

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

February 19, 2015

Via E-mail
Jill C. Milne, Ph.D.
President and Chief Executive Officer
Catabasis Pharmaceuticals, Inc.
One Kendall Square
Bldg. 1400E, Suite B14202
Cambridge, Massachusetts 02139

Re: Catabasis Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted January 23, 2015
CIK No. 0001454789

Dear Dr. Milne:

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.

#### Summary

#### Our Product Candidates, page 2

- 1. In your discussions of CAT-1004, please briefly describe what salicylate and docsahexaenoic acid (DHA) are.
- 2. Please briefly explain the eligibility criteria and significance of orphan drug designation by the FDA and EMA.
- 3. Please explain in lay terminology the expressions "adipose tissue infiltration" and "lipid metabolism" used on page 2 and "gene transcription factor" used on page 4.

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- 4. In your discussion of the CAT-2000 products, please briefly describe what eicosapentaenoic acid (EPA) and nicotinic acid are.
- 5. Please briefly describe, in terms comprehensible to a lay reader, the specific way and the mechanics by which each of your four product candidates modulates the respective cellular pathways.

## Risk Factors, page 9

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates "Adverse events or undesirable side effects caused by, or other unexpected properties of, any of our product candidates may be identified . . .," page 18

6. Please briefly describe the gastrointestinal tolerability issues you identified in your CAT-2003 trials.

# <u>Risks Related to Employee Matters and Managing Growth</u> "Our future success depends on our ability to retain our Chief Executive Officers and other key

executives . . .," page 43

7. Please amend this risk factor to list the names and titles of the principal members of your management, scientific and development team whose departure could have a material effect, apart from your Chief Executive Officer.

#### Special Note Regarding Forward-Looking Statements and Industry Data, page 50

8. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements that you have not independently verified third-party research, surveys and studies could imply that you are not taking liability for this information. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete these statements or include a statement specifically accepting liability for these statements.

#### Use of Proceeds, page 52

9. Where you indicate the estimated amount of offering proceeds you plan to allocate toward clinical development of your CAT-2000 product candidates, please separate the amount you intend to use for each of CAT-2003 and CAT-2054.

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Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates
Valuation of Common Stock, page 66

10. 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 your common stock leading up to the IPO and the estimated offering price.

#### Business, page 76

- 11. Please clarify what you mean by the terms "clinically meaningful" on pages 76 and 79 and "clinically important" on page 89. In particular, please address how such terms relate, if at all, to "statistical significance." For example, we note your statement on page 76 that your Phase 2 CAT-2003 trials demonstrated clinically meaningful reductions in triglyceride levels and improvement in other cardio-metabolic risk factors. It is unclear, however, whether or not this implies the results met the threshold for statistically significant efficacy. If not, please also revise to clarify the import of this distinction.
- 12. You disclose on page 82 and elsewhere in your draft prospectus that your product candidate was observed to be, or appeared to be, "safe." Because FDA approval is dependent on the agency itself making a formal determination (according to criteria specified in law and agency regulations) that a drug is "safe" and "effective," each of these terms has a singular meaning in the context of the FDA approval process. Using these terms or a variant of such terms to describe your product or the results of clinical trials before the drug has been approved by the FDA may suggest to some investors that FDA approval is probable or more likely than is justified. Accordingly, please revise your prospectus on page 82, and elsewhere as necessary, to remove or modify language characterizing your product candidates as "safe."
- 13. Where you discuss the adverse events reported from your completed clinical trials, please indicate how many patients experienced these events, as well as the number characterized as severe.

### Notes to the Financial Statements Note 7. Notes Payable, page F-18

14. Your credit agreement contains a provision of default in the event of the occurrence of a material adverse event, Please tell us why you believe classification as long-term debt is appropriate. Tell us what consideration was given to ASC 470-10-45. Clarify in the filing if a material adverse event could result in an acceleration of the debt.

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#### **Other Comments**

- 15. 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.
- 16. 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.
- 17. We further note that several exhibits have yet to be submitted for our review. Please submit these exhibits to us as soon as practicable.

You may contact Christine Torney at (202) 551-3652 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Steven D. Singer, Esq.
Rosemary G. Reilly,
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109