



DIVISION OF
CORPORATION FINANCE

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

December 2, 2015

Via E-mail

Matthew R. Patterson
President and Chief Executive Officer
Audentes Therapeutics, Inc.
101 Montgomery Street, Suite 2650
San Francisco, California 94104

**Re: Audenties Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted November 6, 2015
CIK No. 0001628738**

Dear Mr. Patterson:

We have reviewed your draft registration statement 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 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.

Prospectus Summary
Overview, page 1

1. Throughout your prospectus, when characterizing the results of your preclinical trials, you include statements that you believe your product candidates are “advantageous for the treatment of Pompe disease,” may provide “long term clinical benefit to...patients,” “may provide long-term improvement in patient symptoms,” “demonstrated an ability to prevent ventricular tachycardia,” and similar statements regarding the potential efficacy of your product candidates. Because approval of the FDA and other comparable regulatory agencies is dependent on such agencies’ making a determination (according to criteria specified in law and agency regulations) that a drug or biologic is both safe and effective, it is premature for you to describe or suggest that your product candidates, or any other non-approved product is safe or effective. Accordingly, please revise your

disclosure as necessary to balance these statements and make clear that any observations you make about your products' potential for safety or efficacy are your own, are not based on the FDA's or any other comparable governmental agency's assessment, and do not indicate that your products will achieve favorable results in any later trials or that the FDA or comparable agency will ultimately determine that your product is safe and effective for purposes of granting marketing approval.

2. Please amend your disclosure to explain what vectors are.
3. Please define "capsid serotypes" where this term is first used.
4. Please note here that no gene therapy products have been approved in the United States to date and that only one has been approved in Europe.

Risks Related to Our Business, page 5

5. Please include additional bullet points that address the risks associated with:
 - the fact that your product candidates based on gene therapy technology may cause side effects, and note how there have been several adverse effects identified in clinical trials on gene therapy treatments in the past;
 - your limited operating history and history of operating losses; and
 - the fact that all of your current product candidates are licensed from or based on licenses from third parties.

Risk Factors

Risks Related to Product Development and Regulatory Approval

"We have not tested any of our product candidates in clinical trials . . .," page 13

6. Please provide examples of the clinical trials performed by other companies on viral vectors and their results.

"Delays in establishing that our manufacturing process and facility comply with Current Good Manufacturing Practices . . .," page 18

7. The possibility that the manufacturing facilities you currently use may not be complying with cGMPs is a distinct material risk that you should address in an independent risk factor. Please amend your disclosure to include such a risk factor, including the range of penalties for non-compliance, under the heading "Risks Related to Manufacturing and Commercialization."

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business
“Product liability lawsuits could cause us to incur substantial liabilities . . .” page 53

8. Please amend this risk factor to include the monetary limit of the product liability insurance you intend to obtain for your planned clinical trials.

Industry and Market Data, page 59

9. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please revise your disclosure to remove your statement that investors “are cautioned not to give undue weight to such estimates.”

Use of Proceeds, page 60

10. Please separate the amounts of offering proceeds you intend to allocate to each of your three product candidates.
11. Please separate the amount you intend to allocate toward hiring, capital expenditures, and public company expenses from the amount for working capital and general corporate purposes.

Management’s Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Estimates
Stock-Based Compensation Expense, page 71

12. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of the common stock leading up to the IPO and the estimated offering price.

Business
Overview, page 80

13. Please provide examples of the “supportive treatment options” for XLMTM and the “limited treatment options” for CPVT that are currently available.

Our AAV Product Candidates, page 85

14. In your discussion of AT001, please explain what a desmin promoter is.
15. In your discussion of preclinical testing performed to date, please clarify the number of subjects in each study and explain the concept of statistical significance, what the p-values you disclose represent, and what the asterisks in your bar graphs are intended to capture.

16. We note your statement that your RECENSUS retrospective medical chart review “may serve as a historical control for the planned Phase 1/2 trial” of AT001. Please revise your discussion to describe the limitations of using such a historical control to demonstrate statistical significance of results in subsequent trials or otherwise for purposes of obtaining FDA approval of marketing or labeling claims.

Manufacturing, page 93

17. In the second risk factor on page 29, you state that you have entered into agreements with manufacturers to support your clinical studies. Please describe these agreements here where you discuss the current status of your manufacturing, including their material terms, and file them as exhibits to your registration statement. If you do not believe these agreements are material, please provide an analysis to that effect in a response to this comment.

Notes to Unaudited Interim Condensed Consolidated Financial Statements

12. Subsequent Events

Series C Financing, page F-38

18. Please ensure the pro forma presentation on your balance sheet reflects the issuance of 9,645,913 shares of Series C convertible preferred stock that occurred in October.

Exhibits and Financial Statement Schedules, page II-3

19. Please file each of the following agreements as an exhibit to your registration statement:
- your Cardiogen acquisition agreement; and
 - the employment agreements with Ms. Holles and Mr. Soloway.

Other Comments

20. 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.
21. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.

Matthew R. Patterson
Audentes Therapeutics, Inc.
December 2, 2015
Page 5

You may contact Tabatha McCullom at (202) 551-3658 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Amy Reischauer at (202) 551-3793 or me at (202) 551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes

Suzanne Hayes
Assistant Director
Office of Healthcare and Insurance

cc: Effie Toshav, Esq.
Robert Freedman, Esq.
James Evans, Esq.
Fenwick & West LLP
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San Francisco, California 94104