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): March 7, 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.)

11611 N. Meridian St, Suite 330
Carmel, IN 46032
(Address of principal executive offices)

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

(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 7, 2024, the Board of Directors (the "Board") of NeurAxis, Inc. (the "Company") appointed Kristin Ferge to the Board to serve until the Company's next annual meeting of shareholders. The Board has determined that Ms. Ferge is an independent director and meets the applicable director independence requirements of the NYSE American and rules promulgated by the Securities and Exchange Commission. The Board also appointed Ms. Ferge to Board's Audit Committee (the "Audit Committee") as the Chairman of the Audit Committee. The Board has determined that Ms. Ferge is an audit committee financial expert as defined by Item 407 of Regulation S-K and, as such, the Board has determined that Ms. Ferge is financially sophisticated as defined by NYSE American Company Guide Section 803.

In connection with her appointment to the Board, the Ms. Ferge will receive an annual compensation of $60,000 and shares of the Company's common stock valued at $50,000.

Kristin A. Ferge, 50, has been President and Chief Financial Officer of Capri Communities and Bridges Home Healthcare, a Wisconsin-based privately held senior living corporation, since 2016. Prior to joining Capri, Ms. Ferge was an executive for 18 years with Brookdale Senior Living Inc. or one of its predecessors. Ms. Ferge ended her tenure at Brookdale, a publicly traded senior living company, as Executive Vice President, Treasurer, and Chief Accounting Officer. Prior to Brookdale, Ms. Ferge was an auditor with KPMG. Ms. Ferge is a certified public accountant.

There is no arrangement or understanding between Ms. Ferge and any other person pursuant to which she was selected as a director of the Company.

There are no transactions in which Ms. Ferge or any of her immediate family members has an interest requiring disclosure under Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosure.

Senior management of the Company and certain members of the Board 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. The Investor Presentation contains certain information about the Company and its industry. 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.

The information in this Item 7.01 and the accompanying Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Neuraxis, Inc. Investor Presentation
104	Cover Page Interactive Data File (formatted as inline XBRL)

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: March 11, 2024

NEURAXIS, INC.

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

NeurAxis

NeurAxis, Inc.

Reimagining an Evidence-Based, Drug Free Alternative For Children

March 11, 2024

NeurAxis is committed to providing solutions that create value and provide better patient outcomes. We believe in improving lives and minimizing suffering. Through innovation and research, we are reimagining the future of patient care.

Forward Looking Statements

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 statements 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.

This PowerPoint discusses ongoing research activities and investor-directed information with percutaneous electrical nerve field stimulator (PENFS) technology. Please note, that the PowerPoint 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/.

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

Strong Data = Strong Policy Coverage & Reimbursement = Strong Revenue Growth

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-gut-axis
- Differentiated PENFS technology
- 700+ published patients[4] by Q1 2024
- Easy-to-learn and efficient procedure

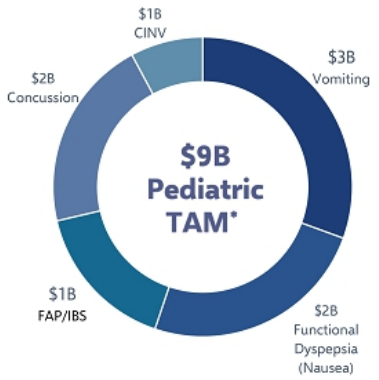
Seasoned Management and Board

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

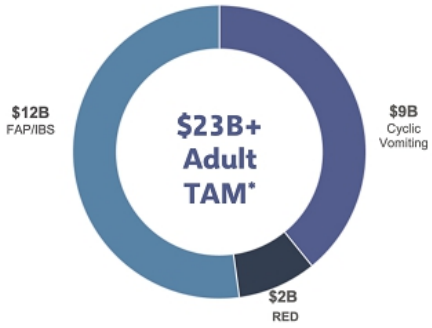
1. Percutaneous Electrical Nerve Field Stimulation
2. FAB/IBS: Functional Abdominal Pain/Irritable Bowel Syndrome
3. Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient
4. Published patient - a patient who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

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

Pediatric Indications



Adult Indications



Why Pediatrics?

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

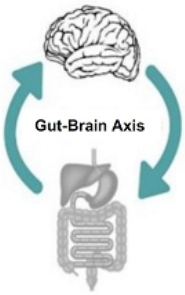
Entering Pediatric markets first with:

- 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

DGBIs: A Problem with an Unmet Need

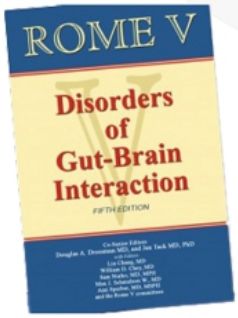
- No FDA-approved therapies for children with abdominal pain-related disorders of the gut-brain interactions (DGBIs)
- Disorders negatively impact quality of life and ability to function (attend school, sports, and social activities)
- Insufficient data to support the use of the most prescribed drugs, some with serious side effects
- A growing number of families and providers are seeking non-pharmacologic alternatives for children

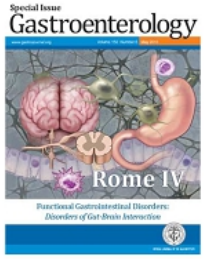


Abnormal processing of signals to and from the gut

Disorders of the Gut-Brain Interaction (DGBIs)

- Functional Dyspepsia
- Irritable Bowel Syndrome
- Cyclic Vomiting Syndrome





Functional Dyspepsia – pain or discomfort located in the upper abdomen

Irritable Bowel Syndrome (IBS) –characterized by abdominal discomfort or pain associated with defecation or a change in bowel habit.

