NeurAxis Reports Fourth Quarter and Fiscal Year 2023 Financial Results

CARMEL, Ind., April 09, 2024 — NeurAxis, Inc. (“NeurAxis,” or the “Company”) (NYSE American: NRXS), a medical technology company commercializing neuromodulation therapies for chronic and debilitating conditions in children and adults, today announced results for the fourth quarter and fiscal year 2023 for the period ended December 31, 2023.

Recent Operational Highlights

- Expanded total covered lives to approximately 16 million individuals, an increase of 300% compared to 4 million individuals as of April 1, 2023. Recent medical policy coverages include:
  - BCBS plan in the mid-Atlantic region, providing coverage for approximately 7 million covered lives.
  - Coverage from a major insurer covering approximately 1 million covered lives.
  - BCBS plan in the mid-Atlantic with approximately 3.5 million covered lives.
- The company remains committed to clinical research in the pediatric space with a total of 15 peer-reviewed published studies using NeurAxis’ PENFS technology. Thirteen of those studies were carried out in US children’s hospitals and included children with disorders of the gut-brain interaction (DGBIs). This level of evidence puts NeurAxis in a great position to continue expanding payor coverage and increase adoption of the technology.
- Announced the results of the largest multicenter, prospective registry in pediatric DGBIs. It evaluated outcomes of pediatric patients (8-18 years) following a 4-week course of IB-Stim in a real world clinical setting. Seven large tertiary care centers enrolled patients with pain-associated DGBIs. Patients were asked to fill out validated pediatric questionnaires, including the abdominal pain index (API). Data was collected weekly for the first 3 weeks and at 3, 6, 9 and 12 months. Compared to baseline scores, there were significant improvements in abdominal pain (API) after 4 weeks of IB-Stim treatment at every time point, including 6 months ($p<0.001$) and 12 months ($p<0.001$).
- Announced the results of a retrospective study led by the Cincinnati Children’s Hospital Medical Center comparing and reviewing the records of 101 adolescent patients with FAPD treated with IB-Stim™ therapy or standard-of-care medications, amitriptyline (tricyclic antidepressant) or cyproheptadine (antihistamine). The comparative analysis noted:
  - at follow-up, IB-Stim™ therapy showed improvements in abdominal pain ($p=0.001$) and functional disability ($p=0.048$) compared to baseline, while amitriptyline showed improvements in abdominal pain ($p=0.034$).
  - in a comparison of outcomes between groups, IB-Stim™ was more effective than cyproheptadine in improving abdominal pain ($p=0.04$) and did not differ from amitriptyline ($p=0.64$). Nausea scores did not differ between groups ($p>0.05$); and

    - disability scores between groups were only more effective for amitriptyline vs. cyproheptadine (p=0.03). Disability scores did not differ from amitriptyline compared with IB-Stim™ (p=0.21).
- Signed an exclusive option agreement with the University of Michigan for the right to license its' innovative rectal expulsion device (RED). RED redesigns the balloon expulsion testing workflow to simplify anorectal function testing. RED can be used in the office and at the point of care to identify treatment targets for patients with chronic constipation.
- Secured $3 million in committed convertible note financing from affiliates of Inspire Health Alliance on November 8, 2023. The Company also secured an additional $3.1 million in committed financing from various investors, including affiliates of Inspire Health Alliance, with identical terms in the first quarter of 2024.

Management Commentary

Brian Carrico, Chief Executive Officer of NeurAxis, commented, "I am excited and pleased with the progress we have made throughout the last year executing our philosophy that the publication of strong data will result in strong insurance medical policy coverage, which will drive strong future revenue growth. Recently, we expanded our portfolio of publications on our proprietary neuromodulation therapies, which have led to early insurance medical policy coverage from major insurance plans nationally. To date, PENFS is covered for more than 16 million lives in the U.S. by multiple health insurers, an improvement from just 4 million lives a year ago. I believe we are on track to achieve our stated goal of having medical policy coverage for at least 50 million lives by the end of 2024, which will set the stage for a significant revenue ramp for our initial pediatric indication for FAP/IBS."

"Beyond driving adoption of our IB-Stim technology for FAP/IBS, we remain on track to expand the number of indications for IB-Stim in the years to come with further pediatric and adult clinical studies in place with expected FDA submissions over the next three years. Furthermore, we remain excited about the commercial opportunity for our recently licensed innovative rectal expulsion device, or RED, a self-inflating balloon expulsion test that allows for point-of-care testing to effectively identify patients with an evacuation disorder, such as constipation. We expect the device, which has the potential to be a significant near-term revenue driver for the company, to become commercialized in 2024," Mr. Carrico continued.

