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 17, 2023

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 7.01. Regulation FD Disclosure.

Senior management and certain members of the Board of Directors of Neuraxis, Inc. (the "Company"), have begun using the materials included in Exhibit 99.1 to this report (the "Investor Presentation") in connection with presentations to existing stockholders of the Company, potential investors of the Company, and the investment community. While some of the materials in the Investor Presentation were previously utilized by the Company in the free writing prospectus filed with the Securities and Exchange Commission (the "SEC") on July 26, 2023, the specific Investor Presentation attached hereto is first being used effective as of August 17, 2023. The Investor Presentation provides an overview of the Company's strategy, performance and future objectives. The Investor Presentation is incorporated into this Item 7.01 by reference and will be available on the Company's website at http://neuraxis.com/.

Without limiting the generality of the foregoing, the "Forward-Looking Statements" disclosure contained in the Investor Presentation is incorporated by reference into this Item 7.01.

On August 17, 2023, the Company issued a press release providing a summary of the revenue generated by the Company's IB-Stim™ technology from 2019 through March 31, 2023.

The information contained in this Item 7.01 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.

Investors and others should note that the Company routinely announces material information to its investors using filings with the SEC, the Company's Investor Relations page on its website at http://neuraxis.com/, https://ir.neuraxis.com/, press releases, public conference calls, public webcasts, its feed on "X" (formerly known as Twitter) (https://twitter.com/NeurAxisInc), its Facebook page (https://www.facebook.com/IBStim.Stimulator), its YouTube page, https://www.youtube.com/@ib-stim, and its Instagram page (https://www.instagram.com/ib_stim_stimulator/). The information posted on the Company's website or social media channels is not incorporated by reference in this report or in any other report or document the Company files with the SEC. While not all of the information that the Company posts to its Investor Relations page on its website or to social media channels is of a material nature, some information could be deemed to be material. Therefore, the Company encourages investors, the media and others interested in the Company to review the information it makes public in these channels.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Exhibits
99.1	Neuraxis, Inc. Investor Presentation (August 17, 2023)
99.2	Press Release of Neuraxis, Inc. entitled "NeurAxis Announces Over $8 Million in IB-Stim™ Revenue"
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 17, 2023

NEURAXIS, INC.

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

Exhibit 99.1

Forward Looking Statements

NeurAxis, Inc. ("NeurAxis") is offering shares of common stock (the "Securities") in a public offering (the "Offering"). The proceeds of the Offering, if completed, are intended primarily to be used for sales and marketing activities, research and development, certain payments to our executive officers pursuant to their respective employment agreements, and general corporate purposes.

Information included herein has been prepared by NeurAxis, Inc. ("NeurAxis") or obtained from sources believed to be reliable, but the accuracy or completeness of such information is not guaranteed by and should not be construed as a representation by NeurAxis or any other person.

This presentation includes 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. Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects NeurAxis's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or NeurAxis actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "could", "would", "should", "plan", "predict", "potential", "project", "expect", "estimate", "anticipate", "intend", "goal", "strategy", "believe", and similar expressions and variations thereof. Forward-looking statements may include statements regarding NeurAxis's business strategy, the market size and potential growth opportunities of NeurAxis current and future product candidates, capital requirements and use of proceeds, pre-clinical and clinical development activities, the timeline for, and results of, clinical trials, regulatory submissions, and potential regulatory approval and commercialization of its current and future product candidates. Although NeurAxis believes that the expectations reflected in such forward-looking statements are reasonable, such statements are based upon numerous estimates and assumptions with respect to industry performance and competition, general business, economic, market and financial conditions and matters specific to the business of NeurAxis, all of which are difficult to predict and many of which are beyond the control of NeurAxis. NeurAxis cannot guarantee future events, results, actions, levels of activity, performance or achievements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in NeurAxis's filings with the Securities and Exchange Commission as well as risks, uncertainties and assumptions relating to or arising from: (1) the ability to integrate any potential new product candidates into NeurAxis's business in a timely and cost-efficient manner; (2) the cooperation of our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; and (3) changes in applicable laws or regulations. Actual results and the timing of events could differ from those anticipated in such forward-looking statement as a result of these risks.

