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 16, 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.
200 Berkeley Street, Floor 18, Boston, Massachusetts 02116
(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 2.02 Results of Operations and Financial Condition

On August 16, 2021, Aerovate Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2021. 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 16, 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: August 16, 2021

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

Exhibit 99.1

Aerovate Therapeutics Announces Second Quarter 2021 Financial Results

WALTHAM, Mass. – August 16, 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 disease, today announced its financial results for the quarter ended June 30, 2021, and recent events.

"It has been an exciting quarter for Aerovate as we received scientific advice from the EMA, received regulatory guidance from the FDA at our end-of-Phase 1 meeting, and we expect to initiate enrollment this year in the Phase 2b portion of our Phase 2b/3 trial of AV-101 in PAH," said Timothy Noyes, chief executive officer of Aerovate. "We are also pleased with investor confidence in Aerovate to support our IPO and provide sufficient capital which we believe will fund Aerovate into the second half of 2025."

Recent Events

FDA Guidance Supports 6MWD as Primary Endpoint for Phase 3. At our April 14, 2021 end-of-Phase 1 meeting with the Food and Drug Administration (FDA), we received regulatory guidance that our Phase 2b/3 trial with AV-101 for the treatment of pulmonary arterial hypertension (PAH), if successful, could support a New Drug Application (NDA) submission using the change in six minute walk distance (6MWD) compared to placebo as the primary endpoint in the Phase 3 portion of the trial.

Received Scientific Advice from EMA Regarding Requirements for Approval. We completed the formal process of seeking scientific advice and regulatory guidance from the European Medicines Agency (EMA) regarding its requirements for approval. We believe that, if successful, our existing clinical program could support a marketing authorization application submission for regulatory approval in Europe.

Orphan Drug Designation Granted by FDA and EMA. We have obtained orphan drug designation from FDA for AV-101 for the treatment of PAH in the United States and received in May 2021 a positive opinion for orphan drug designation for AV-101 for the treatment of PAH from the EMA's Committee for Orphan Medicinal Products in the European Union.

Raised $127.0 Million in Net Proceeds from IPO. On July 2, 2021, we closed our initial public offering (IPO) raising gross proceeds of $139.8 million, which included full exercise of the underwriters' option to purchase additional shares of common stock, at a public offering price of $14.00 per share. We raised net proceeds of approximately $127.0 million after deducting underwriting discounts and commissions and other offering expenses payable by us.

Board of Directors and management team strengthened. We appointed to the Board, and to chair of the Audit Committee, Allison Dorval, who is chief financial officer at Voyager Therapeutics, Inc. and is a member of the Board of Puma Biotechnology, Inc. Ms. Dorval has over twenty years of corporate finance, accounting and operating experience, including 14 years of life sciences executive experience. In addition, Aerovate hired Timothy Pigot as senior vice president, commercial to oversee our pre-commercial activities. Mr. Pigot has over 25 years of industry experience working to launch and commercialize a range of products over multiple therapeutic areas. Mr. Pigot gained significant experience in PAH during his 12 years at Gilead Sciences, Inc. and 11 years at Pfizer, Inc. where his responsibilities included the launches of Revatio and Letairis for the treatment of PAH.

Second Quarter 2021 Financial Results

Cash and cash equivalents totaled $59.2 million as of June 30, 2021, compared to $4.6 million as of December 31, 2020. The increase was primarily driven by the issuance of Series A Redeemable Convertible Preferred Stock during the second quarter of 2021 for $55.5 million in gross proceeds offset by operational costs for the six-month period ending June 30, 2021. Pro forma cash and cash equivalents at June 30, 2021 totaled $186.2 million, when including $127.0 million in net proceeds from our IPO that closed on July 2, 2021.

R&D expenses: Research and development (R&D) expenses for the second quarter of 2021 were $4.3 million as compared to $1.5 million for the second quarter of 2020. The increase in R&D expenses was due primarily to increased clinical trial costs and manufacturing costs in the second quarter of 2021 as compared to the second quarter of 2020.

G&A expenses: General and administrative (G&A) expenses for the second quarter of 2021 were $1.4 million as compared to $0.2 million for the second quarter of 2020. The increase in G&A expenses was due primarily to increased legal fees, accounting fees and consulting expenses in the second quarter of 2021 as compared to the second quarter of 2020.

