



DIVISION OF  
CORPORATION FINANCE

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

May 8, 2024

Michael McFadden  
Chief Executive Officer  
Alpha Cognition Inc.  
1200 - 750 West Pender Street  
Vancouver, BC, V6C 2T8

**Re: Alpha Cognition Inc.**  
**Amendment No. 2 to Draft Registration Statement on Form S-1**  
**Submitted April 23, 2024**  
**CIK No. 0001655923**  
**Registration Statement on Form S-1 filed April 30, 2024**  
**File No. 333-278997**

Dear Michael McFadden:

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

Please respond to this letter by amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our April 17, 2024 letter.

Amendment No. 2 to Draft Registration Statement on Form S-1

Our Business, page 1

1. We note your response to prior comment 1, which we reissue.
  - Please revise your narrative disclosure here and elsewhere as appropriate to expressly state, if true, that the following programs are in the preclinical development phase: (1) the sublingual formulation of ALPHA-1062 for the treatment of mild-to-moderate AD and (2) ALPHA-1062IN for mTBI. For example only, revise your statements that a certain product candidate is "in the early development stages" (page 5) or "is in development" (pages 1, 76 and 101) to provide greater specificity.
  - Remove or revise the following statement on page 1 to reflect the current status of any out-licensing plan: "ALPHA-1062...has been out-licensed to study an intranasal

formulation for cognitive impairment with mTBI," or otherwise advise. In this regard, it appears from your other disclosures that the out-license of ALPHA-1062IN technology has not yet occurred.

2. Refer to the first sentence of the third paragraph in this section. If accurate, please revise to clarify that ALPHA-0602, ALPHA-0702 and ALPHA-0802 are not the Company's only preclinical stage assets. In this regard, we note that the development of certain formulations of ALPHA-1062 are also currently in the preclinical development phase.
3. We note your response to prior comment 2, which we reissue. Notwithstanding the Company's plans to seek to out-license ALPHA-0602, please revise here and throughout where appropriate to briefly describe the eligibility criteria and significance of having obtained Orphan Drug Designation for ALPHA-0602 for the treatment of ALS from the FDA.
4. Please revise your disclosure to describe briefly what you mean by "pivotal" clinical trials the first time you use the term.

Our Products and Approaches to Treatment, page 3

5. With respect to your revised pipeline table on page 3:
  - We reissue prior comment 6 with respect to the final bullet. If the pursuit of any of indication may be delayed or is contingent upon obtaining additional resources (e.g., the out-licensing of ALPHA-1062IN for mTBI to, and funding of, Alpha Seven, or marketing ALPHA-1062 as a treatment for mild-to- moderate AD), please clearly disclose this in a footnote to the table.
  - Revise to provide context for the reference to Alpha Seven in the column captioned "Entity Responsible" in a footnote to the table.
  - It appears the previous heading which clarified that the top three rows reflect the development status of ALPHA-1062 programs has been deleted from the table. Please restore such heading.
6. We note your response to prior comment 7. In the narrative discussion following the pipeline table, you now state in various places that further development of various product candidates will be "contingent upon additional resources" that the Company or Alpha Seven Therapeutics do not currently have, respectively. Please revise further to specify the material resources that must be obtained by either company in order to advance development, and describe any plans to procure such resources, to the extent such plans have been developed.
7. We note your response to prior comment 8. Please further revise page 4 to remove any implications that your product candidates will be approved, will be approved quickly, or are more likely to receive FDA approval. In this regard, please:
  - clarify that use of the 505(b)(2) pathway does not guarantee an accelerated review by the FDA.
  - clarify that FDA approval is not guaranteed notwithstanding the Company's attempts

to conduct its pivotal studies "in direct alignment with the FDA feedback, as well as the FDA guidance document for 505(b)(2) approvals."