These forward-looking statements speak only as of the date of this presentation and NeurAxis undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

This presentation also contains estimates and other statistical data made by independent parties and by NeurAxis relating to market shares and other data about the neuromodulation industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

NeurAxis PENFS[1]: First FDA Cleared Treatment for Pediatric FAP/IBS[2]

Large Global Market with Significant Unmet Need

- $30B+ TAM[3] for target pipeline indications
  - $9B+ TAM[3] for target pediatric indications (near-to-mid term)
  - $21B+ TAM[3] for target adult indications (mid term)
- Large unmet clinical need: high refractory, off label pharmacological treatments with adverse side effects

Clear Commercial Pathway

- FDA De Novo clearance
- Technology specific CPT billing code
- Major Insurance Payer Coverage initiated
- Strong IP on Device and Method

Unique, Innovative Product Supported by Clinical Evidence

- Novel treatment targeting the brain
- Differentiated PENFS technology
- 800+ published patients[4] by Q3 2023
- Easy-to-learn and efficient procedure

Seasoned Management and Board

- Experienced management team and Board of Directors
- Operations and infrastructure built to scale
- Path to profitability

1. Percutaneous Electrical Nerve Field Stimulation
2. FAB/IBS: Functional Abdominal Pain/Irritable Bowel Syndrome
3. Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient
4. Published patient - a patient who went through a study and the study was analyzed and now the study has been published in a peer-reviewed journal

1st Half 2023 Highlights

Q1 2023

- Expanded insurance policy coverage
  - Coverage extends to 4.75M lives from 4M at the end of 2022
  - Notable Plans:
    - BCBS South Carolina
- Hired U.S. Market Development Director from Zimmer Biomet
- +30% sequential revenue growth

Q2 2023

- Submitted CPT CAT I application
- Launched internal prior authorization team to support and strengthen account utilization
- Received FDA feedback earlier than anticipated on the first phase of Adult indications
- Advanced development of AI technology platform that allows for all pediatricians to diagnose and treat FAPDs*

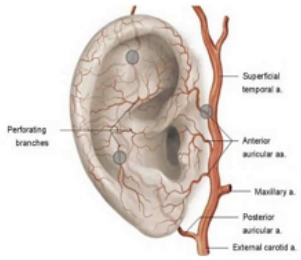
1H 2023

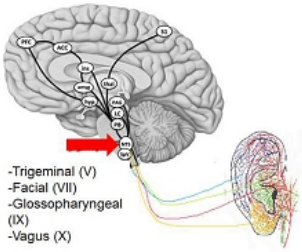
- 10+ Large payers in the policy review stage
- 10+ New Children's Hospital Accounts

* Functional Abdominal Pain Disorders (FAPDs)

Percutaneous Electrical Nerve Field Stimulation (PENFS)

How Does Neuromodulation Work?





1. Access

Direct access to central nervous system (CNS) through peripheral cranial nerves

2. Stimulate

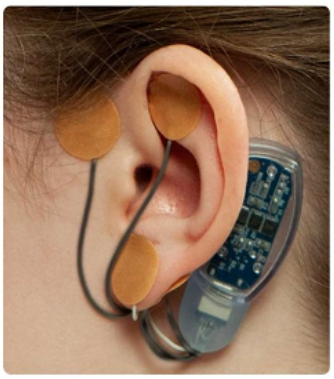
Stimulation reduces firing of amygdala

3. Change

Induces changes in brain pathways/connectivity

* Second Generation Device Pictured

Established Technology with Demonstrated Safety and Efficacy



IB-STIM

What is IB-Stim™

- PENFS system intended for patients 11-18 years of age with functional abdominal pain (FAP) associated with IBS
- Aids in pain reduction via neuromodulation to branches of Cranial Nerves (V,VII,IX and X)
- Non-drug and non-surgical device therapy that can be placed in an outpatient clinic
- Used 120 hours per week for up to 3-4 consecutive weeks*

