Neuraxis, Inc.
11550 N. Meridian Street, Suite 325
Carmel, IN 46032

November 9, 2022

Cindy Polynice
U.S. Securities & Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

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

Dear Ms. Polynice:

By letter dated October 24, 2022, the staff (the "Staff," "you" or "your") of the U.S. Securities and Exchange Commission (the "Commission") provided Neuraxis, Inc. (the "Company," "we," "us" or "our") with its comments to the Company's Draft Registration Statement on Form S-1 (the "Registration Statement") submitted on September 27, 2022. Amendment No. 1 to the Registration Statement ("Amendment No. 1") is being submitted to the Commission today and reflects the Company's responses to the comment letter to the Registration Statement.

For ease of review, we have set forth below each of the numbered comments from your letter followed, in each case, by the Company's response. Unless otherwise indicated, capitalized terms used herein have the meanings assigned to them in Amendment No. 1 and all references to page numbers in such responses are to page numbers in Amendment No. 1.

2022 Cautionary Note Regarding Forward-Looking Statements, 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.

   Response: We have deleted this statement from our disclosure.

Prospectus Summary, 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.

   Response: We have revised our disclosure in the Summary section on page 1 to also discuss our history of recurring net losses, accumulated deficit, and the going concern opinion issued by your auditor in order to provide the requested more balanced presentation.

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.

Response: We have removed the statement that IB-Stim is the “first-ever” therapy for functional abdominal pain, associated with IBS, in children.

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.

Response: We have revised our disclosure to clarify that we developed the IB-Stim device internally.

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.

Response: We have revised our pipeline table in the Prospectus Summary and Business as follows:

- We have clarified that the technology underlying IB-Stim will be used for each of the other indications.
- References to “adult” as a potential patient population have been removed from Amendment No. 1.
- We have revised the captions to each table to clarify that the timelines are the Company’s timing projections, and we revised the lead-in to the tables to indicate that the projected timelines and any approval is not assured and in the sole control and discretion of the FDA.
- We have delineated one of the timeline tables to show each of the Study Design, Human Clinical Trials, 510(k) / De Novo FDA Submission and Commercialization phases.
- We have revised the arrows to reflect the current status of each indication in relation to each regulatory milestone, as requested.

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.

Response: We have revised our disclosure to include a brief summary of the pre-clinical and clinical trial data and removed the graphic on page 2.

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.

Response: We have removed the statement that the pediatrics industry has “efficient, low-barrier market entry” on pages 3 and 51.

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.

Response: We removed all references to data presented at national meetings (NASPGHAN) and included only data published in peer-reviewed journals. All the efficacy and safety data, including the long-term benefits in functional disability, psychological co-morbidities and pain, has been included in Amendment No.1.

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.

Response: We have a signed letter from American Academy of Pediatrics and NASPGHAN supporting our technology and asking for payers to cover the technology due to the strength of evidence and need in children. We have revised the disclosure to clarify that the endorsement is in the form of a letter from these organizations.

10. Please provide support for your references to your “unparalleled body of clinical evidence” where used.

Response: We have removed all references to “unparalleled body of clinical evidence” from Amendment No. 1.

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.

Response: We have revised Our Pipeline section to clarify the stage and progress of these additional clinical trials of PENFS in multiple pediatric conditions. We made conforming changes in the Summary and Business sections, where we cross reference the disclosures of such additional clinical trials.

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.

Response: We have revised Our Solutions section to disclose that we have only submitted one FDA De Novo request and have not submitted any additional 510(k) premarket notifications for the pipeline indications to date.

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.

Response: We have revised the disclosure to clarify that our marketing focus is on 260 children’s hospitals.

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.

Response: We have revised our disclosure to name the parties to the Securities Purchase Agreements and the Pledge and Security Agreement.

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.

Response: We have revised our disclosure to indicate that we have elected not to take advantage of the extended transition period for complying with new or revised accounting standards provided to emerging growth companies under the JOBS Act.

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.

Response: We have revised our disclosure to include repayment of our convertible notes with proceeds of this offering and have added footnotes to clarify how proceeds will be used. In this regard, please note that proceeds from this offering are anticipated to fully fund the regulatory milestones set forth in the chart captioned “FDA Pipeline Indications and Projected Timelines” under “*Prospectus Summary—Pipeline*”, as indicated in footnote (1) on page 39.

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.

Response: We have revised our disclosures regarding growth strategies on pages 5 and 53 to revise references to “93% gross margin” to read “strong gross margin”. We also have added disclosure defining and discussing gross margin in MD&A on pages 44 and 45. In this regard, note that gross margin is a ratio determined using line items calculated in accordance with U.S. GAAP and presented on the face of our financial statements.

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.

Response: We have revised our statement on page 39 to clarify that proceeds from this offering, together with our cash and cash equivalents, are expected to fund our operating expenses and capital expenditure requirements through at least the next 12 months.

