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February 9, 2016

Ms. Suzanne Hayes
Assistant Director
Office of Healthcare and Insurance
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, N.E.
Mail Stop 4720
Washington, D.C. 20549

Re: **Avenue Therapeutics, Inc.**
Registration Statement on Form 10
Filed December 30, 2015
File No. 000-55556

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 January 26, 2016, relating to the Company's Registration Statement on Form 10 filed on December 30, 2015 (the ***"Form 10"***). These responses have been prepared by the Company with our assistance.

Enclosed herewith is a proposed amended version of the Form 10 ("***Proposed Amended Form 10***") that addresses the Commission's comments in its January 26, 2016 letter. The revisions in the Proposed Amended Form 10 are marked for your convenience. We intend to file the amended Form 10 once we have confirmation from the Commission that the proposed revisions in the Proposed Amended Form 10 are acceptable. Please note that the Proposed Amended Form 10 also includes some changes resulting from the addition of Dr. Scott A. Reines as the Interim Chief Medical Officer of Avenue.

General

Comment:

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.

Response:

It is the Company's intention to resolve all open comments prior to the effectiveness of the registration statement, and, if necessary, the Company will withdraw the registration statement prior to the automatic effective date, and continue to work to complete the review process.

Comment:

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.

Response:

Enclosed with this letter is a Confidential Treatment Request for Exhibit 10.1 to the Form 10, which is the Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015. We understand that you will review this Confidential Treatment Request independently.

Business, page 1

Overview, page 1

Comment:

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.

Response:

We propose to remove the following sentence from the Form 10: “Its overall analgesic efficacy is similar to that of morphine or alfentanil and superior to that of pentazocine.”

In its place, we proposed to add the following language:

“In clinical studies, the overall analgesic efficacy of parenteral tramadol is similar to that of morphine and meperidine and comparable or superior to that of pentazocine.

In a study published in *Drugs under Experimental and Clinical Research* (http://www.ncbi.nlm.nih.gov/pubmed/9604144), 70 patients were treated with parenteral morphine or tramadol following abdominal surgery. Both drugs gave rapid and constant pain relief. The study investigators concluded that tramadol given by intramuscular injection has postoperative analgesic activity similar to morphine.

In a study published in *Methods and Findings in Experimental and Clinical Pharmacology* (http://www.ncbi.nlm.nih.gov/pubmed/8738073), 48 patients after total hip or knee replacement were randomly distributed into tramadol, meperidine or saline. The conclusion of the study was that meperidine and tramadol produced comparable analgesia.

In a study published in *International Journal of Pharmacological Research* (http://www.ncbi.nlm.nih.gov/pubmed/9675626), a total of 50 adults were given tramadol or pentazocine by intramuscular injection for three days post-surgery. The first dose of tramadol was significantly more effective than pentazocine after the first hour. Study investigators concluded that final judgements on efficacy and acceptability were in favor of tramadol while both produced good analgesia.”

Please see the Proposed Amended Form 10 for this change.

Comment:

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.

Response:

The basis for these statements is from prescribing labels of oral tramadol, various opioids and NSAIDS, as well as the numerous studies that compared parenteral tramadol with opioids. The side effect profile and tolerability issues of NSAIDS such as bleeding risk, renal toxicity and gastrointestinal irritation are well documented and appear in their labels. A selection of the publications are as follows:

In a study published in *Anesthesia & Analgesia* (http://www.ncbi.nlm.nih.gov/pubmed/1554117), tramadol and morphine were compared in a double-blind, randomized study of 150 female patients after gynecologic surgery. Oxygen saturation, a surrogate for respiratory function, was monitored continuously by pulse oximetry for at least thirty minutes after each injection. In 13.3% of the patients in the morphine group (but in none of the tramadol group), transcutaneous pulse oxygen saturation decreased to less than 86%. The authors concluded that both drugs produced acceptable analgesia, and they underline tramadol's safety for postoperative pain relief.

