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): January 8, 2024

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 7.01 Regulation FD Disclosure.

Aerovate Therapeutics, Inc. (the "Company") is furnishing a corporate presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company intends to use from time to time in meetings with investors and others beginning on January 8, 2024. The corporate presentation will also be available in the "Events & Presentations" section of the Company's website at https://ir.AerovateTx.com/events-presentations.

The information under this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Corporate presentation of Aerovate Therapeutics, Inc., furnished herewith.
104	Cover Page Interactive Data File

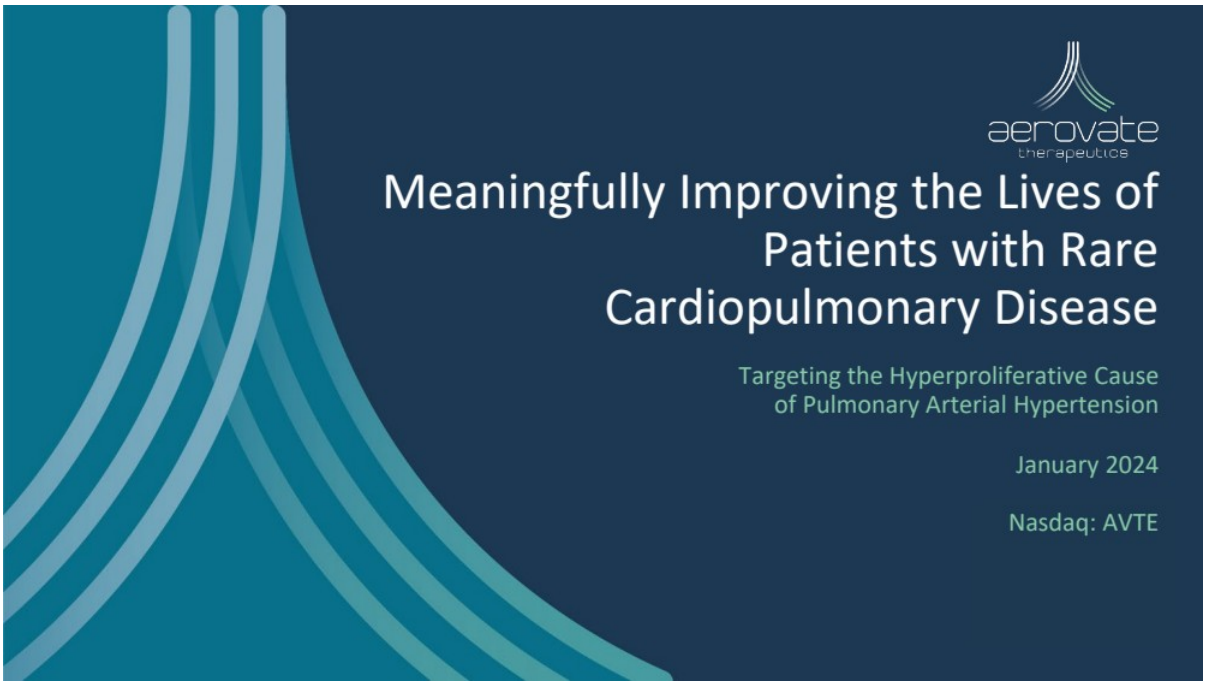
SIGNATURE

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: January 8, 2024

By: */s/ Timothy P. Noyes*
Timothy P Noyes
Chief Executive Officer


aerovate
therapeutics
Meaningfully Improving the Lives of Patients with Rare Cardiopulmonary Disease
Targeting the Hyperproliferative Cause of Pulmonary Arterial Hypertension
January 2024
Nasdaq: AVTE

Disclaimer; Forward-Looking Statements

This presentation has been prepared by Aerovate Therapeutics, Inc. ("we," "us," "our," "Aerovate" or the "Company") and is made for informational purposes only. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and this presentation shall not under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

The following presentation contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as "anticipate," "believe," "could," "estimate," "expect," "future," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "seek," "strategy," "should," "will," "would" and similar expressions regarding future periods. These forward-looking statements include, but are not limited to, statements regarding Aerovate's business plans and objectives; future plans for AV-101, including expectations regarding timing and success of the planned clinical trial, therapeutic potential, clinical benefits and safety thereof; growth as a company; the potential value and market for AV-101; and uses and need of capital, expenses and other financial results currently or in the future. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties and are based on our current beliefs, expectations and assumptions regarding future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Among the factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation are those risks and uncertainties, without limitation, associated with the following: the impact of the COVID-19 pandemic on the company's business, operations, patient enrollment and retention, strategy, goals and anticipated milestones; the therapeutic potential of AV-101, and the timing associated with the initiation, continuation or success of Aerovate's ongoing or planned clinical trials of AV-101; Aerovate's ability to execute on its strategy; positive results from a preclinical or clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; AV-101 may not be successfully developed and commercialized; regulatory developments in the United States and foreign countries; Aerovate's ability to protect and maintain its intellectual property position; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in our Quarterly Report on Form 10-Q, as well as other risks detailed in our subsequent filings with the United States Securities and Exchange Commission (SEC). Any forward-looking statement made by us is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

