



DIVISION OF
CORPORATION FINANCE

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

October 24, 2022

Mr. Brian Carrico
Chief Executive Officer
Neuraxis, Inc.
11550 N. Meridian Street, Suite 325
Carmel, IN 46032

Re: Neuraxis, Inc.
Draft Registration Statement on Form S-1
Submitted September 27, 2022
CIK No. 0001933567

Dear Mr. Brian Carrico :

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, submitted September 27, 2022

Cautionary Note Regarding Forward-Looking Statements, page ii, page ii

1. Your disclosure on page ii which states that you "do not assume any responsibility for the accuracy or completeness of any of these forward-looking statements" may imply an inappropriate disclaimer of responsibility with respect to this information. Please either delete this statement or specifically state that you are responsible for such information.

Prospectus Summary, page 1, page 1

2. The disclosure in the Summary should be a balanced presentation of your business. Please balance the description of the opportunity you see in your market, your value proposition and your growth strategy with equally prominent disclosure of the challenges you face and

the risks and limitations that could harm your business or inhibit your strategic plans. For example, but without limitation, revise your disclosure to also discuss your history of recurring net losses, accumulated deficit, and the going concern opinion issued by your auditor.

3. We note your statement on page 1 that you are "already cleared for the first-ever therapy (IB-Stim) for functional abdominal pain, associated with IBS, in children." Please revise your disclosure to support your statement that IB-Stim is the "first-ever therapy" for this indication, including a statement that the company is not aware of any other therapy available to treat the same indication and patient population at this time.
4. Please revise both the Summary and Business sections to clarify whether the IB-Stim device was developed internally by the company or whether the company acquired the technology from a third party.
5. Please revise your pipeline table here and in the Business section as follows:
 - Clarify that your IB-Stim device is to be used for each of the listed indications;
 - Reconcile in the narrative accompanying the table the listed indication for adults, as you state throughout the filing that you are focused on addressing chronic and debilitating conditions in children;
 - Revise to remove the timeline aspect of the table, as the timeline for FDA review and approval are not assured or within the company's control and implications of assured approval are not appropriate;
 - Include columns for required human clinical trials, broken down into phases if applicable, as well as FDA regulatory milestones that must be achieved, such as the filing of a 510(k) premarket notification or PMA application, prior to commercialization; and
 - Revise the arrows in the table to reflect the current status for each indication in relation to the regulatory milestone columns.
6. We note your disclosure on page 2 that "81% of patients had improvements in global symptoms with no serious adverse events, and minimal to no side effects" using the IB-Stim device. Please revise your disclosure to include a brief summary of the pre-clinical and clinical trial data supporting this statement. In addition, the circles in the graphic on page 2 show equally shaded orange areas despite differing identified percentages. Please explain or revise.
7. We note your statements on pages 3 and 51 that the pediatrics industry has "efficient, low-barrier market entry". Please explain what is meant by this phrase and provide support.
8. We note your statements on pages 4 and 52 that "recent published, peer-reviewed studies and data presented at national meetings, such as NASPGHAN, show compelling safety and efficacy data for this device. Studies have demonstrated long-term benefits in functional disability, psychological co-morbidities and pain." Please revise your disclosure to cite the referenced studies and provide support for these statements.

9. We note your statement on pages 4 and 52 that you have received "society endorsement, including [from] the American Academy of Pediatrics and NASPGHAN." Please explain what you mean by "endorsement" in this context.
10. Please provide support for your references to your "unparalleled body of clinical evidence" where used.
11. We note your statements throughout the prospectus that additional clinical trials of PENFS in multiple pediatric conditions are "underway" focused on unmet healthcare needs in children. Please revise both the Summary and Business sections to clarify the stage or progress of these trials, the indications currently under evaluation, and any preclinical data available.
12. We note the first paragraph of the section entitled Our Solutions on pages 4 and 52. Please expand this section to discuss any additional regulatory submissions made by the company and evaluated by the FDA in addition to the de novo classification request. In this regard, please disclose whether a 510(k) premarket notification was submitted and the status thereof.
13. We note your statement that you have "concentrated market access with focus on 260 children's hospitals." Please clarify what you mean by "concentrated market access" and whether you have, in fact, partnered with or sold your IB-Stim device to the referenced 260 hospitals. If not, please revise the statement to clarify.
14. We note your disclosure of several Securities Purchase Agreements and a Pledge and Security Agreement on page 6. Please revise your disclosure to name the parties to these agreements.

Implications of Being an Emerging Growth Company, page 7

15. Your disclosure on pages 7, 38, 49 and 62 indicates that you have elected to avail yourselves of the extended transition period for complying with new or revised accounting standards. On the cover page, however, you indicate the opposite. Please revise to address this apparent inconsistency.

