

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

CORRECTEDMail Stop 4720

February 26, 2016

Lucy Lu, M.D.
Interim President and Chief Executive Officer
Avenue Therapeutics, Inc.
3 Columbus Circle, 15th Floor
New York, New York 10019

Re: Avenue Therapeutics, Inc.

Amendment No. 1 to Registration Statement on Form 10

Filed February 18, 2016

Letter dated February 9, 2016

File No. 000-5556

Dear Dr. Lu:

We have reviewed your amended filing and your February 9, 2016 response to our comment letter and have the following comments.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response and any amendment you may file in response to these comments, we may have additional comments.

Item 1. Business, page 1

Licensing Agreements and Collaborations, page 4

1. Please expand the disclosure revised in response to prior comment 5 to describe all of the material termination provisions in Article 16 of the Revogenex license agreement or tell us why you do not believe such disclosure is necessary.

Our Development and Regulatory Strategy for IV Tramadol, page 8

2. We note your revised disclosure in response to prior comment 9. Please revise to define the term "QT (QTc) interval" in the first paragraph of this section.

Lucy Lu, M.D. Avenue Therapeutics, Inc. February 26, 2016 Page 2

Item 2. Financial Information, page 30

Liquidity and Capital Resources, page 31

- 3. We note your response to our previous comment 14. Please include this disclosure in your amendment.
- 4. We note your response to our previous comment 15. In addition to including this disclosure in your amendment, please also provide an estimate of the cost to complete the PK study. Refer to Item 303(a)(1) of Regulation S-K, which requires identification of any known trends or any known demands, commitments, events or uncertainties that will result in or that are reasonably likely to result in your liquidity increasing or decreasing in any material way.

Note 2 – Significant Accounting Policies

Net Loss per Share, page F-10

5. Please refer to prior comment 24. You state that 1,000,000 shares of restricted common stock granted to Dr. Lu were excluded from the basic loss per share calculation. Please support this assertion by providing us with your calculation of the weighted average number of common shares outstanding of 8,640,755 shares.

Note 4 —License Agreement, page F-11

6. Please revise your disclosure to include the \$4 million milestone payment and its triggering event as described on page 4.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Exchange Act of 1934 and all applicable Exchange Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Lucy Lu, M.D. Avenue Therapeutics, Inc. February 26, 2016 Page 3

You may contact Franklin Wyman at (202) 551-3660 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at (202) 551-6553 or Mary Beth Breslin at (202) 551-3625 with any other questions.

Sincerely,

/s/ Mary Beth Breslin for

Suzanne Hayes Assistant Director Office of Healthcare and Insurance

cc: Mark McElreath, Esq. Alston & Bird LLP