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June 9, 2021

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
Mail Stop 4561
100 F Street, N.E.
Washington, D.C. 20549
Attention: Kasey Robinson and Christopher Edwards

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

Ladies and Gentlemen:

On behalf of our client, Aerovate Therapeutics, Inc. (the "**Company**"), we are responding to the comments from the Staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") relating to the Company's confidential draft Registration Statement on Form S-1 (the "**Draft Registration Statement**") contained in the Staff's letter dated June 2, 2020 (the "**Comment Letter**"). In response to the comments set forth in the Comment Letter, the Company has revised the Draft Registration Statement and is publicly submitting a revised Registration Statement (the "**Registration Statement**"), together with this response letter. The Registration Statement also contains certain additional updates and revisions. We are also sending, under separate cover, a copy of the Registration Statement (including exhibits) and a marked copy of the Registration Statement showing the changes to the Draft Registration Statement.

Set forth below are the Company's responses to the Staff's comments in the Comment Letter. The responses and information below are based on information provided to us by the Company. For convenience, the Staff's comments are repeated below in italics, followed by the Company's response to the comments as well as a summary of the responsive actions taken. We have included page numbers to refer to the location in the Registration Statement submitted herewith where the revised language addressing a particular comment appears. Capitalized terms used but not defined herein are used herein as defined in the Registration Statement.

Draft Registration Statement on Form S-1, filed May 6, 2021

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 1, 17, 67, 79-81 and 94 of the Registration Statement in response to the Staff's comment.

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.*

RESPONSE: The Company acknowledges the Staff's comment and respectfully advises the Staff that it believes the comparison is appropriate because the Company's Phase 1 clinical trial included multiple doses of AV-101 and a 400 mg dose of oral imatinib as a comparator. All doses of AV-101 resulted in lower systemic plasma levels of imatinib compared to those for 400 mg of oral imatinib. The Company reviewed these data with the FDA as an important element of its plan to follow a 505(b)(2) regulatory pathway, and based on that discussion the Company expects to be able to rely on these data to support an application for marketing approval from the FDA in the United States for the 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.*

RESPONSE: The Company respectfully advises the Staff that systemic adverse events observed in the Phase 3 IMPRES trial conducted by Novartis included anemia, dyspnea, peripheral edema, presyncope and subdural hematoma. All of these were categorized as serious adverse events. For avoidance of doubt, the Company has revised its disclosure on pages 1, 21, 67 and 79 of the Registration Statement in response to the Staff's comment to remove references to "systemic" when referring to the adverse events that were observed during the Phase 3 IMPRES trial.

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.*

RESPONSE: The Company respectfully advises the Staff that based on discussions with the FDA, the Company's clinical trial design and market precedent with another antiproliferative drug that has completed a Phase 2 trial, the Company believes AV-101 is eligible for Breakthrough Therapy Designation and priority review following the successful completion of the Phase 2b trial. For avoidance of doubt, the Company has revised its disclosure on pages 1 and 79 of the Registration Statement in response to the Staff's comment to remove references to "high" when referring to the unmet medical need of PAH patients.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 1-2 and 79-81 in response to the Staff's comment. The Company respectfully advises the Staff that during the end of Phase 1 meeting with the FDA, the Company received regulatory guidance that the Phase 2b/3 clinical trial could, if successful, support an NDA. Such discussion is documented in the FDA's meeting minutes provided to the Company, which the Company can provide the Staff on a confidential basis under separate cover upon request.

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.*

  RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 4 and 30 of the Registration Statement in response to the Staff's comment.

· *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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on page 4 of the Registration Statement in response to the Staff's comment.

· *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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 2 and 4 of the Registration Statement in response to the Staff's comment.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 6 and 60 of the Registration Statement in response to the Staff's comment.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 77-78 of the Registration Statement in response to the Staff's comment to include the fair value of the Company's common stock ("**Common Stock**") for each grant date of stock based awards as well as the significant factors considered by the Company's board of directors in their determination of fair value.

In addition, the Company respectfully advises the Staff as follows with respect to the changes in valuation from grant date to grant date.

December 31, 2019 Valuation and February 14, 2020, May 1, 2020 and May 19, 2020 Stock Option Grants

For the December 31, 2019 valuation (the "**December Valuation**"), the Company utilized the invested capital method to determine the enterprise value and the OPM as the primary allocation methodology. The invested capital method and OPM was used as there had not been any recent third-party financings and the Company was wholly owned by RA Capital. Additionally, the invested capital method considered the Company's preclinical stage of development as well as prospects and related valuations for future third party financings. The concluded Common Stock value was $0.95 per share at the non-marketable, minority level of value.

The Company granted options to purchase a total of 250,000 shares of Common Stock at an exercise price of $0.95 per share from February 14, 2020 to May 19, 2020. The Company's board of directors determined the estimated fair value of the Common Stock at the time of the grants was $0.95 per share based on a number of factors, including the December Valuation by an independent third party as well expected valuations associated with an anticipated preferred stock financing.