Experienced Management Team

Timothy Noyes
Chief Executive Officer

- 30 years' commercial experience in pharma and biotech, including Merck, Genzyme, Proteon
- Extensive launch planning and commercial launch experience

Ben Dake, PhD
President & Founder

- Entrepreneur, Cancer Biologist and Investor
- Conceptualized AV-101 and secured up to $79M in financing for Aerovate

Hunter Gillies, MB ChB
Chief Medical Officer

- Led AMBITION trial for Gilead that established current first-line PAH combination therapy
- Led successful Phase 2 and 3 trials for PAH product candidates at Pfizer and Gilead

Donna Dea
Head of Regulatory

- 35 years of pharmaceutical experience at AstraZeneca
- 20 years of global regulatory experience designing/ implementing strategies resulting in approval of treatments for asthma, COPD, rhinitis and others

Susan Fischer
SVP, Clinical Ops.

- 20 years' experience in clinical operations in both academic and the pharmaceutical industry.
- Previously built/led clinical ops teams at Syndax, EMD Serono, Acetylon

George Eldridge
Chief Financial Officer

- 25 years' experience in biotech, with both public and private companies, including Curis, Targanta, Proteon
- Extensive background raising capital in private, IPO and follow-on settings, investment banking and M&A

Ralph Niven, PhD
Chief Development Officer

- 25 years' broad expertise in translational medicine and inhalation dosage forms
- Managed experimental and clinical development at public and private companies, including Amgen, AIR and Novartis

Timothy Pigot
Chief Commercial Officer

- 25 years' experience in biotech and pharma working to launch and commercialize a range of products
- 10 years' experience in PAH overseeing the US launches of Revatio and Leairis while at Pfizer and Gilead Sciences, respectively

Marco Verwijs
Chief Technical Officer

- 15 years' experience developing drugs from clinical product development thru commercial launch
- Proven leader in drug product scale-up and validation.

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Aerovate: An Inventive Way Forward in PAH

Demonstrated Clinical Benefit

The molecule in AV-101, imatinib, already has shown clinical benefit in a Phase 3 clinical trial conducted by Novartis of oral imatinib mesylate in PAH patients on top of two or more standard of care therapies.

Unfortunately, AEs with oral imatinib were common and development was discontinued

Inventive Solution

Anti-proliferative targeted inhaled dry powder PAH product candidate AV-101 designed to provide robust clinical benefit of imatinib without systemic AEs observed with oral imatinib

Significant Unmet Need

Despite three drug classes approved, 5-year survival for newly diagnosed PAH patients is 61%

Efficient Execution

FDA and EMA orphan designation for AV-101 for the treatment of PAH

Phase 1 SAD/MAD in healthy volunteers complete

Phase 2b dose-ranging portion of a Phase 2b/3 trial in PAH patients. Ph2b portion fully enrolled with Ph2b data expected in June 2024

Established Market

$6B+ market, yet outcomes are poor

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Relentless Disease Progression Impairs Daily Life

No limitation

Activity limited

Comfortable at rest, but ordinary physical activity causes shortness of breath, fatigue, chest pain, fainting

Marked limitation

Comfortable at rest, but less than ordinary physical activity causes shortness of breath, fatigue, chest pain, fainting

Severe limitation

Symptoms at rest. Overt heart failure

Despite standard of care (SOC) most patients progress to overt heart failure

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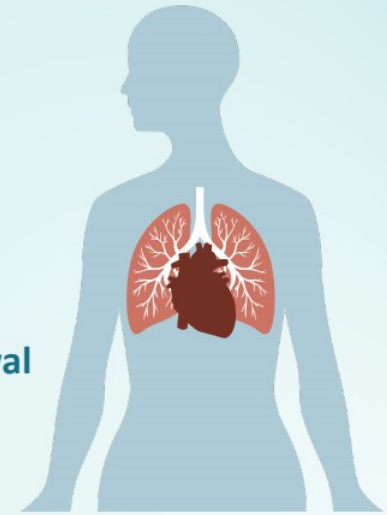
Pulmonary Arterial Hypertension

