
Total current liabilities	4,703	2,550
Operating lease liabilities, net of current portion	335	382
Other liabilities	14	13
Total liabilities	5,052	2,945
Commitments and contingencies:		
Stockholders' equity:		
Total stockholders' equity	161,947	172,418
Total liabilities and stockholders' equity	$ 166,999	$ 175,363

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,	
	2022	**2021**
Operating expenses:		
Research and development	$ 7,255	$ 2,196
General and administrative	3,764	584
Total operating expenses	11,019	2,780
Loss from operations	(11,019)	(2,780)
Other income (expense)	109	(1)
Net loss before income taxes	(10,910)	(2,781)
Provision for income taxes	-	-
Net loss	$ (10,910)	$ (2,781)
Unrealized loss on available-for-sale investments	(585)	-
Comprehensive loss	$ (11,495)	$ (2,781)
Net loss per share, basic and diluted	$ (0.45)	$ (11.49)
Weighted-average shares of common stock outstanding, basic and diluted	24,410,393	243,076

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