



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

DIVISION OF  
CORPORATION FINANCE

Mail Stop 4720

January 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.  
Registration Statement on Form 10  
Filed December 30, 2015  
File No. 000-55556**

Dear Dr. Lu:

We have reviewed your filing 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 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.

General

1. Please note that pursuant to Exchange Act Section 12(g)(1), this registration statement on Form 10 becomes effective automatically 60 days after its initial filing. You will then be subject to the reporting requirements of the Exchange Act of 1934, including the requirements to file Forms 10-K, 10-Q, and 8-K even if comments remain open on the Form 10. If you do not wish to become subject to these reporting requirements before completion of our review, you may wish to consider withdrawing the Form 10 before it becomes effective automatically and submitting a new Form 10 that includes changes responsive to our comments. Please note that we will continue to review your filing until all of our comments have been addressed.
2. We note that you plan to submit an application for confidential treatment with respect to one of the documents you have filed as an exhibit to your registration statement. Please be advised that we will review this application independently and will forward you any comments relating to your confidential treatment request under separate cover.

Business, page 1

Overview, page 1

3. We note your statement that the analgesic efficacy of oral and parenteral tramadol is similar to that of morphine or alfentanil and superior to that of pentazocine. Please expand your disclosure to identify more specifically the basis for this statement.
4. We note your statement that the advantages of IV Tramadol are likely to include a favorable side effect profile and favorable safety compared to standard-of-care opioids and NSAIDS. Please revise to disclose the basis for these statements. To the extent that you do not have any clinical testing to support your statements concerning these indications, please disclose the absence of testing in support of these statements.

Licensing Agreements and Collaborations, page 4

5. Please revise your disclosure of the License Agreement with Revogenex to include:
  - any material rights and obligations under the agreement,
  - the duration of the agreement and the royalty term,
  - a description of termination provisions,
  - investment features or share purchases,
  - the up-front payment made by Fortress,
  - aggregate future potential milestone payments to be paid,
  - any profit or revenue sharing provisions, and
  - any minimum purchase requirements.

We may have additional comments once the agreement is filed as an exhibit.

6. Please expand your disclosure relating to the Founders Agreement to include the full consideration paid and to be paid for the assignment of the License Agreement.

Employees, page 5

7. Please expand your disclosure to include the number of hours per week that the Executive Chairman, interim President and Chief Executive Officer and the interim Chief Financial Officer devote to your business activities. In addition, please add a risk factor to highlight the risks related to not having full-time employees.

Supply and Manufacturing, page 5

8. Please identify the manufacturer that provides your clinical and commercial supply of IV Tramadol. Refer to Item 101(h)(4)(v) of Regulation S-K. In addition, to the extent that

you are substantially dependent on this relationship, please file any underlying agreement with this party as an exhibit to your registration statement.

Government and Industry Regulations, page 5

9. We note that you acquired from Revogenex the rights to an open U.S. Investigational New Drug Application pertaining to IV Tramadol, as well as all supporting documentation and relevant correspondence with the FDA. Under the caption “Our Development and Regulatory Strategy for IV Tramadol,” please provide a description of the preclinical studies and clinical trials that have taken place to date.
10. We note that you anticipate performing a pharmacokinetics (PK) study in 2016. In your discussion regarding the procedural steps for FDA approval to market a product, please describe how a PK study fits into this timeline. Please also describe what a PK study involves.

Item 1A. Risk Factors, page 9

“Fortress has the right to receive a significant grant of shares...,” page 29

11. Please revise your disclosure to state that Fortress has the right to receive a grant of Common Stock rather than Class A Common Stock.

“We might have received better terms from...,” page 29

12. Please reconcile the statement here that your agreements with Fortress include a sublease and your statement under the heading “Properties” on page 32 that you are not currently under a lease agreement. In addition, if there is a sublease agreement, please file it as an exhibit to this registration statement. See Item 601(b)(10)(ii)(D) of Regulation S-K.

“The dual roles of our officers and directors...,” page 29

13. Please add disclosure to this risk factor about the Manager’s exemption from fiduciary duties relating to corporate opportunities under the Management Services Agreement.

Item 2. Financial Information, page 31

Liquidity and Capital Resources, page 31

14. We note that you have received an opinion from your registered public accounting firm that expresses substantial doubt about your ability to continue as a going concern. Please indicate how long you will be able to fund your current operations based on your current financial standing.

15. Please provide disclosure identifying any significant development milestones, an estimate of the material costs associated with achieving those milestones and the sources of funds needed to cover those costs and expenses.

Item 4. Security Ownership of Certain Beneficial Owners, page 32

16. We note your disclosure in the table on page 33 of the number of shares and the percentage of total common equity is aggregated between two different classes of common stock which, according to your disclosure on page 43, have different voting rights and which vote as separate classes of securities. Please revise to present ownership of each class separately.

Item 5. Directors and Executive Officers, page 34

17. Please expand your disclosure in the biographical information provided for your non-executive directors to discuss briefly the specific experiences, qualifications, attributes or skills that led to the conclusion that each director should serve in that capacity pursuant to Item 401(e)(1) of Regulation S-K.

Item 6. Executive Compensation, page 36

18. Please revise to include a Summary Compensation Table per Item 402(n) of Regulation S-K. Include disclosure for the individuals serving as your principal executive officer or acting in a similar capacity during the last completed fiscal year and the two most highly compensated executive officers other than the principal executive officer. Refer to Item 402(m)(2) of Regulation S-K. For instance, we note the grant of options to Dr. Lu in June 2015 and the accrual of expenses paid to Fortress as compensation paid to Dr. Lu.
19. Please provide narrative disclosure regarding the company's compensation policy as it relates to risk management. Refer to Item 402(s) of Regulation S-K.
20. We note that you do not currently have a compensation committee. We also note that your 2015 Incentive Plan is to be administered by the Compensation Committee. Please provide information regarding your plans to form a compensation committee.

Item 7. Certain Relationships and Related Transactions, and Director Independence, page 40

21. Please expand your disclosure to describe the basis on which the CEO of Revogenex is a related party. Also, to the extent it is material, please file the agreement as an exhibit to your registration statement.

Item 15(b). Exhibits, page 45

22. Please file Exhibit A to the Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc. Please also file as an exhibit the agreement with Chord Advisors, LLC or tell us why it is not required to be filed. Refer to Item 601(b)(10)(ii)(A) of Regulation S-K.

Notes to Financial Statements, page F-7

Note 1 – Organization, Plan of Business Operations and Going Concern Consideration, page F-7

Licenses Acquired, page F-10

23. Please tell us why you expensed the \$3 million license payment for the intravenous formulation of Tramadol when you appear to have accounted for the transaction as a business combination. Refer to ASC 730-10-15-4f.

Net loss per Share, page F-10

24. Please tell us how you accounted for the 1,000,000 shares of restricted common stock granted to Dr. Lu in your net loss per share calculation.

Note 9 – Fair Value Measurement, page F-15

25. Please explain why the fair value of the contingently issuable warrants did not change between February 17, 2015 and October 31, 2015.

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.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- 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
- 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.

Lucy Lu, M.D.  
Avenue Therapeutics, Inc.  
January 26, 2016  
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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