~ 70,000 People with PAH in the US/EU	**~ 35,000** People with PAH in the US	**$6B+** Global annual drug spending
65-80% Female	**53 years** Average age at diagnosis	**61-65%** **5-year survival** Newly diagnosed and prevalent patients



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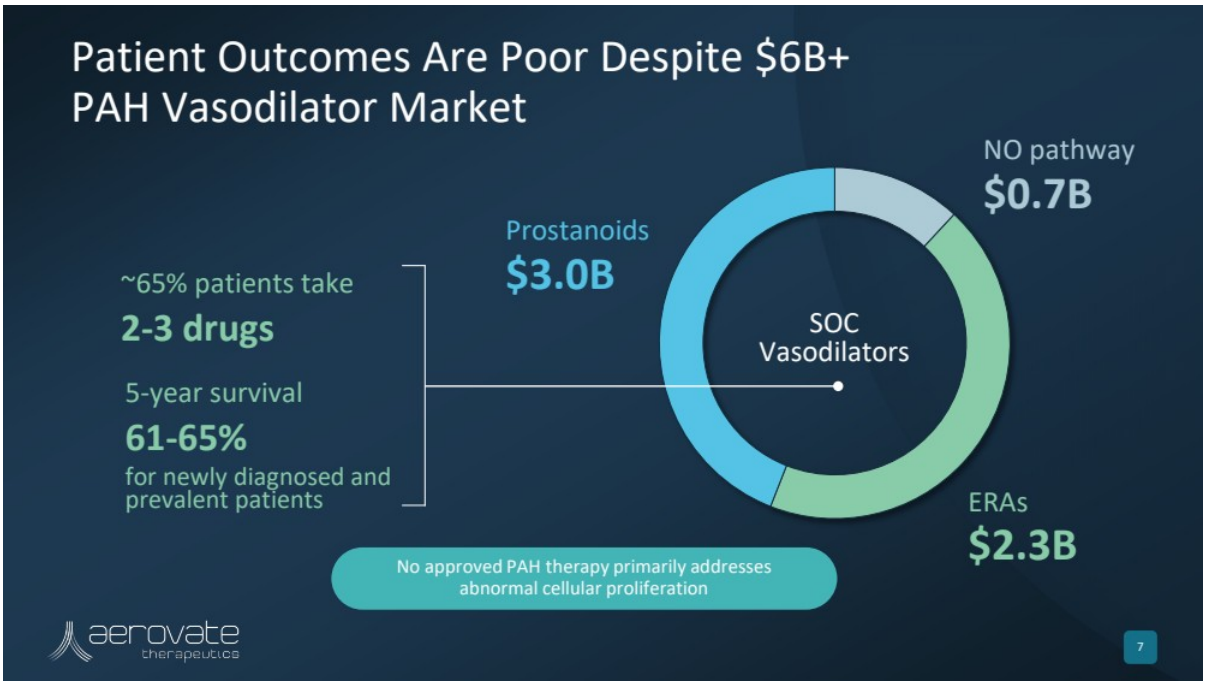
Patient Outcomes Are Poor Despite $6B+ PAH Vasodilator Market
NO pathway
$0.7B
Prostanoids
$3.0B
~65% patients take
2-3 drugs
5-year survival
61-65%
for newly diagnosed and prevalent patients
SOC Vasodilators
ERAs
$2.3B
No approved PAH therapy primarily addresses abnormal cellular proliferation
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Reinventing Imatinib From a Cancer Drug to a Potential PAH Therapy
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8

Phase 3 IMPRES Trial: Oral Imatinib Demonstrated Improvement on Top of Maximal Background

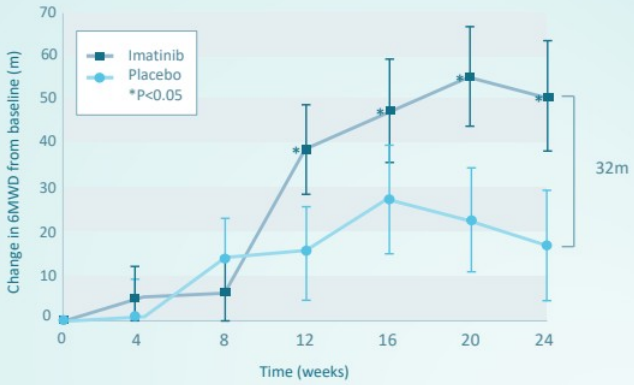
Novartis global Phase 3 trial (n=202) of oral imatinib

Required to be on at least 2 SOC PAH drugs

WHO functional class II- IV

Statistically significant and clinically meaningful benefit on primary endpoint 6MWD after 24 weeks

6MWD is an accepted endpoint for approval in PAH



(Adapted from Circulation. 2013;127:1128-1138.)

