



DIVISION OF
CORPORATION FINANCE

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

January 25, 2021

Stephan Jackman
Chief Executive Officer
Alzamend Neuro, Inc.
3802 Spectrum Boulevard
Suite 112C
Tampa, Florida 33612

Re: Alzamend Neuro, Inc.
Draft Registration Statement on Form S-1
Submitted December 29, 2020
CIK No. 0001677077

Dear Mr. Jackman:

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

Market, Industry and Other Data, page i

1. You state, "[w]hile we believe such information included in this prospectus is generally reliable, we have not independently verified any third-party information." Revise this disclosure to clarify that you are responsible for all disclosure in the document.

Our Company, page 1

2. Please revise to clarify your statement on page 1 and 54 that you are an "early clinical-stage biopharmaceutical company" where you have not yet submitted an IND to the FDA. Similarly clarify the second risk factor, where you state "AL001 and AL002 . . . are in the

IND stage and preclinical stage of development, respectively."

Our Product Candidates, page 1

3. You state that your potential product AL001 "has the potential to improve the therapeutic index of lithium," that the history of lithium use "mitigate[s] the potential regulatory burden for safety data," that lithium has a "preventative effect on the development of dementia in patients with bipolar disorder in comparison with anticonvulsants, antidepressants and antipsychotics," that lithium may have "long-term beneficial effects," "potential efficacy," and we note references to the effectiveness of treatment and "enhanced safety" and that treatments you describe are "proven" to be "effective" or are "efficacious." You also state that your potential product AL002 "reduces beta-amyloid plaque." As safety and efficacy determinations are solely within the FDA's authority and they continue to be evaluated throughout all phases of clinical trials, please remove these and any such references in your prospectus. In the Business section, you may present objective data resulting from your preclinical trials without including conclusions related to efficacy or safety.
4. We note your note your disclosure that AL001 is expected to provide clinicians with a "major improvement" over current treatments. Please tell us on what basis you believe you are able to make comparisons given your early stage of development and the lack of any head-to-head clinical trials or, alternatively, delete any inappropriate comparisons. Please revise the prospectus throughout accordingly.
5. Revise to briefly define "breakthrough therapy designation" and "505(b)(2) regulatory pathway" at first use. Revise to provide the basis on which you "believe that AL001 is an ideal candidate" for both designations. Clarify, if true, that you currently do not qualify for any of these programs and include balancing disclosure that there is no guarantee you will obtain such a designation, as well as an explanation of the factors considered by the FDA in making such a designation. Clarify that the FDA's accelerated approval pathway may not lead to a faster development process or regulatory review and does not increase the likelihood that a product candidate will receive approval. Please also remove your disclosure that you may receive FDA approval for AL001 and AL002 in approximately four years as this disclosure appears to be speculative at this time.
6. On page 1, balance any discussion of your belief that you can speed FDA approval, lessen the "regulatory burden of FDA review," and that you expect your IND to be approved and to begin Phase I clinical trials "by March 31, 2021" with the reality that you have no control over the length of the FDA review process. Provide us the basis for your belief that you will receive IND approval by March 31, 2021, where you have yet to submit an IND.
7. We note the disclosure on page 1 regarding your submission to the FDA and their response. Provide us with any correspondence you have received from the FDA regarding potential products discussed in this registration statement.

Our Development Pipeline, page 2

8. Please revise your pipeline table here and on page 54 to include a column for pre-clinical research and development, columns for each stage of clinical development (i.e., Phase 1, Phase 2, Phase 3), and a column for marketing or regulatory approval. Include arrows in your revised table that show your progress for each product candidate shown in the table.
9. Revise the pipeline table to limit it to only the indications for which you will be submitting your potential product candidates for FDA approval. Remove the designation “strength,” as it implies effectiveness and/or safety, which is inappropriate as discussed in our comment above. Revise to delete the references to when you will commence phase 1 trials, as it implies the FDA will approve your INDs.
10. Please remove your disclosure that AL001 has "the potential of becoming the replacement for all lithium therapy on the market" as that disclosure appears to be speculative at this time.
11. We note your disclosure in the last column of your table that for AL001 that you will be commencing Phase I human clinical trials in Q1 2021 and that for AL002 that you will be commencing Phase I human clinical trials in Q3 2021. Since you have not received IND approval for either product candidate at this time, please revise your disclosure as appropriate.