August 5, 2020 Valuation and September 4, 2020 and November 24, 2020 Stock Option Grants

For the August 5, 2020 valuation (the "**August Valuation**"), the Company utilized the OPM methodology, which was based in large part on the August 5, 2020 pricing of the Series A redeemable convertible preferred stock financing (the "**Series A Financing**"), to derive the implied equity value for the Company. Within the OPM framework, the back solver method for inferring equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility, and risk-free rate and then solving for the value of the equity such that the implied value for the most recent financing equals the amount paid. This method was selected as the Company concluded that the contemporaneous Series A Financing was an arm's length transaction. The Series A Financing was structured as a tranched transaction, affording the initial investors in the Series A Financing the right or obligation, depending on certain outcomes, to participate in three additional tranches of the Series A Financing. The OPM back solve model was designed to take into account these features of the three subsequent milestone closings. The concluded Common Stock value was $0.56 at the non-marketable, minority level of value.

On September 4, 2020, the Company modified the 250,000 previously granted stock options at a per share exercise price of $0.95 to a per share exercise price of $0.56, and, as a result of the modification, recorded incremental stock-based compensation expense for the change in fair value of the modified awards.

In addition to the 250,000 modified stock option grants, the Company granted options to purchase a total of 441,645 shares of Common Stock at an exercise price of $0.56 per share from September 4, 2020 to November 24, 2020. The Company's board of directors determined the estimated fair value of the Common Stock at the time of the grants was $0.56 per share based on a number of factors, including the August Valuation by an independent third party.

February 1, 2021 Valuation and April 2, 2021 Stock Option Grants

On February 1, 2021, the Company completed the first of three milestone closings (the "**First Milestone Closing**") under the Series A Preferred Stock Purchase Agreement and sold 4,224,274 shares of Series A redeemable convertible preferred stock at $1.893 per share for aggregate gross proceeds of $8.0 million. As of the beginning of February 2021, the Company had completed certain preclinical experiments and received the results from its Phase 1 study demonstrating safety and tolerability of doses that were to be carried forward to a Phase 2b/3 trial.

As a result of the Company completing the First Milestone Closing, a valuation was performed as of February 1, 2021 (the "**February Valuation**"). For the February Valuation, the Company used a hybrid of the PWERM and the OPM. The hybrid method applied the PWERM utilizing the probability of going public or exiting through an acquisition transaction and the OPM was utilized in a stay private scenario. The hybrid method was used because the Company was considering a near-term initial public offering ("**IPO**") and a longer term stay private scenario. The resulting estimated fair value of the Company's Common Stock was $0.69 per share on a non-marketable, minority basis.

On April 2, 2021 the Company granted options to purchase a total of 5,285,039 shares of Common Stock at an exercise price of $0.69 per share. The Company's board of directors determined the estimated fair value of the Common Stock at the time of the grants was $0.69 per share based on a number of factors, including the February Valuation by an independent third party.

May 15, 2021 Valuation and June 2, 2021 Stock Option Grants

During April and May of 2021, several events took place that impacted the equity valuation:

- On April 5, 2021, the Company held the organizational meeting for the IPO.
- On April 14, 2021, the Company held an end of Phase 1 meeting with the FDA to present findings from the AV-101 Phase 1 trial along with information on drug substance and drug product. Further, at the meeting with the FDA, the Company reached alignment with the FDA that the AV-101 Phase 2b/3 trial design was acceptable and could, if successful, support a NDA submission.

- On May 6, 2021, the Company confidentially submitted its Draft Registration Statement on Form S-1.

- On May 27, 2021, the Company was notified that the first Internal Review Board accepted as satisfactory the Company's clinical protocol for its Phase 2b/3 clinical trial.

For the May 15, 2021 valuation (the "**May Valuation**"), the Company used a hybrid of the PWERM and the OPM. The hybrid method applied the PWERM utilizing the probability of going public or exiting through an acquisition transaction and the OPM was utilized in a stay private scenario. The hybrid method was used because the Company was considering a near-term IPO and a longer term stay private scenario. The resulting estimated fair value of the Company's Common Stock was $2.47 per share on a non-marketable, minority basis.

On June 2, 2021 the Company granted options to purchase a total of 25,800 shares of Common Stock at an exercise price of $2.47 per share. The Company's board of directors determined the estimated fair value of the Common Stock at the time of the grants was $2.47 per share based on a number of factors, including the May Valuation by an independent third party.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on pages 95-96 of the Registration Statement to include a patent application schedule in response to the Staff's comment.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosure on page 98 of the Registration Statement in response to the Staff's comment.

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.*

RESPONSE: The Company respectfully advises the Staff that it has revised the Exhibit Index of the Registration Statement in response to the Staff's comment to include the offer letter agreements and Senior Executive Cash Incentive Bonus Plan. The current offer letter agreements with the Company's named executive officers have been filed with the Registration Statement and the Senior Executive Cash Incentive Bonus Plan once finalized will be filed with a subsequent filing of the Company's Registration Statement on Form S-1.

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.*

RESPONSE: The Company respectfully advises the Staff that it has completed the final milestone closings under the Series A Preferred Stock Purchase Agreement and has updated the Registration Statement throughout to reflect these closings. The Company respectfully advises the staff that the Company has no further obligations to issue any additional shares under the Series A Preferred Stock Purchase Agreement.

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.*

RESPONSE: The Company respectfully acknowledges the Staff's comment and advises the Staff that it will provide the Staff, on a confidential basis under separate cover, copies of all written communications presented to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of such communications.

If you should have any questions regarding the enclosed matters, please contact the undersigned at (212) 813-8853

Sincerely,

/s/ Edwin M. O'Connor
Edwin M. O'Connor, Esq.

cc:

Timothy P. Noyes, Chief Executive Officer
George A. Eldridge, Chief Financial Officer

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