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Phase 3 IMPRES Trial: Benefit Consistent Across Secondary Endpoints

Secondary Endpoints (24wk)

Demonstrated robust hemodynamic effect

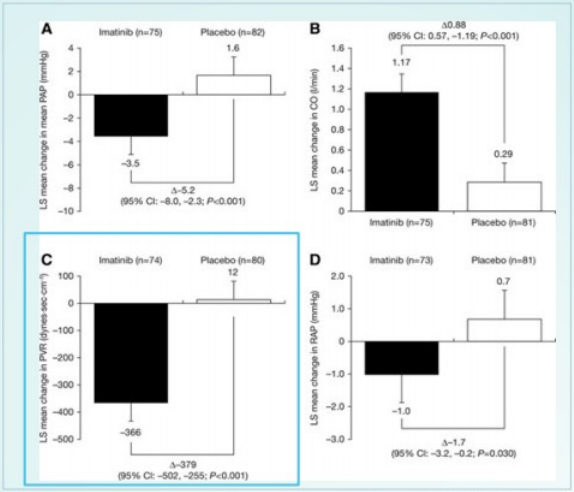
(A) Decreased mean pulmonary artery pressure

(B) Increased cardiac output

(C) Pulmonary vascular resistance (PVR) dropped 32% (P < 0.001), a validated efficacy endpoint typically used for dose-finding

(D) Right atrial pressure lowered

Aerovate's Phase 2b trial will use PVR as the primary endpoint



(Circulation. 2013;127:1128-1138.)

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Oral Imatinib Caused Systemic Adverse Events

	Imatinib n=103 (%)	Placebo n=98 (%)
Adverse Event +	100 (97)	94 (96)
Nausea	57 (55)	23 (24)
Peripheral edema	45 (44)	20 (20)
Diarrhea	36 (35)	19 (19)
Vomiting	31 (30)	10 (10)
Periorbital edema	30 (29)	7 (7)
Headache	25 (24)	22 (22)
Dyspnea	19 (18)	13 (13)
Nasopharyngitis	18 (18)	19 (19)
Hypokalemia	16 (16)	3 (3)
Anemia	14 (14)	3 (3)
Cough	11 (11)	15 (15)
Fatigue	11 (11)	7 (7)
Face edema	10 (10)	1 (1)
Muscle spasms	10 (10)	2 (2)

	Imatinib n=103 (%)	Placebo n=98 (%)
Serious Adverse Event +	45 (44)	29 (30)
Worsening of pulmonary hypertension	6 (6)	8 (8)
Anemia	7 (7)	1 (1)
Dyspnea	6 (6)	2 (2)
Peripheral edema	6 (6)	0
Presyncope	5 (5)	0
Diarrhea	3 (3)	2 (2)
Device-related infection	3 (3)	0
Syncope	1 (1)	5 (5)
Subdural hematoma *	2 (2)	0

* In long-term extension portion of the trial, 6 additional patients experienced a subdural hematoma.

+ Individual adverse events are shown if they occurred in >10% in the imatinib group. Individual serious adverse events are shown if they occurred in ≥3 patients in either group.

(Circulation. 2013;127:1128-1138.)

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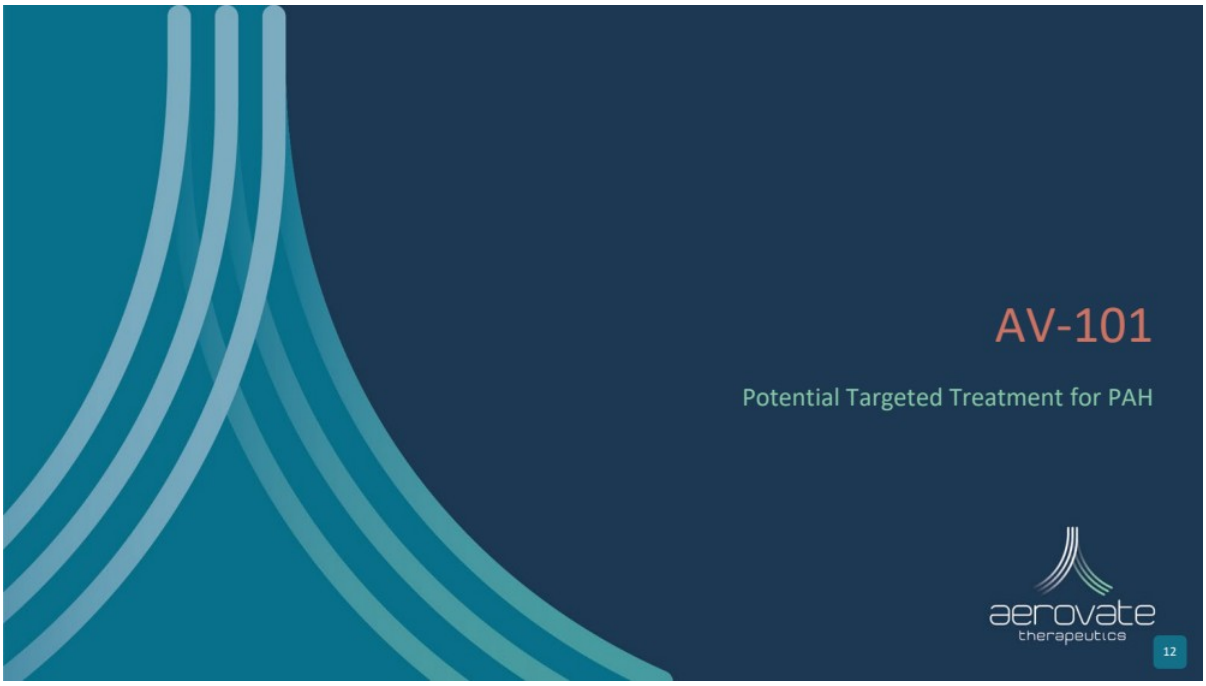
AV-101
Potential Targeted Treatment for PAH
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therapeutics
12