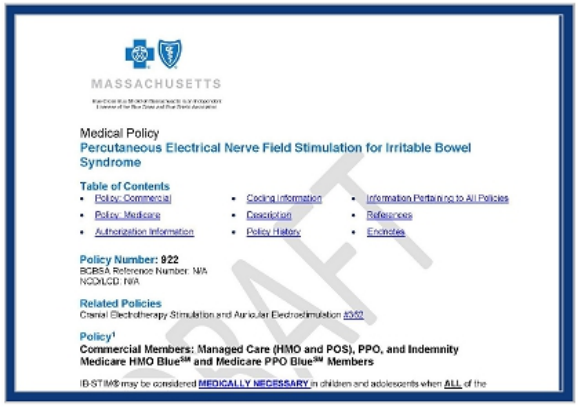
FDA De Novo Clearance

CPT CAT III Effective July 1,2022

* FDA guidance of 3 weeks not to exceed 4 weeks

IB-Stim™ Advantages Over Traditional Care

IB-Stim™		Traditional Care
FDA Indicated	FDA Clearance	No FDA Approved Treatments
Non-Drug Alternative	Physicians / Parents	Rx often Containing FDA Black Box Labels
Localized Skin Irritation	Side Effects	Suicidal Ideation, Depression, & Weight Gain
Targets The Brain Gut Axis	Delivery	Localized and Peripheral



MASSACHUSETTS

Medical Policy

Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome

Table of Contents

- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References
- Endnotes

Policy Number: 922
BCBSA Reference Number: N/A
NCD/LCD: N/A

Related Policies
Cranial Electrotherapy Stimulation and Auricular Electrostimulation 8552

Policy[1]
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

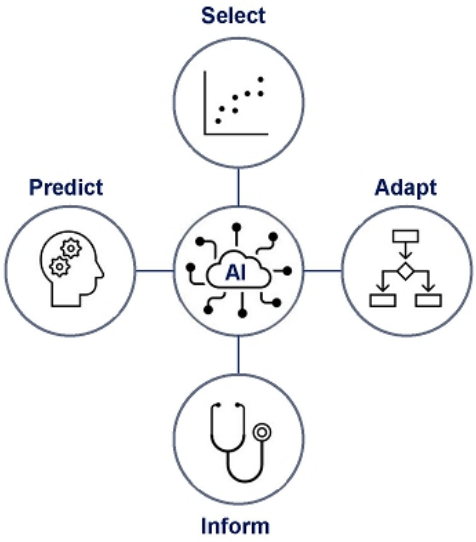
IB-STIM® may be considered **MEDICALLY NECESSARY** in children and adolescents when ALL of the

DRAFT

NeurAxis

Artificial Intelligence to IB-Stim™

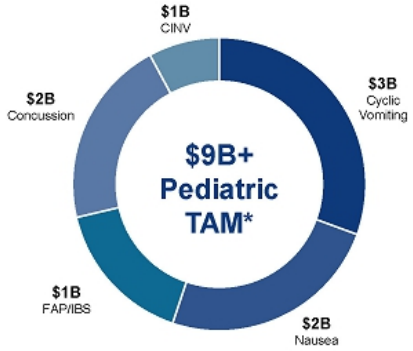
- Artificial Intelligence will analyze large datasets, allowing for the automated diagnosis of FAPDs
- Select patients via EMR with a higher likelihood of response to IB-Stim™
- Predict response to treatment using IB-Stim™
- Obviate the need for referral to pediatric subspecialists
- Treatment in the general pediatrician's office



NeurAxis

$30B+ Total Addressable U.S. Market for Pipeline Indications

Near-to-mid term Target



Mid-term Target

Why Pediatrics?

- Significant unmet need
- Lack of FDA approved treatment options
- Single call point for future indications

Entering Pediatric markets first with:

- First FDA cleared treatment for Pediatric FAP/IBS
- Growing Body of Clinical Evidence
- Coding, Coverage and Payment
- KOL and AAP/NASPGHAN endorsement

* Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient

NeurAxis

IB-Stim™ Research – By the Numbers

800+ Published Patients
Expected by Q3 2023

6 Current Publications

15 Publications Expected by Q3 2023

7 Types of Studies

- Double Blind Placebo Controlled
- Long-Term Data
- Registry Data
- Quality of Life Data
- Real World Clinical Data
- Head-to-Head Research vs. SoC
- Health Economic Study

13 Children's Hospital Study Sites

Cincinnati Children's
Boston Children's Hospital
Riley Children's Health
Indiana University Health
CHOC Children's
Children's Wisconsin
Kids deserve the best.
Duke Children's

