United States securities and exchange commission logo

May 27, 2021

Joshua B. Cohen, Justin B. Klee
Co-Chief Executive Officers
Amylyx Pharmaceuticals, Inc.
43 Thorndike St.
Cambridge, Massachusetts 02141

Re: Amylyx Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted April 26, 2021
CIK No, 0001658551

Dear Mr. Cohen:

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.

Draft Registration Statement on Form S-1

Summary, page 1

1. Please revise to explain the term foundational therapy.
2. Please revise the disclosure on page 1 to explain why FDA has requested that you conduct an additional trial in support of a New Drug Application. Identify the type(s) of topline data that you seek from the Phase 3 trial to support the NDA submission.
3. Please address the following with respect to your pipeline table:
   - revise to clearly demarcate where each phase or column begins and ends;
   - revise the first arrow to clarify that you did not conduct a Phase 3 trial, or advise; and
   - include upcoming milestones for the bottom two indications, or advise.

4. Please revise the Pipeline Overview to clarify that the PB and TURSO molecules are not proprietary and to clarify more specifically what is proprietary.
5. With reference to the risk factor disclosure on page 27, please revise the disclosure on page 3 to explain that the EU and Canadian authorizations you are seeking may be limited

or subject to restrictions, or advise.

6. Please revise the Summary, where appropriate, to highlight:
   - your disclosure on page 33 that you are aware of one ongoing clinical study in Europe which is evaluating the effects on ALS of TURSO, one of the two components in AMX0035, and
   - your disclosure on page 69 that there is uncertainty as to whether claims in your pending patent applications, including those claims covering the composition of matter of AMX0035, will be considered patentable by the USPTO or by patent offices in foreign countries.

The Offering, page 9

7. Please disclose on page 10 whether the number of shares of your common stock to be outstanding after this offering includes or excludes shares of your common stock that may be issuable upon conversion of the $27.3 million of convertible promissory notes you issued and sold to investors in January 2021.

Clinical Development of AMX0035 for ALS, page 130

8. Please revise here and on page 3 to explain who conducted and funded the survey and its purpose. Present in the Business section all material information concerning how the trial was conducted and its results.

9. Please revise to present the full open label extension results or advise.

Clinical Development Plan of AMX0035 in ALS, page 135

10. We note your disclosure concerning the size and duration of the planned Phase 3 trial. Please revise to identify the primary endpoint(s) or revise to clarify, if true, that the endpoint(s) are yet to be determined.

Clinical Development of AMX0035 for Alzheimers Disease, page 136

11. Please revise to qualitatively and/or quantitatively discuss each of the key endpoints.

Commercialization, page 138

12. Please revise the discussion to explain in greater detail your plans for obtaining coverage and reimbursement for AMX0035 to treat ALS in the U.S., Canada and the EU. For instance, please discuss, if material, whether your plan is to obtain coverage and reimbursement that is similar to the two currently approved ALS treatments cited on page 139. Explain what you would need to demonstrate in order to achieve orphan drug-like

prices in ALS in specific geographies. As applicable, discuss reimbursement codes and the dollar values associated with them.

13. Revise to discuss the duration of patient treatments. For instance, we note that your CENTAUR trial measured median survival rates.

14. With reference to your disclosure on page 167, please discuss when you would need to decide whether expensive pharmacoeconomic studies will or will not be necessary to demonstrate medical necessity and cost-effectiveness of AMX0035.

Intellectual Property, page 142

15. Please expand your disclosure to address the following:
   - for each of your patent families, disclose the foreign jurisdictions where you have been issued or granted patents and where you have patent applications pending;
   - for your second and third patent families, disclose any pending patent applications you have and the jurisdiction(s), thereof.

In this regard, it may be useful to provide tabular disclosure.

16. With reference to the disclosure on page 69, please revise your intellectual property discussion to address the significance of composition of matter patents to each patent family. With reference to your disclosures on pages 128-129, discuss whether these or other patents cover specific ratios of PB and TURSO. Also identify your one issued composition of matter patent and describe your issued European Patent, EP2978419 in greater detail.

Certain Relationships and Related Party Transactions
2021 Convertible Promissory Note Financing, page 190

17. Please expand your disclosure to describe the material terms of the 2021 Notes, including the terms of their conversion.

Principal Stockholders, page 193

18. Please identify the natural person(s) with voting and/or dispositive power over the shares owned by ALS Invest 1 B.V. and Morningside Venture Investments Limited.

General

19. Please 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.

You may contact Christine Torney at (202) 551-3652 and Al Pavot at (202) 551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact David Gessert at (202) 551-2326 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance

Office of Life Sciences

cc: Benjamin K. Marsh, Esq.