AV-101

AV-101 is a combination product comprised of a proprietary dry powder imatinib formulation in a capsule delivered by a dry powder inhaler designed to:

- Deliver drug to the lungs
- Limit systemic exposure
- Be easily administered

Imatinib molecular structure unmodified

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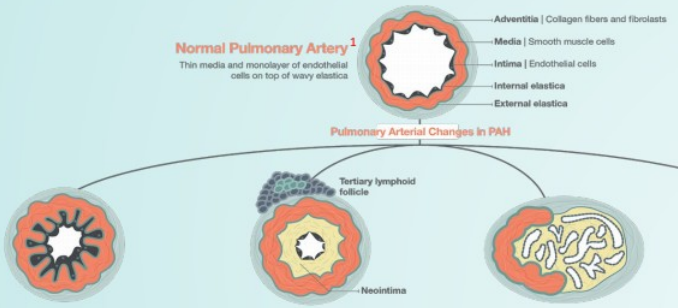
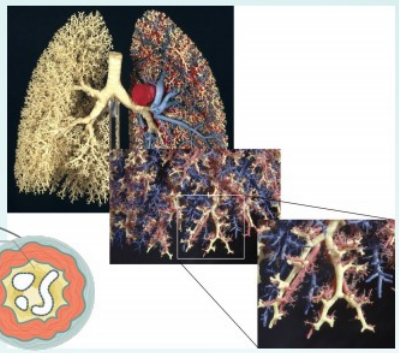
PAH is a Disease of All Layers of the Pulmonary Arteries





Latex cast of human airway (white), arterial tree (red), and venous tree (blue)[3]

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1. Adapted from J Am Coll Cardiol. 2015 May 12;65(18):1976-97. 2. Eur Respir J. 2019 Jan 24;53(1):1801887. 3. J Appl Physiol (1985). 2011 Apr;110(4):1119-29.)

AV-101 Phase 1 Trial

A single and multiple ascending dose Phase 1 study (n=82) in healthy volunteers to determine safety and tolerability

SAD	MAD	STUDY ASSESSMENTS
Five AV-101 cohorts from 1 mg to 90 mg n=6 Active / 2 Placebo	Seven days of BID dosing	Vital Signs
400 mg imatinib tablet for systemic exposure comparison n=8	Low dose 10 mg	Pulmonary Function Testing (FEV1 and FVC)
	Med dose 30 mg	Oxygen Saturations
	High dose 90 mg	QTc
		Adverse Events
n=8 per cohort	**n=12 per cohort; 9 Active / 3 Placebo**	

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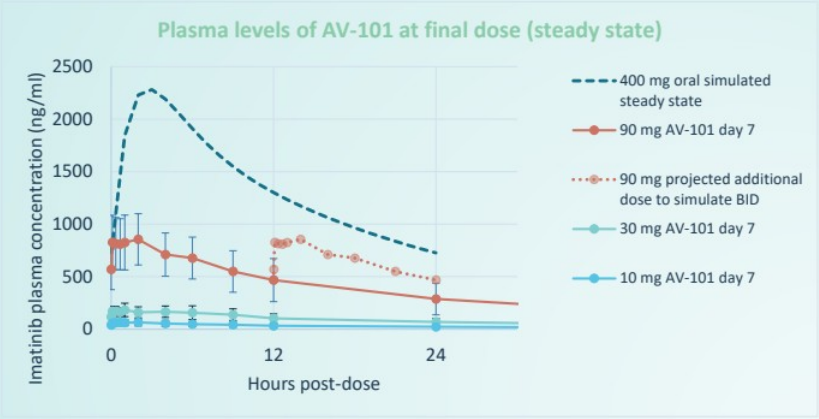
AV-101 Phase 1 Trial: Lower Systemic Exposures Observed