In a study published in *Methods and Findings in Experimental and Clinical Pharmacology* (http://www.ncbi.nlm.nih.gov/pubmed/8738073), 48 patients after total hip or knee replacement were randomly distributed into tramadol, meperidine or saline groups. The conclusion of the study was that meperidine and tramadol produced comparable analgesia, but meperidine induced sedation and respiratory depression, whereas tramadol did not.

Based on the foregoing, we propose to re-word the applicable bullet point in the Form 10 to read as follows: "Based upon various studies and other available information, a favorable side effect profile compared to current standard-of-care opioids and injectable NSAIDs, including a reduced risk of respiratory depression, excessive sedation, hemodynamic effects (such as hypotension), dependency, bleeding risk, renal toxicity and gastrointestinal irritation, and immune system depression."

Please see the Proposed Amended Form 10.

Licensing Agreements and Collaborations, page 4

Comment:

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.

Response:

Please see the Proposed Amended Form 10 for the revised disclosure.

Comment:

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.

Response:

We have added a cross reference in this section to the full summary of the Founders Agreement on page 40 of the Proposed Amended Form 10.

Employees, page 5

Comment:

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.

Response:

Dr. Lucy Lu, our Interim President and Chief Executive Officer, will serve in a full-time capacity as Avenue's President and Chief Executive Officer once the Form 10 becomes effective. Please see the Proposed Amended Form 10 for language we have added to explain this.

As can be seen from her biography, she has extensive experience in the biopharmaceutical industry and in healthcare-related equity research and investment banking. We therefore do not believe any revisions or an additional risk factor are warranted. Further, under the Management Services Agreement, any assistance Avenue may need will be provided by Fortress.

Supply and Manufacturing, page 5

Comment:

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.

Response:

Z.F. Polpharma S.A. ("Polpharma") is the manufacturer that supplies us with both clinical and commercial supply of IV Tramadol. We are not substantially dependent on Polpharma for our supplies, and we believe it would be relatively easy to find another supplier if Polpharma cannot meet its obligations.

Government and Industry Regulations, page 5

Comment:

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.

Response:

Revogenex completed two nonclinical PK and toxicology studies in dogs, a Phase I dose proportionality study, as well as a TQT study of IV tramadol. The dose proportionality study was designed to compare maximum exposure and cumulative exposures of IV tramadol to that of oral tramadol, and to assess the dose proportionality of IV tramadol in healthy adult volunteers. The TQT study was done to evaluate whether IV Tramadol has the potential to affect the corrected QT (QTc) interval in healthy volunteers.

Please see the Proposed Amended Form 10 for the revised disclosure.

Comment:

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.

Response:

We are running a PK study to determine a dosing regimen for IV tramadol that provides a similar exposure profile to that of oral tramadol. This dosing regimen will be utilized in our Phase III program. If the PK study and the Phase III program are successful, we would then expect to submit an NDA for approval of IV Tramadol to treat moderate to moderately severe post-operative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act.

A PK study generally involves dosing an experimental medicine in healthy volunteers and taking a series of blood measurements from the study participants to understand how the body handles the drug. A PK study provides information on important parameters such as systemic exposure, maximal and minimal levels of drug concentration in the blood, and their time courses.

Please see the Proposed Amended Form 10 for the revised disclosure.

Item 1A. Risk Factors, page 9

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

Comment:

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.

Response:

Please see the Proposed Amended Form 10 for the revised disclosure.

"We might have received better terms from...," page 29

Comment:

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.

Response:

Our agreements with Fortress do not include a sublease. The disclosure has been revised to correct this mistake.

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

Comment:

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.

Response:

Please see the Proposed Amended Form 10 for the revised disclosure.

Item 2. Financial Information, page 31

Liquidity and Capital Resources, page 31

Comment:

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.

Response:

Based on Avenue's current financial standing, Avenue expects that it will have sufficient resources to complete the PK study, but will need to raise capital to initiate its planned Phase III program for IV Tramadol.

