UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

June 2, 2021

Timothy Noyes
Chief Executive Officer
Aerovate Therapeutics, Inc.
200 Berkeley Street, Floor 18
Boston, MA 02116

Re: Aerovate Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted May 6, 2021
CIK No. 0001798749

Dear Mr. Noyes:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary
Overview, page 1

1. We note your statement that "oral imatinib also demonstrated statistically significant and clinically meaningful benefit in PAH patients in an international Phase 3 trial conducted by Novartis" and similar statements throughout the registration statement. Since findings of safety or efficacy are solely within the authority of the FDA or similar foreign regulators, and oral imatinib has not been approved for the treatment of PAH, please revise to remove any statements that suggest the safety and efficacy of this product candidate. Where you deem appropriate, you may present objective data without including your conclusions related to safety or efficacy.

2. We note your comparison of the results of your Phase 1 trial of AV-101 to the results observed in the Phase 3 IMPRES clinical trial of oral imatinib. Given that it appears you have not conducted head-to-head trials, and the significant variables across clinical trials, please tell us why you believe it is appropriate to include this comparison. Include in your response whether you expect to be able to rely on this data to support an application for marketing approval from the FDA or comparable regulatory body for commercialization of AV-101.

3. Please describe the “systemic" adverse events that were observed during the Phase 3 trial conducted by Novartis and whether these were categorized as serious adverse events.

4. We note your use of the term “high unmet medical need” here and elsewhere in the document. Such a term might imply that your products are eligible for fast track designation or priority review granted by the FDA for products that treat certain serious unmet medical needs. Please remove your use of this term throughout or otherwise please explain why you believe use of this term is appropriate.

5. We note your statement that you have received regulatory guidance from the FDA that your clinical program could support a NDA submission. Please revise to provide context for such statement and balance your disclosure by stating that the process of clinical development is inherently uncertain and there can be no guarantee that you will obtain marketing approval. We also note your statements that your "focus on developing AV-101 is driven by promising historical results from the Phase 3 IMPRES clinical trial of oral imatinib," that you are "pursuing an efficient clinical development program utilizing established endpoints for development and approval of previous PAH drugs" and similar statements throughout the registration statement. These statements could imply that the FDA has approved, or will more easily approve, your product candidate. As your drug is distinct from prior drugs that have been approved by the FDA, please revise your disclosure to remove any implication that your product candidate is more likely to receive FDA approval than others. Additionally, revise your statements on page 79 that you intend to pursue a "rapid development path" that "employs a seamless adaptive design to streamline the development timeline to a potential NDA filing" and similar disclosure throughout the prospectus to remove any implication that you will be successful in obtaining regulatory approval or commercializing your product candidate in a rapid or accelerated manner as such statements are speculative.

Risks Associated with Our Business, page 3

6. Please revise this section as follows:

- Add a bullet point highlighting that your patent portfolio is pending and that you do not own any issued patents with respect to AV-101. In this regard, we note your disclosure on page 30.
- Add a bullet point highlighting the risks related to the concentration of ownership of your common stock, as discussed on page 49. Please include in this bullet and in the

corresponding risk factor on page 49 a discussion of the number of your executive officers and directors who are affiliated with your principal stockholders.

- Expand your disclosure in the ninth bullet point or add a new bullet point to highlight that you plan to conduct clinical trials for AV-101 outside the United States and that if the FDA, EMA, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, as discussed on page 38. Please also revise the disclosure in your prospectus summary to discuss that you plan to conduct your clinical trials outside the United States and clarify where you conducted your Phase 1 trial.

Use of Proceeds, page 60

7. Please revise your disclosure that you expect to use net proceeds from this offering to fund further development of AV101, including the global Phase 2b/3 clinical trial, to provide an estimate of how far in the clinical development process for AV101 the allocated proceeds of the offering will enable you to reach. For example, if you will not complete the Phase 2b or Phase 3 portion of the trial, please revise to so state. If any material amounts of other funds are necessary to complete your clinical trials for this candidate, please revise your disclosure to state the amounts and the sources of such other funds. Refer to Instruction 3 of Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Common Stock Valuations, page 74

8. Please disclose the fair value of your common stock for each grant date of stock-based awards, as determined by your board of directors, as well as the significant actual factors considered by them in their determination of fair value. As part of the revised disclosure, identify the reasons for grant date-over-grant date changes in fair value.

Business
Intellectual Property, page 93

9. Please revise your intellectual property disclosure to disclose for each material patent application the specific products or technologies to which such patent applications relate. Also clearly describe on an individual basis the type of patent protection sought for each product or technology (composition of matter, use, or process), the expected expiration of each patent, and the jurisdiction, including any foreign jurisdiction, of each pending patent. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included.

Competition, page 95

10. We note your statement that AV-101 is a "potentially first-in-class inhaled medication" targeting certain PAH patients. Given the stage of development, and your

acknowledgement that obtaining FDA approval is inherently uncertain, this statement would appear to be premature. Please revise this statement as appropriate.

Employment Arrangements with Our Named Executive Officers, page 122

11. We note your disclosure on page 122 that you have entered into offer letter agreements with certain of your named executive officers. We also note your disclosure on page 126 regarding the Senior Executive Cash Incentive Bonus Plan. Please file such offer letter agreements and the Senior Executive Cash Incentive Bonus Plan as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

General

12. Please confirm that you will update your disclosure for any shares you become obligated to issue under the Stock Purchase Agreement prior to the completion of the initial public offering.

13. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Michael Fay at 202-551-3812 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Kasey Robinson at 202-551-5880 or Christopher Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Edwin O'Connor, Esq.