Systemic exposures for all doses of AV-101 observed to be lower than simulated steady-state exposure of 400 mg of oral imatinib

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AV-101 Phase 1 Tolerability Profile

AV-101 was generally well tolerated

- No serious adverse events were reported
- No change in pulmonary function, oxygen saturation, and QTc interval
- Most AEs mild to moderate
- One discontinuation due to vomiting on Day 1 in the MAD 90 mg Cohort
- Most common AE, cough, was at max dose and limited to within 30 minutes of dosing

Adverse Event n(%)	10 mg (n=8)	30 mg (n=9)	90 mg* (n=9)
Cough	1 (13)	1 (11)	5 (56)
Persistent cough	-	-	-
Headache	-	-	4 (44)
Nausea	-	-	2 (22)
Chest discomfort	-	-	2 (22)
Throat irritation	-	1 (11)	1 (11)
Musculoskeletal pain	-	-	2 (22)

Single incidence AEs: Vomiting (discontinued), Dysgeusia, Musculoskeletal chest pain, Nasal congestion, Oropharyngeal pain, Back pain, Abdominal pain, Covid-19, Presyncope, Alanine aminotransferase increased

*90mg dose was administered as 9 x 10mg capsules

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Phase 2b Dose-Ranging Trial

- Placebo controlled dose-ranging study
  - 10 mg, 35 mg and 70 mg AV-101 BID for 24 weeks
  - Targeting 200 patients across 4 dose groups
- Multicenter international trial
- Two or more background PAH therapies
- Functional class II - IV
- Primary endpoint: change in pulmonary vascular resistance (PVR) at 24 weeks
  - Statistically significant improvement on PVR already demonstrated with oral imatinib in multiple third-party clinical trials
  - Validated endpoint
  - Powered to detect statistically significant change
- Key secondary endpoints: Change in 6MWD, NTproBNP, QoL

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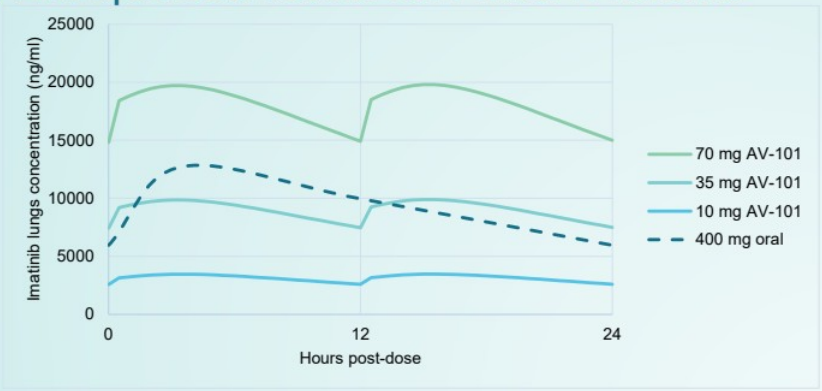
Expected AV-101 Lung Exposures of Planned Phase 2b Doses, Extrapolated based on Phase 1 Results



Predicted lung concentrations of planned Phase 2b doses of AV-101 overlap or surpass 400 mg oral imatinib dose. Predicted lung concentrations extrapolated based on a PK model using published method for the extrapolation of lung exposures, based on plasma levels observed in Phase 1 trial

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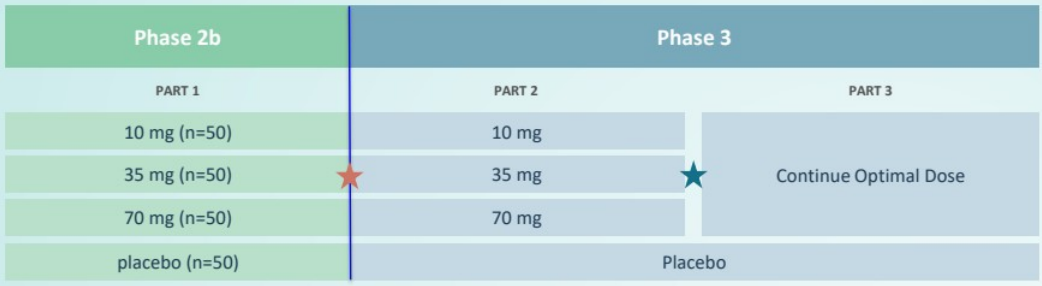
Phase 2b/3 Adaptive Continuous Trial of AV-101