Dr. Adrian Miranda, Chief Medical Officer of NeurAxis, commented, "I am proud of the depth and breadth of the 14 studies that we have published, which include 10 different types of research such as placebo, long-term data, health-economic data, quality of life data, and real-world registry data. In recent months, we have announced results for multiple studies, including our retrospective comparative study led by the University of Cincinnati and investigators at Children's Hospital of Orange County. We are pleased with the outcomes of our studies, which have been conducted by renowned institutions, and remain steadfast in

leveraging our research publications to expand written policy coverage."

Mr. Carrico concluded, "I am excited about the opportunities we have in 2024 to further commercialize our lead pediatric indication for IB-Stim, while advancing our development pipeline for a number of new indications leveraging our unique neuromodulation therapy. I anticipate growth in 2024 to be driven by our expanding insurance coverage, and the commercialization of RED. With a strengthened balance sheet through a key investment from Inspire Health Alliance and long-term investors who understand the medical space well, I believe we are well positioned to execute our business plan in 2024."

Fourth Quarter and Fiscal Year 2023 Financial Results

Revenue in fiscal year 2023 of $2.5 million was down 8.4% compared to $2.7 million in fiscal year 2022. The decrease was primarily due to fewer shipments to certain customers as they manage through the insurance reimbursement process. While we have made great strides in recent months in gaining coverage, note that there is a lag between insurance coverage and order placement due to billing and coding implementation processes unique to each of our customers. Given our recent success with new payor coverage, we expect our revenue to increase in late 2024 and into 2025.

Fourth quarter revenue in 2023 of $531.5 thousand was down 13.3% compared to $613.1 thousand for the same period in 2022. While revenue was down in the quarter, we had more account accounts ordering from us and we had more patients coming to us via our Guidance and Patient Services (GPS) assistance program.

Gross profit margin in fiscal year 2023 was 87.7%, compared to 88.9% in fiscal year 2022. The change in gross margin was primarily due to growth in our patient assistance program that provides discounts to patients without insurance coverage. Gross profit margin in the fourth quarter of 2023 was 86.4%, compared to 87.7% for the same period in 2022.

Selling expenses for fiscal year 2023 were $323.6 thousand, a decrease of 21.3% compared to $410.9 thousand for fiscal year 2022. The decrease was primarily due to lower commission costs, with the commission rate being lowered at the beginning of 2023, and lower revenue. Selling expenses for the fourth quarter of 2023 were $72.6 thousand, an increase of 10.1% compared to $66.0 thousand for the fourth quarter of 2022.

Research and development (R&D) costs for fiscal year 2023 were $169.3 thousand, a decrease of 25.0% compared to $225.6 thousand for fiscal year 2022. The decrease was primarily due to the initiation, payment and expense of more patient trials in fiscal year 2022 as the Company prepared for more FDA submissions. These trials continued into fiscal year 2023.

General and administrative (G&A) costs for fiscal year 2023 were $8.3 million, an increase of

62.6% compared to $5.1 million for fiscal year 2022. Increased costs were primarily due to incremental headcount to build out market access and patient assistance teams including recruiting costs, as well as higher insurance, investor relations and board of director costs post-IPO, one-time advisory costs and higher advertising costs in order to expand market awareness. G&A costs for the fourth quarter of 2023 were $2.0 million, an increase of 46.1%, compared to $1.4 million for the fourth quarter of 2022. The increase was primarily due to higher wages, higher public company expenses such as insurance and board fees post-IPO and professional services as the Company obtains market access.

The net loss in fiscal year 2023 expanded to $14.6 million, versus $4.8 million in fiscal year 2022 primarily due to non-cash charges taken on debt conversion upon the IPO, including $4.9 million in amortization of the debt discount and deferred issuance costs and a $3.6 million charge taken on the extinguishment of debt, and higher G&A costs. The net loss in the fourth quarter of 2023 was $5.3 million due to higher G&A costs, significantly lower non-cash changes in the fair value of warrants and derivative financial instruments as they were either exercised or converted upon the IPO and the extinguishment of debt.

