NeurAxis Reports First Quarter 2024 Financial Results

May 22, 2024

CARMEL, Ind., May 22, 2024 (GLOBE NEWSWIRE) -- 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 first quarter 2024 for the period ended March 31, 2024.

Recent Operational Highlights

- Expanded total covered lives to approximately 22.5 million covered lives, an increase of 400% compared to 4.5 million covered lives as of May 1, 2023. Recent medical policy coverages include:
  - BCBS licensee in Florida covering over 6 million lives.
  - BCBS licensee in North Dakota covering over 310,000 people.
  - BCBS plan in the mid-Atlantic region, providing coverage for approximately 7 million covered lives.
  - Medical Policy with a BCBS licensee 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 during therapy and then every 3 months up to 1 year. 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 DGBIs 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. FDA clearance is expected in the fourth quarter of 2024.
- In addition to securing $3.0 million in committed convertible note financing from affiliates of Inspire Health Alliance on November 8, 2023, the Company also closed 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, with the majority of such financing expected to be paid in monthly amounts through the first quarter of 2025. The Company further strengthened its balance sheet and liquidity position this week by signing documents for an additional $3.0 million in convertible notes from a reputable healthcare focused fund.

Management Commentary

Brian Carrico, Chief Executive Officer of NeurAxis, commented, “We are pleased with the continued execution of our commercialization strategy for IB-Stim™, our FDA cleared device for functional abdominal pain associated with irritable bowel syndrome in adolescents 11-18 years old. IB-Stim™ is based on our proprietary technology known as Percutaneous Electrical Nerve Field Stimulation (PENFS) technology, which targets nerves to alter pain transmission at the CNS level. The demand for our product is at record levels and continues to increase and as the payer coverage continues to expand, we expect to see continued revenue growth. We remain focused on leveraging the strong data from our studies, which we expect will lead us

to wider insurance acceptance from the 22.5 million lives we have under coverage today to a projected 50 million lives by the end of 2024. In recent weeks, we received verbal approval for our first state Medicaid program and written approval for a managed Medicaid in South Carolina. As such, we expect continued revenue growth in 2H24 as hospitals put the proper billing processes in place and begin purchasing the product."

"Further contributing to our growth acceleration in 2H24 will be the commercialization of RED, our option to licensed innovative rectal expulsion device, a self-inflating balloon expulsion test that allows for point-of-care testing to effectively identify patients with an evacuation disorder, such as pelvic floor dysfunction. We expect the device to receive FDA clearance in the fourth quarter of 2024" Mr. Carrico continued.

Dr. Adrian Miranda, Chief Medical Officer of NeurAxis, commented, "Our robust research studies are integral and have resulted in gaining industry acceptance and insurance coverage. Thus far there have been 15 published studies using PENFS technology, including the most recent "real-world" registry data that shows the sustainability of the improved response in children and adolescents.

Mr. Carrico concluded, "We remain steadfast in executing on our near-term goals to further commercialize our lead pediatric indication for IB-Stim. In addition, we are advancing our development pipeline for a number of new indications leveraging our unique neuromodulation therapy, including Functional Dyspepsia, Cyclic Vomiting Syndrome, Post-concussion Syndrome, and more. 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."

First Quarter 2024 Financial Results

Revenues in the first quarter of 2024 were $646.6 thousand, down 19.7% compared to $805.1 thousand in the first quarter of 2023. The decrease was primarily due to fewer shipments to certain customers as they manage through the insurance reimbursement process, partially offset by an increase in volume to our patient assistance customers that receive devices at a discount. 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.

Gross profit in the first quarter of 2024 was $571.6 thousand, a 19.4% decrease compared to $709.2 thousand in the first quarter of 2023 due to the lower sales volume. Gross margin of 88.4% in the first quarter of 2024 expanded from 88.1% in the first quarter of 2023 due to growth in the patient assistance program at lower discounts.

Operating loss in the first quarter of 2024 was $1.8 million, an increase of 104.4% compared to $896.3 thousand in the first quarter of 2023. The increase was primarily due to (i) lower sales volume, (ii) the build out of the market access and sales teams, (iii) recurring costs of becoming a publicly-held company including legal, insurance, investors relations and board fees, (iv) advertising costs in order to expand market access and (v) $287.0 thousand of non-cash, non-recurring consulting and hiring costs, partly offset by lower selling and research and development expenses.

The net loss in the first quarter of 2024 was $2.1 million, an improvement of 2.4% compared to $2.2 million in the first quarter of 2023. The improvement was primarily due to the reduction of debt discount and issuance cost amortization and interest expense upon the conversion of convertible notes in the August 2023 IPO, partly offset by increased general and administrative costs, the absence of a benefit from debt extinguishment in 2023, lower benefit from the revaluation of warrants and derivatives and a $230.0 thousand non-cash, non-recurring charge to settle a 2023 convertible note dispute.

Cash on hand as of March 31, 2024 was $81.7 thousand. Cash used by operations of $1.3 million in the first quarter of 2024 was 113.9% higher compared to $622.9 thousand in the first quarter of 2023 due to the higher operating loss as the Company continues to build out its market access and sales teams including advertising spend and adjust to an incremental recurring public company cost structure as well as payments to past due vendors which did not occur in the first quarter of 2023. Although the Company had no long-term debt as of March 31, 2024, short-term debt, net of deferred financing fees, totaled $1.4 million due to proceeds received from convertible notes in the first quarter of 2024. The addition of the recently signed $3.0 million convertible note will significantly improve the Company's liquidity position.

Conference Call Details

Date and Time: Wednesday, May 22, 2024, at 9:00am 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/jbecdhzi 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/jbecdhzi 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 which include, but are not limited to, statements regarding FDA clearance in the fourth quarter of 2024, the timing of the receipt of financing proceeds, revenue growth, and wider insurance acceptance of our products 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, but are not limited to,, 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 timing of decisions by insurance companies to provide coverage of our products, 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.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Net sales	$ 646,635	$ 805,110
Cost of goods sold	75,081	95,900
Gross profit	571,554	709,210
Selling expenses	80,030	107,932
Research and development	5,570	16,797
General and administrative	2,318,074	1,480,755
Operating loss	(1,832,120)	(896,274)
Other (expense) income, net:		
Financing charges	(230,824)	(2,772)
Interest expense	(26,560)	(161,689)
Change in fair value of warrant liability	(9,284)	234,807
Change in fair value of derivative financial instruments	-	191,297
Amortization of debt discount and issuance cost	(21,683)	(2,662,655)
Extinguishment of debt liabilities	-	1,129,498
Other expense, net	(180)	(5,622)
Total other (expense) income, net	(288,531)	(1,277,136)
Net loss	$ (2,120,651)	$ (2,173,410)