

**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 15, 2021

AEROVATE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40544
(Commission
File Number)

83-1377888
(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)

200 Berkeley Street, Floor 18, Boston, Massachusetts 02116
(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 November 15, 2021, Aerovate Therapeutics, Inc. announced its financial results for the quarter ended September 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 November 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: November 15, 2021

By: /s/ George A. Eldridge

George A. Eldridge
Chief Financial Officer



Aerovate Therapeutics Announces Third Quarter 2021 Financial Results

WALTHAM, Mass. – November 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 disease, today announced our financial results for the quarter ended September 30, 2021, and recent events.

“We continue to make progress with clinical trial sites to participate in our global Phase 2b/3 trial of AV-101 in PAH and expect to initiate enrollment this year in the Phase 2b portion of the trial,” said Timothy Noyes, chief executive officer of Aerovate. “We are also pleased with investor support for our IPO, which we believe provides sufficient capital to fund Aerovate into the second half of 2025.”

Recent Events

Raised \$126.9 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 \$126.9 million after deducting underwriting discounts and commissions and other offering expenses payable by us.

Preparation Continues for Global Phase 2b/3 Clinical Trial. We continued preparing for the initiation of our Phase 2b/3 trial of AV-101, our dry powder inhaled formulation of imatinib for the treatment of pulmonary arterial hypertension, or PAH, a devastating disease impacting approximately 70,000 people in the United States and Europe. Drug supply has been manufactured and we have begun scheduling site activation meetings in the United States. We anticipate including experienced PAH centers from more than 20 countries in our Phase 2b/3 trial. We have obtained orphan drug designation from the U.S. Food and Drug Administration and the European Medicines Agency for AV-101 for the treatment of PAH in the United States and the European Union.

Third Quarter 2021 Financial Results

Cash and cash equivalents totaled \$180.9 million as of September 30, 2021, compared to \$59.2 million as of June 30, 2021. The increase was primarily driven by net proceeds of \$126.9 million from the Company’s IPO, which closed on July 2, 2021, offset by operational costs for the three-month period ending September 30, 2021.

R&D expenses: Research and development (R&D) expenses for the third quarter of 2021 were \$3.4 million as compared to \$2.0 million for the third quarter of 2020. The increase in R&D expenses was due primarily to increased clinical trial costs and manufacturing costs in the third quarter of 2021 as compared to the third quarter of 2020.

G&A expenses: General and administrative (G&A) expenses for the third quarter of 2021 were \$2.8 million as compared to \$0.3 million for the third quarter of 2020. The increase in G&A expenses was due primarily to increased headcount-related costs, insurance costs, legal fees, accounting fees and consulting expenses in the third quarter of 2021 as compared to the third quarter of 2020.

Net loss: Net loss for the third quarter of 2021 was \$6.2 million as compared to \$2.3 million for the third quarter of 2020. Net loss included stock-based compensation expense of \$0.8 million for the third quarter of 2021 and \$21,000 for the third quarter of 2020.

Financial guidance: We expect that our cash and cash equivalents will be sufficient to fund our 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, our 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 expectations of identifying clinical site locations and recruitment of patients for our Phase 2b/3 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 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; and 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 identification of clinical sites, patient recruitment, initiation and 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
(Unaudited)
(in thousands)

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 180,878	\$ 4,573
Prepaid expenses and other current assets	2,224	103
Total current assets	183,102	4,676
Property and equipment, net	162	39
Operating lease right-of-use assets	583	-
Other long-term assets	278	-
Total assets	\$ 184,125	\$ 4,715
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,555	\$ 618
Accrued and other current liabilities	1,123	1,156
Operating lease liabilities	147	-
Total current liabilities	3,825	1,774
Operating lease liabilities, net of current portion	452	-
Total liabilities	4,277	1,774
Commitments and contingencies		
Series A redeemable convertible preferred stock	-	12,285
Series Seed redeemable convertible preferred stock	-	4,000
Stockholders' equity (deficit):		
Stockholders' equity (deficit)	179,848	(13,344)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 184,125	\$ 4,715

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 3,418	\$ 1,966	\$ 9,941	\$ 4,643
General and administrative	2,782	277	4,813	583
Total operating expenses	6,200	2,243	14,754	5,226
Loss from operations	(6,200)	(2,243)	(14,754)	(5,226)
Total other income (expense)	16	(64)	14	(719)
Net loss and comprehensive loss	\$ (6,184)	\$ (2,307)	\$ (14,740)	\$ (5,945)
Net loss per share, basic and diluted	\$ (0.26)	\$ (10.13)	\$ (1.80)	\$ (25.20)
Weighted-average shares of common stock outstanding, basic and diluted	23,885,017	242,901	8,180,359	241,949

Contact:

Julio Cantre
Info@AerovateTx.com
202.930.4762

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