8. We note your response to prior comment 9, which we reissue. Please specifically revise the Summary in an appropriate place to disclose the geographic locations of completed clinical trials to date as you have on page 29. Alternatively, you may revise the summary risk factor on page 11 to clarify, if true, that all completed clinical trials of your product candidates to date have been conducted outside the United States.

Traumatic Brain Injury (TBI) Market, page 3

9. We refer to your disclosure that you commissioned a market research report by Decision Resources Group/Clarivate.
- Please revise to clarify the date of this market research report.
  - With respect to the statements in your prospectus that are based on this report, please revise to clarify whether such statements are statements of the third party or statements of the Company.
  - If your disclosure attributes a statement to the third party, or if you commissioned any other market or industry data cited in the prospectus including but not limited to research conducted by Infinity Group, please revise your filing to identify such third party and file a consent from such third party. Please see Securities Act Rule 436 and Question 233.02 of the Securities Act Rules Compliance and Disclosure Interpretations.

Traumatic Brain Injury: ALPHA-1062 Intranasal Formulation, page 5

10. We note your response to prior comment 11, which we reissue. The basis for the Company's expectation that Alpha Seven will complete the additional pre-clinical toxicity and manufacturing work for ALPHA-1062IN by the end of 2024 remains unclear, particularly in light of your disclosure that "further development work for ALPHA-1062IN will require additional resources which Alpha Seven Therapeutics does not currently have."

Recent Developments, page 9

11. We note your response to prior comment 14, which we reissue. In this regard, we note that the reference to the Issuer's Form 2A Listing Statement still appears at the bottom of page 9.

Research and development of pharmaceuticals is lengthy and inherently risky., page 31

12. Please revise the first sentence of this risk factor to clarify, if true, that other than the oral tablet formulation of ALPHA-1062 for AD, all of your other programs, including those related to other formulations of ALPHA-1062, are in pre-clinical development.

The regulatory approval processes of the FDA and other comparable foreign regulatory

authorities are lengthy..., page 51

13. We note your response to prior comment 18, which we reissue with respect to the first bullet. Your statement on page 52 that you have not submitted for regulatory approval for any product candidate is inconsistent with your disclosure elsewhere throughout that you have filed an NDA for ALPHA-1062 in AD. Please revise or advise.
14. The basis for your statement that you "have managed the regulatory approval process with the FDA or any other regulatory authority only a limited number of times" is unclear. In this regard, we note your disclosure on page 18 that to date, you have not yet demonstrated your ability to obtain regulatory approvals, among other things. Please revise or advise.

Our officers also serving as officers of Alpha Seven may give rise to a conflict of interest..., page 59

15. Your disclosure that the Company owns approximately 47.5 of the issued and outstanding shares of common stock of Alpha Seven is inconsistent with disclosure on page 1 that the Company retains 85.4% ownership of Alpha Seven. Please reconcile or otherwise advise.

ALPHA-1062 Clinical Development, page 80

16. We note your response to prior comment 19, which we reissue with respect to the first bullet. You state on page 80 that the Company completed two studies of ALPHA-1062 in Q2 2022 and a third in Q3 2022. However, it appears that you have only disclosed the results of one study completed in Q2 2022. Please revise or advise.
17. We note your response to prior comment 22, which we reissue in part. With respect to each completed clinical trial discussed in this section, please revise to disclose the trial date(s) and trial location(s).
18. We note your response to prior comment 23, which we reissue in full. In this regard, we reiterate that determinations as to safety, efficacy, and/or the sufficiency of any data the Company submitted to the FDA are solely within the authority of the FDA. As such, please revise the following disclosure that implies or states a conclusion as to these matters:
  - Revise the references to "positive pivotal study results" on page 80, and to "positive results" and "positive pivotal data" on page 81.
  - Remove the columns from the tables on page 80 captioned "Sufficient Data for NDA Filing."
  - Below the tables on page 80, revise bulleted statements that "data confirmed" ALPHA-1062 was bioequivalent to galantamine hydrobromide, and provide "necessary data for NDA filing (scientific bridge)."
  - Similarly, remove or revise statements that data "confirmed" or "established" bioequivalence of ALPHA-1062 and galantamine hydrobromide (pages 80-81). In this regard, we note you may present objective clinical trial data resulting from trials

without stating your conclusions as to bioequivalence.

