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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 9, 2024

Neuraxis, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41775**	**45-5079684**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

11550 N. Meridian Street, Suite 325
Carmel, IN 46032
(Address of principal executive offices)

Registrant's telephone number, including area code: **(812) 689-0791**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	NRXS	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On August 9, Neuraxis, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information contained in Item 2.02 (including Exhibit 99.1) shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and such information is not incorporated by reference into any registration statements or other document filed under the Securities Act of 1933, as amended or the Exchange Act, regardless of the general incorporation language contained in such filing, except as shall be expressly set forth by specific reference to this filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Exhibits
99.1	Neuraxis, Inc. press release dated August 9, 2024, announcing second quarter 2024 financial results.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 9, 2024

NEURAXIS, INC.

By: */s/ Brian Carrico*
Name: Brian Carrico
Title: President and Chief Executive Officer

Exhibit 99.1

NeurAxis Reports Second Quarter 2024 Financial Results

Conference call will be held today, Friday, August 9 at 9:00 am ET

Carmel, Ind., August 9, 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 second quarter period ended June 30, 2024.

Recent Operational Highlights

- Expanded total covered lives to approximately 22.5 million covered lives 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.
- One of the nation's largest not for profit health plans, serving over 12 million members, has committed to provide formal coverage beginning October 1st, 2024. Once this policy is in the public domain, the covered lives will be over 35 million.
- Submitted to the FDA its innovative rectal expulsion device (RED) product, which was licensed from the University of Michigan. RED's innovative design simplifies anorectal function testing and can be used without interrupting clinical workflow. FDA clearance is expected in the fourth quarter of 2024.
- Announced a submission to the FDA for the expansion of IB-Stim label to allow for a larger patient population beyond the current 11-18 years of age to 8-21 years.
- The Company remains committed to clinical research in the pediatric space, with 16 peer-reviewed publications. All studies were carried out in US children's hospitals using NeurAxis' PENFS technology. This level of evidence puts NeurAxis in a great position to continue expanding payor coverage and increasing 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™ ($p=0.21$).

- In addition to closing $6.1 million in committed financing from various investors, including affiliates of Inspire Health Alliance, in the first quarter of 2024, the Company secured an additional $3.0 million of funding in May 2024 with identical terms from a reputable healthcare-focused fund. The remainder of the financing is expected to be paid monthly through 2025.

Management Commentary

Brian Carrico, Chief Executive Officer of NeurAxis, commented, "We are excited about another strong quarter of continued execution, bringing us much closer to having the complete foundation in place to scale revenues. Our commercialization strategy for IB-Stim™, based on strong data publication leading to insurance coverage, is beginning to bear fruit. We now have 22.5 million lives under insurance coverage with many pending decisions, a significant increase from 4.5 million a year ago. While revenues in 2Q24 declined 5.3% on a year-over-year basis, this is a significant improvement compared to year-over-year declines of 19.7% and 13.3% in 1Q24 and 4Q23, respectively. Most importantly, the revenue we lost in the previous quarters is not due to lost accounts but rather accounts receiving "no-authorization required" responses from payers, which means the claim will likely not be paid. These accounts are set up and ready to begin treating again once the larger payers have a policy in place. The fact that we are alleviating the losses without these accounts shows we are adding accounts, and current accounts are treating more and more children as their insurance coverage increases. The demand for our product is at record levels and continues to increase. In the second half of 2024, we expect to roughly double our lives under insurance coverage to 50 million, setting the stage for growth acceleration in late 2024 and into 2025. In recent weeks, we received a commitment from our largest payer to date with over 12 million covered lives, with launch expected on October 1st."

“Further contributing to our growth acceleration in 2H24 will be the commercialization of RED, our 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 have made the submission to the FDA and expect the device to receive FDA clearance late in the fourth quarter of 2024” Mr. Carrico continued.

Mr. Carrico concluded, “We remain committed to further commercializing our lead pediatric indication for functional abdominal pain associated with IBS in children. We have recently made an FDA submission to expand our label beyond the current 11-18 year old patient population to the 8-21 year old patient population and four devices. 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, and more. As a result of recent financings with long-term investors in the healthcare space, our balance sheet is well positioned to execute our business plans for the foreseeable future.”

Second Quarter 2024 Financial Results

Revenues in the second quarter of 2024 were $611.5 thousand, down 5.3% compared to $646.0 thousand in the second 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, a lag exists 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 second quarter of 2024 was $538.0 thousand, a 6.9% decrease compared to $578.2 thousand in the second quarter of 2023 due to the lower sales volume. The decline in gross margin to 88.0% in the second quarter of 2024 from 89.5% in the second quarter of 2023 was due to growth in deliveries from our financial assistance programs that are discounted to patients without insurance coverage.

Operating loss in the second quarter of 2024 was $2.2 million, an increase of 97.5% compared to $1.1 million in the second 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, exchange listing and board fees, (iv) advertising costs in order to expand market access, (v) expenses related to the introduction of an annual short-term incentive bonus program (vi) $435 thousand of non-recurring severance and consulting costs, partly offset by lower selling and research and development expenses.

The net loss in the second quarter of 2024 was $2.9 million, an increase of 30.5% compared to $2.2 million in the second quarter of 2023. The increase was primarily due to (i) higher general and administrative costs and (ii) the non-cash settlement of certain pre-IPO Series A Preferred Stock shareholder claims, partly offset by the elimination of debt discount, issuance costs, debt extinguishment and derivative fair valuation charges.

Cash on hand as of June 30, 2024 was $1.8 million as compared to $51.4 thousand as of June 30, 2023. Although the Company had no long-term debt as of June 30, 2024, short-term debt, net of deferred financing fees, totaled $4.8 million due to proceeds received from the issuance of notes payable during the six months ended June 30, 2024.

Conference Call Details

Date and Time: Friday, August 9, 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://ir.neuraxis.com/ or https://edge.media-server.com/mmc/p/bettcvsw. 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/bettcvsw 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/.

Contacts:

Company
NeurAxis, Inc.
info@neuraxis.com

Investor Relations

Lytham Partners
Ben Shamsian
646-829-9701
shamsian@lythampartners.com

NeurAxis, Inc.
Condensed Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net sales	$ 611,500	$ 646,021	$ 1,258,135	$ 1,451,131
Cost of goods sold	73,458	67,813	148,539	163,713
Gross profit	538,042	578,208	1,109,596	1,287,418
Selling expenses	62,274	78,791	142,304	186,723
Research and development	54,312	109,789	59,882	126,586
General and administrative	2,628,288	1,507,169	4,946,362	2,987,923
Operating loss	(2,206,832)	(1,117,541)	(4,038,952)	(2,013,814)
Other (expense) income:				
Financing charges	-	-	(230,824)	(2,772)
Interest expense	(80,697)	(194,690)	(107,257)	(356,378)
Change in fair value of warrant liability	7,576	(36,050)	(1,708)	198,757
Change in fair value of derivative financial instruments	-	860	-	192,157
Amortization of debt discount and issuance costs	(63,817)	(887,937)	(85,500)	(3,550,592)
Extinguishment of debt liabilities	-	-	-	1,129,498
Other income	2,961	2	2,961	1,552
Other expense	(576,901)	(258)	(577,081)	(7,430)
Total other (expense) income, net	(710,878)	(1,118,073)	(999,409)	(2,395,208)
Net loss	$ (2,917,710)	$ (2,235,614)	$ (5,038,361)	$ (4,409,022)