Risks Associated with our Business, page 6

12. Revise to clarify that this section addresses the principal factors that make an investment in your company speculative or risky, and revise any outlined risks accordingly. Refer to Item 105(b) of Regulation S-K.

Risk Factors, page 12

13. Although disclosure of generic risks is discouraged, to the extent any risk factor including in your prospectus could involve any registrant or any offering, revise this section to include all such risk factors at the end, under the caption "General Risk Factors." Refer to Item 105(a) of Regulation S-K and Section II.D. of Release No. 33-10825, "Modernization of Regulation S-K Items 101, 103, and 105."
14. Revise to provide a separate risk factor to highlight the risks that Spartan Capital Securities, LLC, must consent to any future financing, as discussed in the risk factor on page 13.

Use of Proceeds, page 36

15. You identify several principal purposes of the offering, including “increase our capitalization and financial flexibility, establish a public market for our common stock in order to facilitate future access to the public equity markets,” “to continue to make substantial expenditures to fund proprietary research and development of our AL001 and

AL002 therapeutic drug candidates and to support preclinical testing and clinical trials necessary for regulatory filings,” for “working capital and other general corporate purposes,” and that you “expect that the net proceeds from this offering will fund us through receipt of topline data readouts for our planned Phase I trial of AI001, as well as IND-enabling studies, IND application and Phase I trial of AI002.” Where you acknowledge the proceeds will be insufficient to fund the identified products through regulatory approval, revise to quantify and prioritize the proceeds to be used for each named product candidate, and otherwise revise to eliminate inconsistent disclosure.

Capitalization, page 38

16. Please clearly disclose in the notes to the capitalization table how you computed each pro forma and pro forma as adjusted amount. For example, we note that the pro forma amounts reflect the conversion of all outstanding shares of series A convertible preferred stock into 15,000,000 shares of common stock effective upon the closing of this offering. In this regard, it is not clear why there was an increase in pro forma cash and no change to the pro forma common stock and additional paid-in capital amounts.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Our Plan of Operations, page 42

17. We note your disclosure that you began a toxicological preclinical study for AL002 with Charles River Laboratories, Inc. and that completion of this toxicological study is anticipated to occur in the by the end of 2020. Please update your disclosure to indicate whether this study has been completed and its results.

Critical Accounting Policies and Estimates, page 42

18. You disclose on page F-7 that the Company’s critical accounting policies that involve significant judgment and estimates include share-based compensation. Please expand your critical accounting policy disclosure related to stock-compensation to include:
- the methods that management used to determine the fair value of your shares and the nature of the material assumptions involved;
 - the extent to which the estimates are considered highly complex and subjective; and
 - the estimates will not be necessary to determine the fair value of new awards once the underlying shares begin trading.

Contractual Obligations, page 50

19. Revise to clarify to which products these licenses relate. Also revise to disclose all the licenses described in the risk factor on pages 13-14.

Impact of Coronavirus on Our Operations, page 50

20. As it has been almost one year since the onset of the pandemic, revise this section to clarify what, if any, effect the pandemic has had on your operations.

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21. On page 68 you state that you had one full-time employee and three part-time employees as of December 29, 2020. Here, you state that your offices are in Orange County, your senior management members work in Atlanta and New York and your offices are temporarily closed and “non-essential staff continue to work remotely.” Revise to clarify which employees are “non-essential” and clarify to what extent working remotely has “adversely affected their efficiency.”

Business

Alzheimer’s Therapeutic Landscape, page 60

22. We note several URL references starting in this section. Note that referring investors to sources outside your filing for material information is not sufficient to meet your disclosure obligation. Please revise your disclosure to ensure that all material information is included in your filing.