- Remove or revise statements that data from a BABE study "strength the NDA application for ALPHA-1062..." (page 81) and "strengthen the NDA data set..." (page 82).

BABE Study vs. Extended Release, page 81

19. We note your response to prior comment 24.
- We reissue the first bullet of the prior comment in part. Please revise to disclose the feedback the Company received regarding the ALPHA-1062 RESOLVE trial.
  - We also reissue the second bullet of the prior comment in part. Please further revise page 82 to highlight that although a PDUFA date has been provided, there is no guarantee that the Company will not have to complete additional trials or studies in order to seek regulatory approval for ALPHA-1062, and that ultimately such approval may never be obtained.
20. You state that following the Q2 2022 meeting with FDA regarding the ALPHA-1062 program for mild-to-moderate AD, the "Company has since demonstrated required stability endpoints for twelve months of long-term stability data in the three to-be-marketed strengths of ALPHA-1062."
- Please revise this conclusory statement to avoid any suggestion that your data has demonstrated or is likely to demonstrate stability to the satisfaction of the FDA. You may disclose the stability endpoints and present objective stability data without concluding that your data has met FDA requirements.
  - Additionally, revise to qualify the phrase "to-be-marketed," as ALPHA-1062 has not yet been approved.
21. We note your response to prior comment 25. Please disclose the information contained in your response letter in your prospectus. Specifically, please:
- Revise your disclosure beginning on page 80 in an appropriate place to disclose that the completed BABE studies were conducted on study participants from the general population rather than an Alzheimer's population.
  - Disclose the reason(s) why the Company determined the RESOLVE trial, which you state was designed in part to measure adverse events in an Alzheimer's population, would not be implemented. Disclose whether, and if so how, the decision to forego completing the RESOLVE trial may impact the NDA filed with the FDA.
  - Make conforming revisions to the risk factor disclosure on page 18 as appropriate.

ALPHA-1062 Patent Portfolio, page 86

22. Although your response letter advises that page 86 was revised to address prior comment 30, we are unable to locate responsive revisions. We reissue prior comment 30 in full.

ALPHA-1062 Regulatory Matters, page 90

23. We note your revisions in response to prior comment 33. You have added a cross-reference to disclosure on page 33 as it relates to potential partnership agreements in non-US territories. We are unable to locate the disclosure to which you refer on page 33. Please revise or advise.

Financing Activities, page 107

24. We note your response to prior comment 36, which we reissue with respect to the first bullet. Please define acronym "NLS" at first use in the prospectus.

Alpha 1062 Technology, page 109

25. We note your response to prior comment 37. You state on page 110 that the Memogain Technology License Agreement will terminate upon the later of twenty years from the Commencement Date (March 15, 2035) or the expiration of the last patent obtained. Please revise to clarify when this patent is expected to expire.

Experts, page 163

26. Please update this section to reflect the financial statements that are included in the registration statement.

Financial Statements

Note 2: Significant Accounting Policies

Grant Accounting, page F-12

27. Please explain to us why \$69,416 from the federal wage tax credits refund relating to subcontractor costs is included in grant income. If this amount is not specifically related to the grant, please revise to remove this amount from grant income. If this expense is related to the grant, specifically disclose this fact or explain why the amount is appropriately classified as grant income.

Form S-1 filed April 30, 2024

Exhibit Index, page II-8

28. Please have your auditors revise their auditor consent filed as Exhibit 23.1 to correctly state the audit report date.

General

29. Please revise your exhibit index to include the filing fee table. Refer to Item 601 of Regulation S-K.
30. 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,

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present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Please contact Sasha Parikh at 202-551-3627 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Chris Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Jason Brenkert