



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

DIVISION OF  
CORPORATION FINANCE

Mail Stop 4546

April 24, 2017

Lucy Lu, M.D.  
Interim President and Chief Executive Officer  
Avenue Therapeutics, Inc.  
2 Gansevoort Street, 9th Floor  
New York, New York 10014

**Re: Avenue Therapeutics, Inc.  
Draft Registration Statement on Form S-1  
Submitted March 28, 2017  
CIK No. 0001644963**

Dear Dr. Lu:

We have limited our review of your draft registration statement to the issues we have addressed in our 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.

Business, page 54

Advantages of IV Tramadol, page 57

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 or 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.

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Underwriting, page 99

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

Other Comments

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.
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.

Please contact Jeffrey Gabor at (202) 551-2544 or Mary Beth Breslin at (202) 551-3625 with any questions.

Sincerely,

/s/ Mary Beth Breslin for

Suzanne Hayes  
Assistant Director  
Office of Healthcare and Insurance

cc: Mark McElreath, Esq.  
Alston & Bird LLP