



DIVISION OF  
CORPORATION FINANCE

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

January 9, 2024

Amit Etkin  
Chief Executive Officer  
Alto Neuroscience, Inc.  
369 South San Antonio Road  
Los Altos, CA 94022

**Re: Alto Neuroscience, Inc.**  
**Amendment No. 1 to Draft Registration Statement on Form S-1**  
**Submitted December 28, 2023**  
**CIK No. 0001999480**

Dear Amit Etkin:

We have reviewed your amended draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No. 1 to Draft Registration Statement on Form S-1

Prospectus Summary

Overview, page 1

1. We note your response to prior comment 3, which we reissue in part.
  - Please describe, where appropriate, each of the discussions you have had with the FDA regarding your novel approach to the discovery and development of your product candidates using your Platform, as well as any material outcomes of such discussions.
  - Explain whether you are basing your current expectation that you may be required to develop and obtain FDA approval of a companion diagnostic for any of your product candidates upon your prior discussions with the FDA. Also, please describe when you expect to know more definitively the FDA's views on this subject and how such views may affect your plans.

2. We note your revisions in response to prior comment 5, which we reissue. Please further revise the disclosure on pages 1, 103, and 123 to include the information contained in your response to prior comment 5 in your letter dated December 28, 2023 concerning your goal to ultimately provide treatments, if approved, that are tailored to specific patient populations and explain how this might allow you to avoid the current lengthy paradigm of treating psychiatric patients.

Our Pipeline, page 3

3. We note your revisions in response to prior comment 7, which we reissue in part. Please revise your disclosure on pages 4, 104, and 125 to clarify whether or not the Company's representatives have had any interaction to date with the FDA regarding its willingness to accept foreign clinical trial data underpinning the recently submitted IND covering ALTO-203 in MDD. Also, please revise the Prospectus Summary to disclose the risk that the FDA or comparable regulators may not accept earlier clinical data generated abroad, in which case you may need to conduct additional clinical trials, as referenced in your risk factor on page 31.
4. We note your revisions in response to prior comment 13, which we reissue in part. Please further revise your discussion of the clinical development of your ALTO-202 program here and in the Business section where appropriate to disclose the following information with respect to any material clinical trials that third parties conducted:
  - the trial design;
  - the number of participants in the trial;
  - the primary and secondary endpoints as well as the results as they relate to those endpoints; and
  - the occurrence of any serious adverse events.

Additionally, please include a description of any material development activities you have conducted to date since licensing ALTO-202, relevant clinical work conducted or in process, and the remaining steps to develop and commercialize the product and disclose when you plan to initiate a Phase 2 trial for ALTO-202 and expect to report data from that trial.

Risk Factor Summary, page 8

5. Consistent with your disclosure on page 162 and elsewhere, please revise your summary risk and risk factor disclosure where appropriate to highlight that issued patents covering the composition of ALTO-202 are due to retire in 2024 (compound) and 2035 (polymorph) and patents covering the composition of ALTO-203 in 2027.

Business

ALTO-101 Biological Rationale, page 151

6. We note your response stating that you have revised disclosure on page 152 to ensure that the graphics included are legible. However, we observe that the revisions are not sufficient

Amit Etkin  
Alto Neuroscience, Inc.  
January 9, 2024  
Page 3

to render your disclosures easily readable without magnification, as certain text remains too small to be clear. Please further review and revise as appropriate.

Please contact Li Xiao at 202-551-4391 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Divakar Gupta