Comment:

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.

Response:

Significant development milestones include the completion of the PK study and the planned Phase III program. The planned Phase III program will cost approximately $20 million to complete, and Avenue will need to raise funds to complete the Phase III program.

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

Comment:

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.

Response:

Please see the Proposed Amended Form 10 which has been revised in response to this comment.

Item 5. Directors and Executive Officers, page 34

Comment:

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.

Response:

The experiences, qualifications, attributes and skills of each of Avenue's non-executive directors set forth below led to the conclusion that such directors should serve on Avenue's board of directors, and their unique experiences, qualifications, attributes and skills are all important for members of Avenue's board of directors to have.

Mr. Michael S. Weiss has experience as an executive of biotech companies and the Fortress group of companies, specifically. Mr. Neil Herskowitz has experience serving as a director of other public companies. Dr. Jeffrey Paley has experience in medicine and clinical trials and experience as a director of other biotech companies. Dr. Akhtar Samad has experience in biopharmaceutical equity research, strategy and finance.

Please see the Proposed Amended Form 10, which has been revised in to include the foregoing information.

Item 6. Executive Compensation, page 36

Comment:

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.

Response:

A Summary Compensation Table has been added to the Proposed Amended Form 10.

Comment:

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.

Response:

According to the final adopting release 33-9089, Item 402(s) of Regulation S-K does not apply to smaller reporting companies.

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.

Response:

Please see the Proposed Amended Form 10 for disclosure we have added explaining that although the Compensation Committee has not yet been formed, it will be formed before any necessary actions to be taken by the Compensation Committee with respect to the 2015 Plan are taken.

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

Comment:

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.

Response:

The Chief Executive Officer of Revogenex is not a related party and therefore we have removed this disclosure.

Please see the Proposed Amended Form 10.

Item 15(b). Exhibits, page 45

Comment:

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.

Response:

Exhibit A to the Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc. was included in Exhibit 10.4 to the Form 10.

With regard to the agreement with Chord Advisors, LLC, we believe that it is "immaterial in amount or significance" and, further, none of the persons mentioned in the lead phrase of Item 601(b)(10)(ii)(A) of Regulation S-K are "parties" to the agreement.

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

Comment:

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.

Response:

The acquisition of the IV Tramadol license and the assumption of liabilities in connection with this license was accounted for as a transaction among businesses under common control. Because the license and assumption of liabilities met the definition of a business (as defined in ASC 805), the transfer of the business represented a transfer among entities under common control which should be accounted for at carrying amount with retrospective adjustment of prior period financial statements similar to the manner in which a pooling-of-interest was accounted for under APB 16, *Business Combinations.* Therefore, the acquisition of the license by Fortress (and transferred to Avenue) represented a Research and Development expenditure, which should be expensed pursuant to ASC 730 *Research and Development.*

Net loss per Share, page F-10

Comment:

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.

Response:

The first sentence of the net loss per share disclosure on page F-10 will be replaced with the following sentence: "Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding (excluding the impacted of unvested restricted stock) during the period." Specifically, the 1,000,000 shares granted to Dr. Lu were excluded from the basic loss per share pursuant to ASC 260 because they were unvested and were also excluded from the diluted loss per share because they were antidilutive.

Please see the Proposed Amended Form 10.

Note 9 – Fair Value Measurement, page F-15

Comment:

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

Response:

The only underlying assumption that changed from the assumed measurement date of the contingently issuable warrants, February 17, 2015 through through October 31, 2015, was the risk free rate and the expected term. All other inputs remained constant (expected volatility, stock price or estimated probability of a Qualified Financing). There were no triggering events that occurred from February 2015 to October 2015 that impacted the expected volatility, stock price or estimated probability of a Qualified Financing. Therefore, the change in fair value was considered immaterial and Avenue did not record a change in fair value of the contingently issuable warrants.

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,

/s/ Mark F. McElreath

Mark F. McElreath