- All patients are treated for 24 weeks
- 6MWD is primary endpoint in Phase 3

★ Phase 3 enrollment begins immediately upon completion of Phase 2b enrollment

★ Phase 3 dose selected based on Phase 2b data after 24 weeks of follow up

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PAH Clinical Pipeline For Novel Mechanisms is Limited

PAH Trials with Non-Vasodilatory MOAs:

	Oral Imatinib	Merck/Acceleron Sotatercept (activin trap)			Gossamer Seralutinib (TKI)
	IMPRES (Ph3)	PULSAR (Ph2)		STELLAR (Ph3)	TORREY (Ph2)
		low	high		
PVR	-31.8%	-20.5%	-33.9%	-30.7%	-14.3%
6MWD	+32 m p=0.002	+29 m p=0.02	+21 m p=0.08	+40.8 m p=0.001 *median	+6.5m p=0.597

The data in the chart above are based on a cross-trial comparison and not a head-to-head clinical trial. Such data may not be directly comparable due to differences in trial design, study protocols, conditions and patient populations.

Other Potential Non-Vasodilator PAH Therapies in Clinical Development:

- Aerami/Philip Morris – AER-901 (nebulized imatinib) Phase 1 complete
- Sumitomo (Enzyvant) – Rodatristat (tryptophan hydroxylase inhibitor) in Phase 2 (**Failed Trial**)

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AV-101: Potential to Be An Ideal Add-On Agent

- At Launch, AV-101 potential to be an ideal add on agent*
  - Compelling clinical profile in combination with current therapies
  - Simplicity and ease-of-use
  - Potential to be part of the future standard of care
- Potential positioning within target populations*
  - In front of inhaled and oral prostacyclin therapy
  - In front of sotatercept for patients sotatercept ineligible patients and patients who prefer inhalation vs injection
  - Patients who remain at moderate to high risk of poor outcomes despite sotatercept and prostacyclin therapy
  - Patients who do not tolerate sotatercept and prostacyclin therapy

*Assumes data and FDA discussions support FDA approval with supportive labeling

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AVTE's Perspective on Current And Future PAH Landscape Informed by Extensive Experience, Stakeholder Engagement, and Market Research

- Global Advisory Boards with PAH Experts and PAH Patients
- Interactions with Investigators, KOL's, PAH Treaters, Nurses, Patients, Advocacy Associations*
- Robust Market Research
  - 100+ U.S. Physician Market Landscape Research (Oct 2021)
  - 100+ European Physician Market Landscape Research (June 2022)
  - 150+ U.S. Physician Conjoint Demand Study post Sotatercept Data (Aug 2023)

Prof. Vizza MD investigator discussion

*Individual interactions focus solely on treatment landscape unless seeking bona-fide advice with an appropriate consulting agreement

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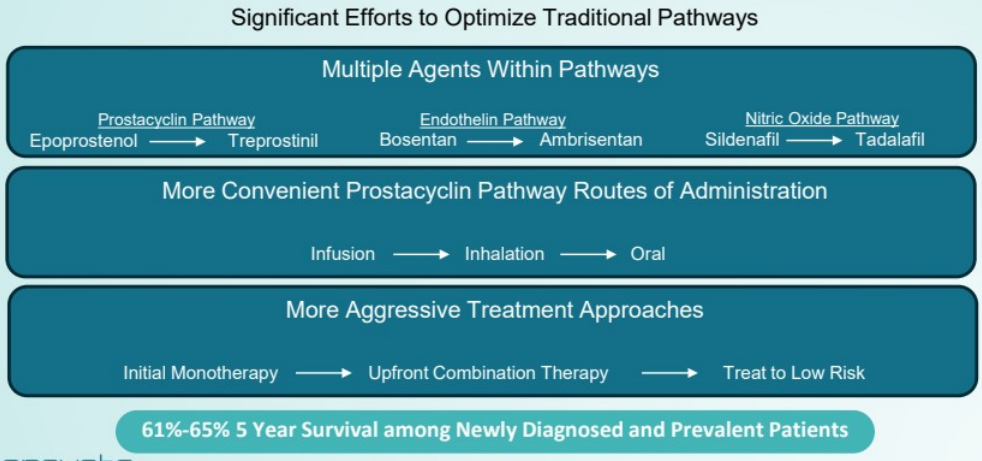
PAH Treatment Pathways Have Not Changed Since 2005 and Outcomes Remain Poor