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.

Response: We have replaced referenced graphic and chart, and we believe all graphics and charts are now legible.

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.

Response: We have revised our disclosure to remove references to Helius Medical Technologies, Inc.

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.

Response: We have revised our disclosure to include further information of our Clinical Data results.

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.

Response: We have revised our patent table 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.

Response: We have revised the disclosure on page 61 to clarify the nature and scope of the intellectual property transferred to Masimo.

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.

Response: We have revised our disclosure of the TKBMN exclusive license agreement on page 61 to disclose TKBMN’s relationship with the Company and to clarify the terms of the agreement.

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.

Response: We have revised our disclosure to provide a description of the factual basis alleged and underlying the lawsuits.

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.

Response: Masimo Corporation is publicly traded company (Nasdaq: MASI), and according to their public disclosures, there are no natural persons that beneficially own a controlling interest the company. We have reconciled the individual share ownership shown for each officer and director with the aggregate 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.

Response: We have included a table showing the calculation of basic and diluted net loss per share and the effect of preferred stock dividends in Note 2 on page F-13.

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.

Response: The table has been corrected to reflect the actual weighted average exercise price and to distinguish between warrants for the purchase of common stock and preferred stock. The corrected table is in Note 8 on page F-23.

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.

Response: The Masimo warrant was prefunded and based on a price of $18.87 per share. The table of outstanding warrants shows the remaining nominal exercise price of $.0001.

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.

Response: The Masimo Series A warrants have adjustments triggered by the following events: stock dividends and splits; pro rata distributions; and fundamental transactions. Management considered these adjustments under ASC 815 and concluded that there are no added protections from these adjustments. The investor is simply entitled to receive what they would have received if they had exercised the warrants before an adjustment event. Accordingly, management concluded that these features are deemed to be indexed to the Company's common stock.

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.

Response: The aggregate purchase price of the Series A Preferred was $9,321,165, of which $7,692,664 was comprised of cash and the remaining $1,628,501 was comprised of converted debt and common stock. The aggregate purchase price of the Series Seed Preferred shares was $0, as all such shares were in exchange for then-outstanding s shares of common stock as an incentive to invest in the Series A Preferred. We have added these details to Note 9 on page F-24.

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.

Response: Common stock was converted into Series Seed Preferred on two different dates, in both cases as an incentive to invest in the Series A Preferred. On September 6, 2019, 89,778 shares of common stock were converted and, on November 25, 2019, an additional 25,699 shares of common stock were converted. In connection with these two conversion events, an aggregate of 115,477 shares of Series Seed Preferred were issued. These exchange transactions were based on a Company valuation of $100 million and an original Series Seed Preferred liquidation preference of $70.04 per share. The Series Seed company valuation of $100 million was based on a 2017 independent 409A valuation of $63 million and was adjusted by our board of directors to reflect FDA approval of our IB-Stim device and private insurance coverage, which events occurred after the 2012 valuation was delivered.

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 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.

Response: We have concluded that the Company's reliance on their supplier for key components does not present a vulnerability that is required to be disclosed in the Company's financial statement footnotes under ASC 275-10-50. In determining the disclosure requirements on concentrations under ASC 275, we considered the following definitions in that standard as guidance: (i) ASC 275-10-50-16 defines vulnerability from concentrations as exposure to a risk of loss that is greater than it would have been had we mitigated the risk through diversification, which manifests itself based on the nature of the concentration and varies depending on circumstances; (ii) ASC 275-10-50-16 goes on to require disclosure only if all of the criteria are met, which involves vulnerability due to the risk of a near-term, severe impact. "Near term" signifies a period not to exceed one year from the date of the financial statements. An impact is "severe" when there is a significant financial disruption on the normal functioning of the entity, a threshold higher than a material effect.

While a supplier concentration arguably existed at the date of the financial statements, we do not believe that this concentration makes the Company vulnerable to the risk of any near-term severe impact. We have arrived at this conclusion based on the following factors: (i) the Company is continually meeting with our supplier to gauge its financial health and continuity of supplies; (ii) the Company lost their single supplier in 2019 and, within five months, a new supplier was fully functioning and delivering new inventory. (iii) the Company has been in contact with suppliers in the past that management believes would be able to replace the current supplier, if necessary or appropriate; and (iv) our supplier has not experienced any significant difficulty in the past in obtaining the materials necessary to meet our production needs. Management has taken steps to stockpile and maintain six months of key inventory to protect the Company if the current supplier is unable to fulfill the Company's product demands

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.

Response: We have added the Manufacturing Services Agreement to the Exhibit Index in Amendment No. 1 and will file this agreement with our first public filing.

Thank you for your assistance in reviewing this filing.

Regards,

/s/ Brian Carrico

Mr. Brian Carrico
Chief Executive Officer