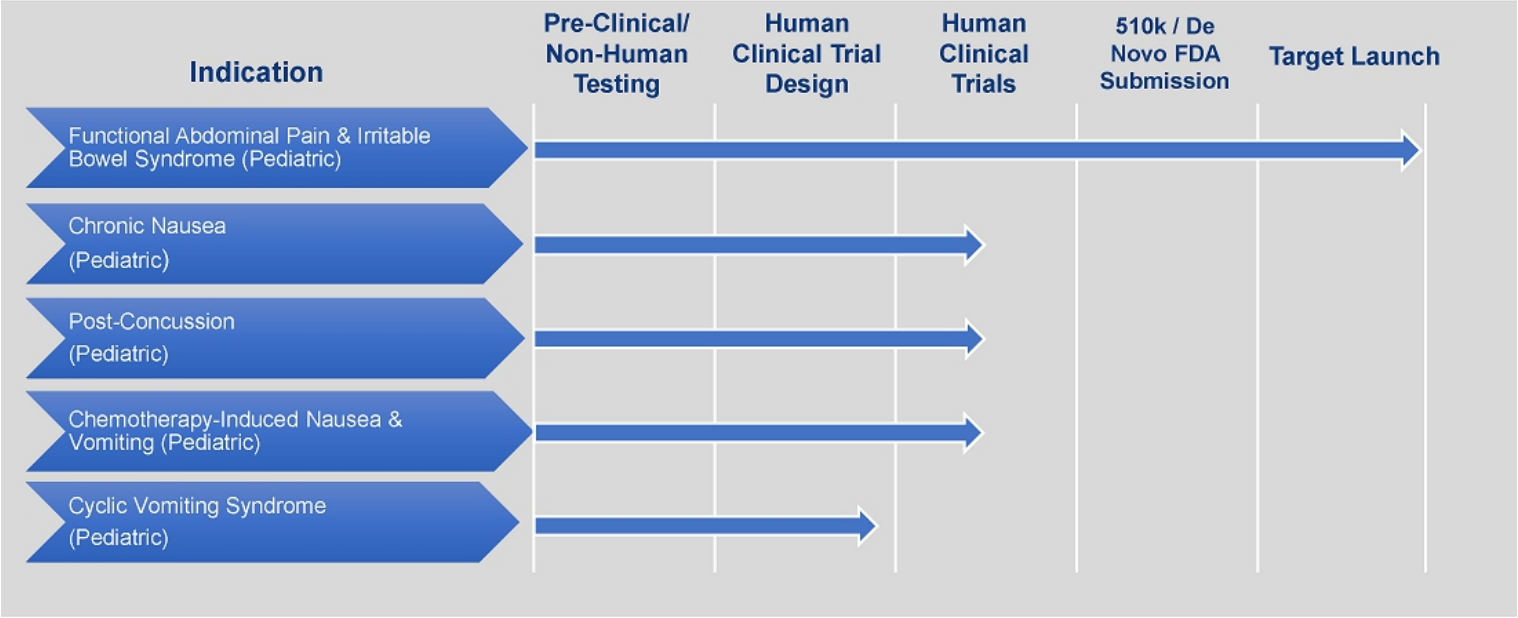
NeurAxis

IB-Stim™ Competitive Landscape

			Antidepressants		Adult Use (Peripherally Acting at the Gut Level)			
	IB-Stim™	Psychological Therapy	Amitriptyline	Citalopram	Amitiza	Linzess	Trulance	Viberzi
FDA Approved for IBS in Children and Adolescents	✓	✓						
Improves Functional Disability	✓	✓						
Targets Brain-Gut Axis	✓	✓	✓	✓				
Better Than Placebo for Pain in IBS	✓	✓			✓	✓	✓	✓
Improves Pain Catastrophizing	✓	✓						
Improves Global and Somatic Symptoms	✓	✓						
Most Serious Potential Side Effects	Localized Skin Irritation	None	Suicidal Ideation, Dementia (long term use)	Suicidal Ideation, Dementia (long term use)	Abdominal Pain, Allergic Reaction	Diarrhea, Abdominal Pain	Diarrhea, Serious Allergic Reaction	Pancreatitis, Serious Allergic Reaction, Intestinal Obstruction
Easily Accessible	✓		✓	✓	✓	✓	✓	✓