Use of Proceeds, page 39

16. We note your disclosure in this section that you intend to use the proceeds of this offering for working capital, sales and marketing, and research and development. Please revise this section to more specifically identify how the proceeds will be used. For instance, you state elsewhere that you plan to repay your convertible notes with proceeds of the offering; however, this purpose is not included in the table on page 39. Please reference General Instruction 4 to Item 504 of Regulation S-K in relation to this purpose. In relation to the categories listed, please revise to provide more granularity regarding the intended use, and clarify whether additional funds will be required to accomplish any specifically stated purpose (i.e., to achieve certain regulatory milestones). If any material amount of other funds are necessary to accomplish the specified purposes for which the proceeds are to be

obtained, state the amounts of such other funds needed for each such specified purpose and the sources thereof.

Management's Discussion and Analysis Of Financial Condition and Results Of Operations
Results of Operations, page 44

17. We note that you had a gross profit representing 82.8% of net sales in 2021 and 75.1% of net sales in 2020. Please tell us how this reconciles with your disclosures regarding growth strategies on pages 5 and 53 which state a 93% gross margin.

Liquidity and Capital Resources, page 46

18. We note your statement on page 46 that you expect proceeds from the offering to fund your capital needs for the following 12 months. However, on page 39 you state that the proceeds will fund your operating expenses and capital expenditure requirements through at least the next 24 months. Please reconcile.

Business, page 50

19. Please ensure that all graphics and charts are legible. For example, the "Technology" graphic of the medical device on page 55 and "Table 2" in your "Clinical Data" section on page 57 are not entirely legible due to pixilation.
20. We note your disclosure on page 53 which states that Helius Medical Technologies, Inc. is your main competitor. Please briefly explain how Helius' Portable Neuromodulation Stimulator competes directly with the company's IB-Stim device.
21. We note your disclosure on page 56 discussing your Clinical Data results. Please revise your disclosure to include further information about the trial development phases, number of participants, endpoints, p-value, etc.
22. Please revise your patent table starting on page 59 to disclose whether the listed patents are owned, in-licensed or out-licensed, the type of patent protection granted or applied for, and the expiration year or anticipated expiration year of each.
23. Please revise your disclosure on page 61 to discuss the nature and scope of the intellectual property transferred to Masimo in relation to the NSS-2 Bridge device.
24. We note that the TKBMN Exclusive License Agreement was granted for \$1.00. Please disclose TKBMN's relationship to the company, if any. In addition, please clarify the terms of the agreement, providing more detail regarding the year of the last to expire valid claim within the Patent Rights.

Legal Proceedings, page 76

25. Please revise your disclosure regarding the disclosed lawsuit to provide a description of the factual basis alleged to underlie the proceedings. See Item 103 of Regulation S-K.

Principal Stockholders, page 91

26. Please revise the table to address the following:
- identify by footnote the natural persons who are the beneficial owners of the shares held by Masimo Corporation; and
 - reconcile the figures provided in the column titled "Percent of Class Before the Offering" with the total shown for the officers and directors as a group.

Note 2. Summary of Significant Accounting Policies

Basic and Diluted Net Income (Loss) per Share, page F-13

27. Please add a table here to disclose the effect given to preferred dividends and the income available to common stockholders or add such disclosure to your statement of operations. Refer to ASC 260-10-50-1 and 260-10-55-52.

Note 8. Common Stock and Warrants, page F-23

28. Please correct the weighted average exercise prices in the table presented. Also, revise the table to distinguish between warrants for the purchase of common stock and preferred stock.
29. You have disclosed a warrant issued to Masimo Corporation to purchase 144,890 shares of Series A Preferred Stock at \$18.87 per share that is subject to adjustment for certain equity events. The table of outstanding warrants shows this warrant has a strike price of \$0.0001. Please tell us the reason for this difference. If the reason is due to an adjustment for certain equity events, describe the events and how the adjustment in strike price was measured and recognized in the financial statements.
30. The Masimo Corporation Series A warrant has provisions that allow for further adjustments thereafter from time to time. Please explain the terms of these provisions and how you accounted for them, including the accounting guidance relied upon.

Note 9. Preferred Stock, page F-24

31. The original purchase price of the Series A Preferred and Series Seed Preferred appear to be relevant to the Accruing Dividend and liquidation rights. Please disclose the aggregate purchase price of the Series A Preferred and Series Seed Preferred shares.
32. Please tell us when the conversion of common stock into Series Seed Preferred stock occurred. Also, please tell us the relevance of the disclosure as to the \$100 million valuation and how it was determined. Refer to ASC Topic 820.

Note 14. Commitments and Contingencies

Manufacturing Services Agreement, page F-27

33. This agreement indicates you have a concentration of business with a single supplier as described under ASC 275-10-50-18.a. Please tell us your assessment as to whether the

Mr. Brian Carrico
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criteria of ASC 275-10-50-16 are met as of the date your financial statements were issued. If you conclude all of the criteria are met, provide the disclosures under the guidance of ASC 250-10-55-8.

Item 16. Exhibits and Financial Statement Schedules, page II-4

34. We note your discussion of a Manufacturing Services Agreement on page F-27. Please file this agreement as an exhibit or provide an analysis supporting your decision not to file the agreement, referencing Item 601(b)(10) of Regulation S-K.

You may contact Gary Newberry at 202-551-3761 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Cindy Polynice at 202-551-8707 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Lahdan Rahmati