# **ALSTON & BIRD**

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April 28, 2017

Ms. Suzanne Hayes Assistant Director Office of Health Care and Insurance Division of Corporation Finance Securities and Exchange Commission 100 F Street, N.E. Mail Stop 3561 Washington, D.C. 20549

Re: Avenue Therapeutics, Inc.

**Draft Registration Statement on Form S-1** 

Submitted March 28, 2017 CIK No. 0001644963

Dear Ms. Hayes:

At the request and on behalf of our client, Avenue Therapeutics, Inc., a Delaware corporation (the "Company"), we hereby submit the following responses to the comments of the Staff of the Securities and Exchange Commission (the "Commission") received by letter dated April 24, 2017, relating to the Company's registration statement on Form S-1 submitted confidentially on March 28, 2017. The responses set forth in this letter have been prepared by the Company with our assistance.

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# Business, page 54 Advantages of IV Tramadol, page 57

#### **Comment:**

1. We note the survey on page 58 that was conducted outside of clinical trials suggests your candidate is safer than and as effective as a currently approved drug. Because approval of the FDA is dependent on its making a determination (according to criteria specified in law and agency regulations) that a drug is both safe and effective, it is premature to describe or suggest that your product candidate is safe of effective. Although you may rely upon the FDA's previous findings of safety and efficacy of an approved product, your product is still distinct from prior products approved by the FDA. Please revise this section, and throughout your disclosure, to remove any suggestions that your product candidate is safe or effective, will be approved, is more likely to receive FDA approval, or will be approved quickly.

## Response:

We have revised the survey on page 59 to reflect your comment. Furthermore, we have reviewed the disclosure throughout the document and revised it accordingly to remove any suggestions that the product candidate is safe or effective, will be approved, is more likely to receive FDA approval, or will be approved quickly.

#### Underwriting, page 99

#### Comment:

2. Please provide the disclosure required by Item 505 of Regulation S-K.

#### Response:

The Company has revised its disclosure on pages 102-103 in response to this comment.

#### Comment:

3. We note your disclosure on page 101 of a conflict of interest with one of the underwriters and that your offering will be conducted in accordance with the requirements of FINRA Rule 5121. Please expand your disclosure to describe briefly the specific impact of these requirements on your offering.

## **Response:**

The Company has revised its disclosure on page 101 in response to this comment

# **Comment:**

4. 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:

Neither the Company nor any authorized persons have presented any written communications, as defined in Rule 405, to potential investors in reliance on Section 5(d).

# **Comment:**

5. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

## Response:

The Company is not currently providing any graphics, visual or photographic information in its printed prospectus, but will provide this information if included in future supplements.

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The Company acknowledges that it is responsible for the adequacy and accuracy of the disclosure in the filing, that staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing and that the Company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

If you have any further questions, comments or informational requests relating to this matter, please do not hesitate to contact me at the telephone number above.

Sincerely,

Mark F. McElreath