NeurAxis

FDA Pipeline Indications



NeurAxis

Go-To-Market Strategy

2023 Coverage

Total Plans	Total # Lives covered
4 plans	4.75M

Insurance plans	# Lives covered
BCBS of Massachusetts	3M
BCBS of South Carolina	750k
BCBS of Nebraska	700k
Quartz of Wisconsin	300k

Actively leveraging publications to expand coverage

Expecting Society position paper and guideline changes supporting IB-Stim™ as standard of care

Commercialization Strategy

Direct Sales Force

Reimbursement Strategy

Technology Specific CPT coding

CPT code*	• CAT III code (0720T)
List Price	• $1,195 (~$4,800 per patient)

Engage with AAP and NASPGHAN to apply for CAT I CPT code in 2023

Launch internal prior authorization team

Customers

Children's Hospitals
260 in the U.S.

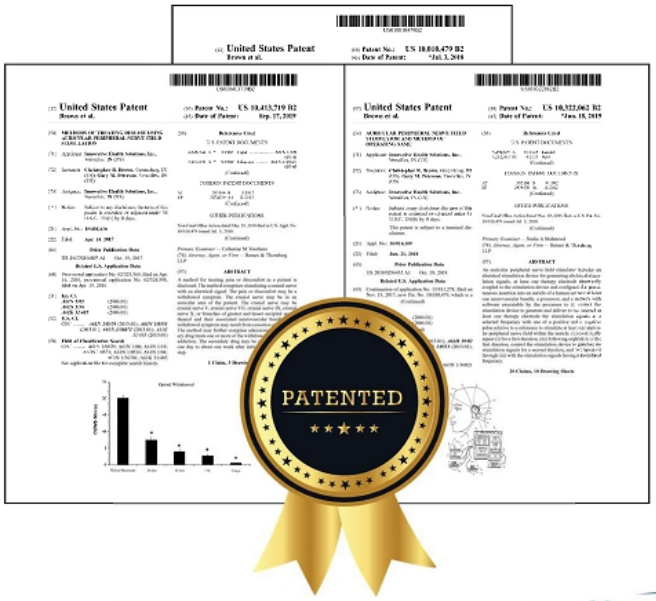
~33k
U.S. Pediatricians

~10k
U.S. Adult Gastroenterologists

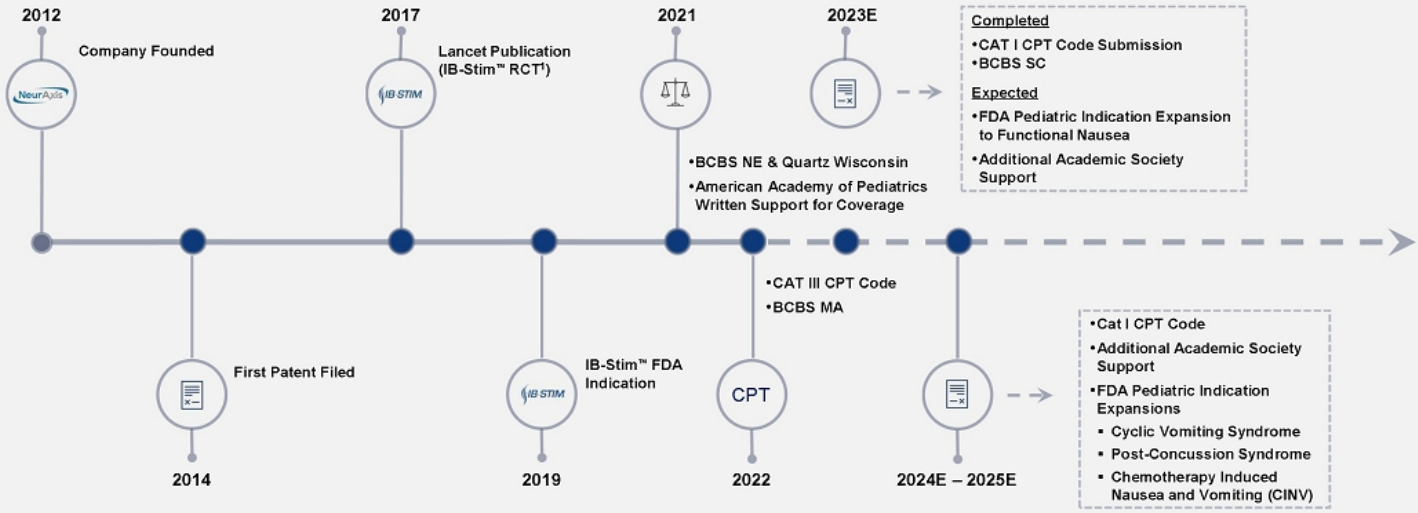
* CPT Code Effective July 1st, 2022

NeurAxis IP Portfolio

- 8 issued and 18 pending patents
  - Device
  - Method
- U.S. IP runs through 2039 for now
- International IP in process
- Freedom to operate



Key Achievements and Milestones



1. RCT: Randomized Controlled Clinical Trials

Management Team

Brian Carrico
Chief Executive Officer, Board Member

ST. JUDE MEDICAL
BARD

Dr. Adrian Miranda
Chief Medical Officer

MEDICAL COLLEGE OF WISCONSIN
Children's Hospital of Wisconsin

John Seale
Chief Financial Officer

RBSK PARTNERS PC
AICPA American Institute of CPAs

Dan Clarence
Chief Operating Officer

Shark NINJA
Walmart Save money. Live better.
BLACK+DECKER

Dr. Tom Carrico
Chief Regulatory Officer

INTEGRATIVE HEALTH CARE PARTNERS

Dr. Chris Brown
Director of Innovation, Founder, Board Member

NeurAxis

Key Investment Highlights

Large Global Market with Significant Unmet Need

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Exhibit 99.2

NeurAxis Announces Over $8 Million in IB-Stim™ Revenue

CARMEL, Ind., Aug. 17, 2023 (GLOBE NEWSWIRE) — NeurAxis, Inc. (NYSE American: NRXS) (“NeurAxis” or the “Company”), a medical technology company commercializing neuromodulation therapies that address chronic and debilitating conditions in children and adults, today announced it has generated over $8 million in revenue following the commercial launch of its proprietary IB-Stim™ technology. Sales began after NeurAxis received FDA clearance for IB-Stim™ in the pediatric treatment of functional abdominal pain and irritable bowel syndrome. NeurAxis is conducting clinical trials with IB-Stim™ for four additional pediatric indications, including chronic nausea, post-concussion syndrome, chemotherapy induced nausea and vomiting, and cyclic vomiting syndrome.