Current Drugs for Alzheimer’s Disease, page 60

23. You disclose 2017 data in this chart. Please update this information.

Manufacturing, page 61

24. In the risk factor on page 16, you state that you are responsible for the manufacture of your product candidates, but on page 61, you state this is outsourced to third-party contractors. Revise to clarify.
25. Revise to clarify if you have entered into agreements with Alcami and Lonza to manufacture your products, and if so, disclose the material terms of those agreements.

Our Intellectual Property, page 67

26. With respect to the patents you license, please disclose the specific products to which such patents relate, the type of patent protection represented by the application, such as composition of matter, use or process, the expiration dates, the applicable jurisdictions and whether there are any contested proceedings or third-party claims.

Facilities, page 69

27. On page 50, you state that your offices are in Orange County, California, your senior management members work in Atlanta and New York, and your offices are temporarily closed. Here, you state that your corporate offices are at the University of South Florida’s Incubator Center in Tampa, Florida. Revise this section to clarify.

Management, page 70

28. Please file the consent of each director nominee as an exhibit to your registration statement. See Rule 438 of Regulation C under the Securities Act. Should either of the nominees have become directors of the company by the time that you amend your

registration statement, please update your disclosure accordingly.

Executive Compensation, page 74

29. The disclosure in the table does not appear to correspond to the narrative disclosure that follows. For example you state you entered into an agreement with Mr. Jackman in November 2018, pursuant to which he would receive a base salary of \$225,000; however, the table discloses he received a salary of \$200,000 for the fiscal year ended April 30, 2020.

Certain Relationships and Related Party Transactions, page 80

30. To the extent you have not done so, revise the disclosure here to provide the information required by Item 401(a) for each transaction since the beginning of the last fiscal year and the two preceding fiscal years, and file the agreements as exhibits. Refer to Instruction 1 to Item 404 of Regulation S-K and Item 601(b)(10)(ii) of Regulation S-K. For example, provide the name of the related person for each transaction and identify the relationship, and file the consulting agreement with Mr. Horne, the April 10, 2018 Avalanche agreement, the DPW December 2020 short-term advance, the pledge of the shares purchased by ALSF, and the August 2020 DPW securities purchase agreement as exhibits. Revise the discussion of the April 20, 2019 securities purchase agreement to clarify the relationship between MCKEA and ALSF. Revise page 81 to clarify the “2019 PPM” reference, which does not appear to be otherwise identified in this section.

Principal Stockholders, page 82

31. Please revise the table to clarify how many shares Ault Life Sciences Fund, LLC currently owns.
32. Please identify the natural person or persons who directly or indirectly exercise sole or shared voting and/or dispositive power with respect to the common stock held by Spartan Capital Securities, LLC. Refer to Item 403 of Regulation S-K.

Description of Capital Stock, page 84

33. It appears from the disclosure here that you intend to amend your charter and bylaws prior to the offering, yet the exhibit index lists only your current bylaws and charter. Neither of those contains the exclusive forum provisions or exceptions thereto discussed here and in the risk factors. Please provide the form of amended bylaws and charter as exhibits to your registration statement or revise the disclosure here and on page 34.

Underwriting, page 88

34. Identify the underwriter(s) in your next amendment.

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Financial Statements

Loss Per Common Share, page F-9

35. Your disclosures indicate that you excluded 7,500,000 stock options, with an exercise price of \$0.0004, from your anti-dilutive securities. Please further clarify why they have been excluded, including if these shares have been included in your determination of basic loss per share as they represent shares issuable for little or no cash consideration upon the satisfaction of certain conditions pursuant to ASC 260-10-45-13.

Note 7. Stock-Based Compensation, page F-30

36. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Signatures, page II-5

37. Your registration statement must be signed by your controller or principal accounting officer. Please indicate who will signing in either of those capacities. Refer to Instruction 1 to Signatures on Form S-1.

General

38. 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.

You may contact Nudrat Salik at (202) 551-3692 or Vanessa Robertson at (202) 551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Tim Buchmiller at (202) 551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Spencer G. Feldman, Esq.