
**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): March 29, 2023

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, 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:

<u>Title of each class</u>	<u>Trade Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 March 29, 2023, Aerovate Therapeutics, Inc. announced its financial results for the fourth quarter and year ended December 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 March 29, 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: March 29, 2023

By: /s/ George A. Eldridge

George A. Eldridge
Chief Financial Officer



Aerovate Therapeutics Announces Full-Year 2022 Financial Results and Business Highlights

- Progress continued on the IMPAHCT global Phase 2b/Phase 3 clinical trial of AV-101 for pulmonary arterial hypertension (PAH)
- Expanded intellectual property portfolio with four issued patents in 2022
- Management team strengthened and expanded in 2022
- Sufficiently funded into second half of 2025

WALTHAM, Mass. – March 29, 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 year ended December 31, 2022, and recent business highlights.

“Aerovate had a productive year in 2022 as evidenced by the progress made with our lead pipeline candidate AV-101 and strategic additions to our management team,” said Tim Noyes, Chief Executive Officer of Aerovate. “We believe AV-101, if approved, has the potential to become part of a new standard of care for patients with PAH by directly delivering a novel antiproliferative therapy to the pulmonary vasculature in a way that may offer broad efficacy and a low side effect burden to complement current and future treatment options. With its convenient twice daily dosing and easy-to-use pocket-size inhaler, we are optimistic about the potential of AV-101 to help us deliver on our vision of providing patients with meaningful treatment solutions.”

2022 Highlights

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. During 2022, we had additional clinical site activations and additional patients enrolled. 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.

Trial Data Published and Presented at Scientific Conferences. The Phase 1 AV-101 results, published in ERJ Open Research and presented at the American Thoracic Society (ATS) International Conference in May, demonstrated AV-101 delivered by dry powder inhalation to healthy adult volunteers was generally well-tolerated at doses from 10mg twice daily to 90mg twice daily with significantly reduced systemic exposure compared with 400mg oral imatinib, the dose used in Novartis’ IMPRES trial in PAH, and no serious treatment-emergent adverse events reported. In October 2022, the IMPAHCT trial design was presented at the American College of Chest Physicians Annual Meeting (CHEST) in a poster session. The adaptive, operationally seamless trial design for our Phase 2b/Phase 3 trial allows for continuous enrollment across phases and a more efficient drug development timeline.

Expanded Intellectual Property Portfolio. We continued expanding our intellectual property portfolio in 2022 with the issuance of four patents. The United States Patent and Trademark Office issued Patents 11,229,650, 11,298,355, 11,413,289, and 11,464,776. to us and we continue prosecuting multiple additional applications to cover our product globally.

Strengthened Management Team. We added four key members to our management team this past year, including the additions of Marco Verwijs as SVP, CMC (Chemistry, Manufacturing and Controls), Susan Fischer as SVP, Development Operations, Stephen Yu as SVP, Quality, and Sanjeev Khindri as SVP, Clinical Development. All have decades of experience in the biopharmaceutical space.

Expanded Board of Directors. We appointed Donald Santel to our Board and our Nominating and Corporate Governance Committee. Mr. Santel is Chairperson of the Board of two biopharmaceutical companies and was Chief Executive Officer for CoTherix, Inc., a biopharmaceutical company focused on developing therapies for cardiopulmonary disease, including PAH.

2022 Financial Results

Cash, cash equivalents and short-term investments totaled \$129.2 million as of December 31, 2022, compared to \$142.6 million as of September 30, 2022. The decrease was primarily driven by operational costs for the three-month period ended December 31, 2022.

R&D expenses: Research and development (R&D) expenses for the year ended December 31, 2022 were \$38.6 million as compared to \$15.0 million for the year ended December 31, 2021. The increase in R&D expenses was due primarily to clinical trial costs, manufacturing costs, and increased headcount-related costs in 2022 as compared to 2021.

G&A expenses: General and administrative (G&A) expenses for the year ended December 31, 2022 were \$14.6 million as compared to \$8.0 million for the year ended December 31, 2021. The increase in G&A expenses was due primarily to operating as a public company inclusive of insurance costs, legal and accounting fees, and increased headcount-related costs in 2022 as compared to 2021.

Net loss: Net loss for the year ended December 31, 2022 was \$51.5 million as compared to \$23.0 million for the year ended December 31, 2021. Net loss included stock-based compensation expense of \$5.5 million and \$2.0 million for the years ended December 31, 2022 and December 31, 2021, respectively.

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

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 the abnormal smooth muscle cellular hyperproliferation in the distal pulmonary arteries, caused by an imbalance of activity between growth factors and apoptosis. 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 presented at the 2022 American Thoracic Society (ATS) annual meeting 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 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 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," "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; 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 the second half of 2025; our expectations regarding the strength of our intellectual property portfolio globally; 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 contribution of the members of our board of directors and management team to our operations and progress; 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 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)

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 129,220	\$ 167,375
Other assets	6,081	7,988
Total assets	<u>135,301</u>	<u>175,363</u>
Liabilities and Stockholders' Equity		
Accounts payable and accrued and other current liabilities	\$ 7,397	\$ 2,358
Other liabilities	1,161	587
Total liabilities	<u>8,558</u>	<u>2,945</u>
Total stockholders' equity	126,743	172,418
Total liabilities and stockholders' equity	<u>\$ 135,301</u>	<u>\$ 175,363</u>

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 12,221	\$ 5,047	\$ 38,622	\$ 14,987
General and administrative	3,631	3,225	14,615	8,035
Total operating expenses	<u>15,852</u>	<u>8,272</u>	<u>53,237</u>	<u>23,022</u>
Loss from operations	<u>(15,852)</u>	<u>(8,272)</u>	<u>(53,237)</u>	<u>(23,022)</u>
Total other income	856	49	1,751	62
Net loss before income taxes	<u>(14,996)</u>	<u>(8,223)</u>	<u>(51,486)</u>	<u>(22,960)</u>
Provision for income taxes	25	—	25	3
Net loss	<u>\$ (15,021)</u>	<u>\$ (8,223)</u>	<u>\$ (51,511)</u>	<u>\$ (22,963)</u>
Net loss per share, basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.34)</u>	<u>\$ (2.10)</u>	<u>\$ (1.87)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>24,610,723</u>	<u>24,410,393</u>	<u>24,472,104</u>	<u>12,293,629</u>

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