Approximately $2 million of the over $8 million in IB-Stim™ revenue through March 31, 2023 was generated in 2020 and 2019.

Brian Carrico, Chief Executive Officer of NeurAxis, said, “We are pleased to have reached over $8 million in sales of our proprietary IB-Stim™ technology and look forward building upon our momentum with the funds received from our recently completed IPO. We continue to drive increasing adoption of our IB-Stim™ therapy, supported by a significant and growing body of positive clinical data and commercial large health insurance company payor support. We believe the growing movement of patients gravitating towards non drug related therapies, especially for children, will continue to fuel our rapidly increasing adoption and the market for our new indications.”

Forward Looking Statements

This document contains certain “forward-looking statements”. All statements other than statements of historical fact are “forward-looking statements” for purposes of federal and state securities laws, including, but not limited to, any projections of earnings, revenue or other financial items; any statements of the plans, strategies, goals and objectives of management for future operations; any statements concerning proposed new products and services or developments thereof; any statements regarding future economic conditions or performance; any statements or belief; and any statements of assumptions underlying any of the foregoing.

Forward looking statements may include the words “may,” “could,” “estimate,” “intend,” “continue,” “believe,” “expect” or “anticipate” or other similar words, or the negative thereof. These forward-looking statements present our estimates and assumptions only as of the date of this document. Accordingly, readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the dates on which they are made. We do not undertake to update forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made. You should, however, consult further disclosures and risk factors we include in our filings with the Securities and Exchange Commission.

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.

The estimated revenues generated in 2019 and 2020 reflect our estimated financial results which were not audited nor reviewed by an independent registered public accounting firm.

Contacts:

Company
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info @neuraxis.com

Investor Relations
Gilmartin Group
IR@neuraxis.com