Net loss: Net loss for the second quarter of 2021 was $5.8 million as compared to $2.2 million for the second quarter of 2020. Net loss included stock-based compensation expense of $0.3 million for the second quarter of 2021 and $6,100 for the second quarter of 2020.

Financial guidance: We expect that our cash and cash equivalents along with net proceeds from our IPO will be sufficient to fund its operations into the second half of 2025, based on our current operating plan.

About Aerovate Therapeutics

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 dry powder inhaled formulation of the drug imatinib for the treatment of pulmonary arterial hypertension, or PAH. For more information, please visit www.aerovatetx.com.

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 that we will initiate enrollment in the second half of 2021 for the Phase 2b portion of our Phase 2b/3 trial of AV-101 in PAH; our belief that we will have capital to fund Aerovate into the second half of 2025; the statement that our phase 2b/3 trial with AV-101 for the treatment of PAH, if successful, could support a NDA submission; the statement that, if successful, our existing clinical program could support a marketing authorization application submission for regulatory approval in Europe; our business plans and objectives, future plans for AV-101, including expectations regarding timing and success of the our Phase 2b/3 clinical trial, the therapeutic potential and clinical benefits of AV-101 and potential regulatory submissions and approvals for AV-101, our growth as a company and the anticipated contribution of the members of our board of directors to our operations and progress. 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 the initiation or continuation of our Phase 2b/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, 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.

Aerovate Therapeutics, Inc.
Condensed Balance Sheets
(in thousands)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 59,150	$ 4,573
Prepaid expenses and other current assets	159	103
Total current assets	59,309	4,676
Property and equipment, net	35	39
Other long-term assets	3,090	-
Total assets	$ 62,434	$ 4,715
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,042	$ 618
Accrued and other current liabilities	1,151	1,156
Total current liabilities	4,193	1,774
Commitments and contingencies		
Series A redeemable convertible preferred stock	75,819	12,285
Series Seed redeemable convertible preferred stock, $0.0001 par value;	4,000	4,000
Stockholders' deficit	(21,578)	(13,344)
Total liabilities, redeemable convertible preferred stock and stockholders’ deficit	$ 62,434	$ 4,715

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 4,327	$ 1,471	$ 6,523	$ 2,677
General and administrative	1,447	154	2,031	306
Total operating expenses	5,774	1,625	8,554	2,983
Loss from operations	(5,774)	(1,625)	(8,554)	(2,983)
Other expense:				
Interest income (expense)	2	(37)	2	(75)
Change in fair value of convertible promissory notes	-	(540)	-	(580)
Other expense	(3)	-	(4)	-
Total other expense	(1)	(577)	(2)	(655)
Net loss and comprehensive loss	$ (5,775)	$ (2,202)	$ (8,556)	$ (3,638)
Net loss per share, basic and diluted	$ (23.80)	$ (9.12)	$ (35.29)	$ (15.07)
Weighted-average shares of common stock outstanding, basic and diluted	243,076	241,467	243,076	241,467

The following table sets forth certain condensed balance sheet items on an actual basis and on a pro forma basis, as if the IPO had occurred on June 30, 2021.

- on a pro forma basis to reflect (i) the automatic conversion of all shares of our convertible preferred stock into an aggregate of 14,182,854 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, as if such conversion had occurred on June 30, 2021, (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately prior to the closing of this offering and (iii) our issuance and sale of 9,984,463 shares of our common stock, including 1,302,321 shares associated with the full exercise of the underwriters' option to purchase additional shares, at an offering price of $14.00 per share generating approximately $127.0 million in net proceeds.

The pro forma information below is illustrative only.

Aerovate Therapeutics, Inc.
(in thousands)

	As of June 30, 2021	
	Actual	Pro Forma
	(in thousands, except share and per share amounts)	
Cash and cash equivalents	$ 59,150	$ 186,150
Redeemable convertible preferred stock	79,819	-
Common stock	-	2
Additional paid-in capital	407	207,224
Total shareholders' (deficit) equity	$ (21,578)	$ 185,241

Contact:

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