61%-65% 5 Year Survival among Newly Diagnosed and Prevalent Patients

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Unmet Need Beyond Sotatercept


EDITORIAL

Continued Progress

ORIGINAL ARTICLE

Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension

The STELLAR trial represents significant progress in therapy for PAH however…

- 60% of patients did not meet multi-component improvement measure
- 60% of patients did not achieve low risk on the simplified French risk model
- 70% of patients did not improve functional class
- Long term effects not fully established

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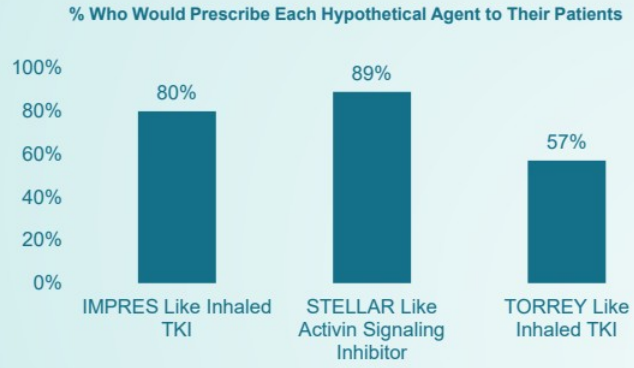
80% of Physicians Would Prescribe an "IMPRES" Like Inhaled TKI if it Were Available Alongside Sotatercept

Market Research with >150 U.S. PAH Treating Physicians Conducted Post STELLAR Data*



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*Proprietary Market Research with U.S. PAH Treating Physicians; Aug 2023. Data based on product allocation exercise assuming all hypothetical agents were available

AV-101: Unmet Need, Blockbuster Potential

Positioning

Added to 2 agents before prostacyclin

Added to 3 agents before parenteral prostacyclin

~65% (~22,750)

We estimate to be taking 2-3 drugs

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Positive Initial Regulatory Interactions and Feedback

Regulatory Interactions Completed

- FDA Pre-IND meeting in January 2020
- FDA and EMA Orphan Designation granted for AV-101 for the treatment of PAH
- Received EMA Scientific Advice in March 2021
- End-of-Phase-1 Meeting with FDA in April 2021

Feedback from FDA and EMA on Clinical Development

- A single Phase 2b/3 trial could support NDA
- Aligned on Phase 2b/3 endpoints for potential NDA/MAA submission

Intellectual Property Protection for AV-101 to 2040+

Multiple issued US patents covering AV-101 drug product and methods of use

- Patent coverage extends at least until 2040
- Current US patents being extended worldwide

Multiple additional pending applications pursuing

- Methods of manufacture
- Filing on other aerosol compositions
- Filing on mechanism of action (composition agnostic)

Regular reviews enacted to extend or file new IP based on discoveries in research, clinical trials and CMC

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Chemistry, Manufacturing and Controls

Stability of AV-101

- Release and stability testing supports
  - API stability of at least 36 months
  - Drug product stability of at least 30 months
- Filled product stability testing ongoing

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AV-101 Device and Delivery Performance

AV-101 Device

- Off-the-shelf commercial scale dry powder inhaler
  - No batteries, compressors or cords
  - No sterile vials containing solutions or suspensions
  - CE mark in EU and Device Master File registered with FDA
- Designed for ease of use and convenience
- Intended dosing of 2 capsules twice a day
- Replaced weekly

AV-101 Delivery Performance

- Consistently high delivered and fine particle dose
- Ideal size and size distribution for lung penetration

NOTE: Device planned for Phase 2b/3 trial was not used in Phase 1 trial, but delivery performance has been assessed.

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Aerovate: An Inventive Way Forward in PAH

Demonstrated Clinical Benefit

The molecule in AV-101, imatinib, already has shown clinical benefit in a Phase 3 clinical trial conducted by Novartis of oral imatinib mesylate in PAH patients on top of two or more standard of care therapies.

Unfortunately, AEs with oral imatinib were common and development was discontinued

Inventive Solution

Anti-proliferative targeted inhaled dry powder PAH product candidate AV-101 designed to provide robust clinical benefit of imatinib without systemic AEs observed with oral imatinib

Significant Unmet Need

Despite three drug classes approved, 5-year survival for newly diagnosed PAH patients is 61%

Efficient Execution

FDA and EMA orphan designation for AV-101 for the treatment of PAH

Phase 1 SAD/MAD in healthy volunteers complete

Phase 2b dose-ranging portion of a Phase 2b/3 trial in PAH patients. Ph2b portion fully enrolled with Ph2b data expected in June 2024

Established Market

$6B+ market, yet outcomes are poor

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Thank you!
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