Cash on hand at December 31, 2023 was $78.6 thousand. Cash used by operations of $6.7 million was substantially less than our net loss of $14.6 million for the same period primarily due to the $4.9 million non-cash debt discount charge upon conversion at the IPO and the $3.6 million non-cash debt extinguishment charge. Although the Company had no long-term debt as of December 31, 2023, $6.1 million in convertible note financing has been secured with $1.5 million funded as of March 31, 2023.

Restatement of Third Quarter 2023 Financial Results

The Company filed a Current Report on Form 8-K today regarding a restatement of the Company's financial statements as of and for the three and nine month periods ended September 30, 2023 that will be included in the Company's Annual Report on Form 10-K as of and for the year ended December 31, 2023. The restatement will result, among other items, in a $3.7 million increase to the Company's net loss and a $3.7 million increase to additional paid in capital as of and for the three and nine month periods ended September 30, 2023 and is unrelated to revenues or cash expenses. The Company's cash position as of September 30, 2023 did not change.

Conference Call Details

Date and Time: Tuesday, April 9, 2024, at 4:30pm ET

Live Webcast Information: Interested parties can access the conference call via a live webcast, which is available in the Investor Relations section of the Company's website at https://edge.media-server.com/mmc/p/mir4a7uc or https://ir.neuraxis.com/. For participants listening through the webcast, questions can be sent in through the portal using the "Ask a

Question" link or by emailing questions to NRXS@lythampartners.com.

Call-in Information: Interested parties can also access the live conference call by initially registering at the following link. Upon completion of the registration link, call-in participants will receive the dial-in info and a unique PIN to join the call as well as an email confirmation with the details.

Replay: A webcast replay will be available in the Investor Relations section of the Company's website at https://edge.media-server.com/mmc/p/mir4a7uc or https://ir.neuraxis.com/.

About NeurAxis, Inc.

NeurAxis, Inc., is a medical technology company focused on neuromodulation therapies to address chronic and debilitating conditions in children and adults. NeurAxis is dedicated to advancing science and leveraging evidence-based medicine to drive adoption of its IB-Stim™ therapy, which is its proprietary Percutaneous Electrical Nerve Field Stimulation (PENFS) technology, by the medical, scientific, and patient communities. IB-Stim™ is FDA cleared for functional abdominal pain associated with irritable bowel syndrome (IBS) in adolescents 11-18 years old. Additional clinical trials of PENFS in multiple pediatric and adult conditions with large unmet healthcare needs are underway. For more information, please visit http://neuraxis.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. There are a number of important factors that could cause actual results, developments, business decisions or other events to differ materially from those contemplated by the forward-looking statements in this press release. These factors include, among other things, the conditions in the U.S. and global economy, the trading price and volatility of the Company's stock, public health issues or other events, the Company's compliance with applicable laws, the results of the Company's clinical trials and perceptions thereof, the results of submissions to the FDA, the results of the shareholder vote to enable the issuance of the Preferred Stock, and factors described in the Risk Factors section of NeurAxis's public filings with the Securities and Exchange Commission (SEC). Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date of

this press release and, except to the extent required by applicable law, the Company undertakes no obligation to update or revise these statements, whether as a result of any new information, future events and developments or otherwise.

This page discusses research activities with percutaneous electrical nerve field stimulator (PENFS) technology. Please note, the research being described includes information about technology and intended uses of that technology which have not been reviewed or approved/cleared by the U.S. FDA, and is being provided for informational purposes only. NeurAxis does not recommend or suggest the use of its PENFS™ IB-Stim™ device for uses beyond those that are cleared by the U.S. FDA. See https://ibstim.com/important-information/.

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NeurAxis, Inc.
Statements of Operations
(Unaudited)

	(Unaudited) Year Ended December 31,	
	2023	2022
Net sales	$ 2,460,049	$ 2,684,735
Cost of goods sold	303,345	297,060
Gross profit	2,156,704	2,387,675
Selling expenses	323,569	410,883
Research and development	169,315	225,610
General and administrative	8,328,315	5,123,420
Operating loss	(6,664,495)	(3,372,238)
Other (expense) income, net:		
Financing charges	(2,772)	(2,322,216)
Interest expense	(476,416)	(318,666)
Change in fair value of warrant liability	844,854	606,049
Change in fair value of derivative financial instruments	198,551	713,989
Amortization of debt discount and issuance cost	(4,881,622)	(98,935)
Extinguishment of debt liabilities	(3,649,561)	–

Other income	4,778	11,956
Total other (expense) income, net	(7,962,188)	(1,407,823)
Net loss	$ (14,626,683)	$ (4,780,061)