Cyclic Vomiting Syndrome – recurrent episodes of intense nausea and vomiting lasting hours to days with intervals of normal wellbeing lasting weeks to months.

Data Does Not Support Standard Pharmacotherapy in Children with IBS

No data to support use of Antidepressants in Children with Functional Abdominal Pain:

- Amitriptyline (TCA) did not beat placebo in RCT[1]
- Citalopram (SSRI) did not beat placebo in RCT[2]

Significant Risk of TCA Side Effects in Children:

- Increased risk of suicidal ideation (black box warning)[3]
- Mood changes
- EKG disturbance[4]
- Long-term risk of dementia[5]

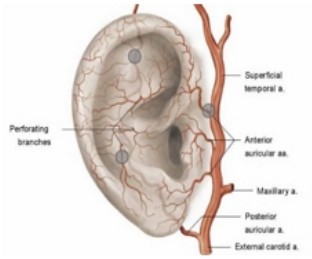
Substantial Patient Need for Safe & Effective, Non-Pharmacological Alternatives:

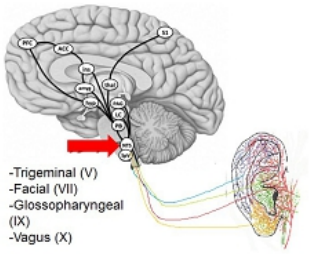
- Growing number of families seeking alternative therapies for pain in children[6]

1. Saps M, Youssef N, Miranda A, et al. Multicenter, randomized, placebo-controlled trial of amitriptyline in children with functional gastrointestinal disorders. *Gastroenterology*. 2009;137:1261-1269.
2. Roohafza H, Pourmoghaddas Z, Saneian H, Gholamrezaei A. Citalopram for pediatric functional abdominal pain: a randomized, placebo-controlled trial. Neurogastroenterol Motil. 2014;26:1642-1650.
3. Jick H, Kaye JA, Jick SS. Antidepressants and the risk of suicidal behaviors. JAMA. 2004;292:338-343.
4. Chogle A, Saps M. Electrocardiograms changes in children with functional gastrointestinal disorders on low dose amitriptyline. World J Gastroenterol. 2014;20:11321-11325.
5. Coupland CAC, Hill T, Dening T, Morriss R, Moore M, Hippisley-Cox J. Anticholinergic Drug Exposure and the Risk of Dementia: A Nested Case-Control Study [published online ahead of print, 2019 Jun 24]. JAMA Intern Med. 2019;179:1084-1093.
6. Groenewald CB, Beals-Erickson SE, Ralston-Wilson J, Rabbitts JA, Palermo TM. Complementary and Alternative Medicine Use by Children With Pain in the United States. Acad Pediatr. 2017;17:785-793.

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

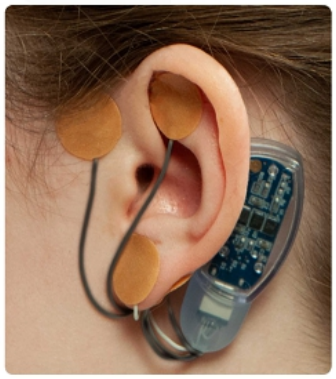
Stimulation reduces firing of amygdala

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*

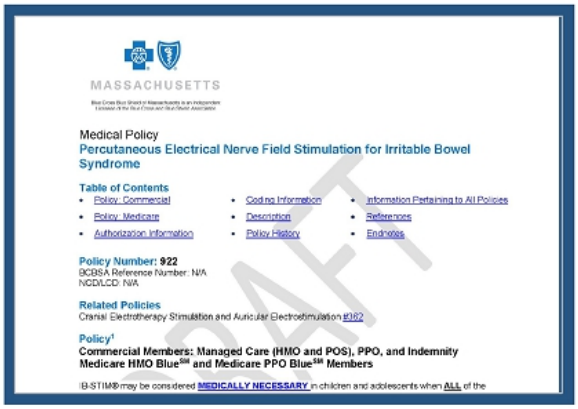
FDA De Novo Clearance

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
Minimal	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 #382

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

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

DRAFT

Patient Journey

1. Persistent Pain

Patient experiences frequent and often debilitating abdominal pain (weeks, months or years)

2. Consultation

General Pediatrician

- Pain is generalized, non-specific, showing no "red flags"
- Counsels on lifestyle changes
  - If no benefit, trial of medication
  - If no benefit, referral to Pediatric Gastroenterologist

Families often skip PCP since referral is not required

Pediatric Gastroenterologist

- Blood work (CBC, metabolic panel, inflammatory markers, celiac screen) and stool test
  - If negative, treatment with medication is started
    - Antidepressants (TCAs and SSRIs) used for pain
    - Anti-histamine (Cyproheptadine)
    - Anti-spasmodics (Hyoscyamine)
    - Cognitive behavioral therapy, where available

IB-STIM

FDA cleared IB-Stim™ can be used first vs. traditional, off-label pharmacotherapy-based approach

3. Placement

- Outpatient (in-office) procedure placement by acting Physician
- Requires no anesthesia

4. Use/Care

- Stays on for 120 hours (5 days)
- No special care requirements except to avoid getting wet

5. Follow-Up

- Patient takes off at home after 5 days, gets a 2-day break, then visits a physician for next prescribed treatments for up to 4 weeks.
- Further follow up visits / titration as needed

NeurAxis

IB-Stim™ Research – By the Numbers

Strong Data = Strong Policy Coverage & Reimbursement = Strong Revenue Growth

16 Current Publications Utilizing NeurAxis' PENFS Technology

10 Types of Studies

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

13 Children's Hospital Study Sites

Boston Children's Hospital

Riley Children's Health
Indiana University Health

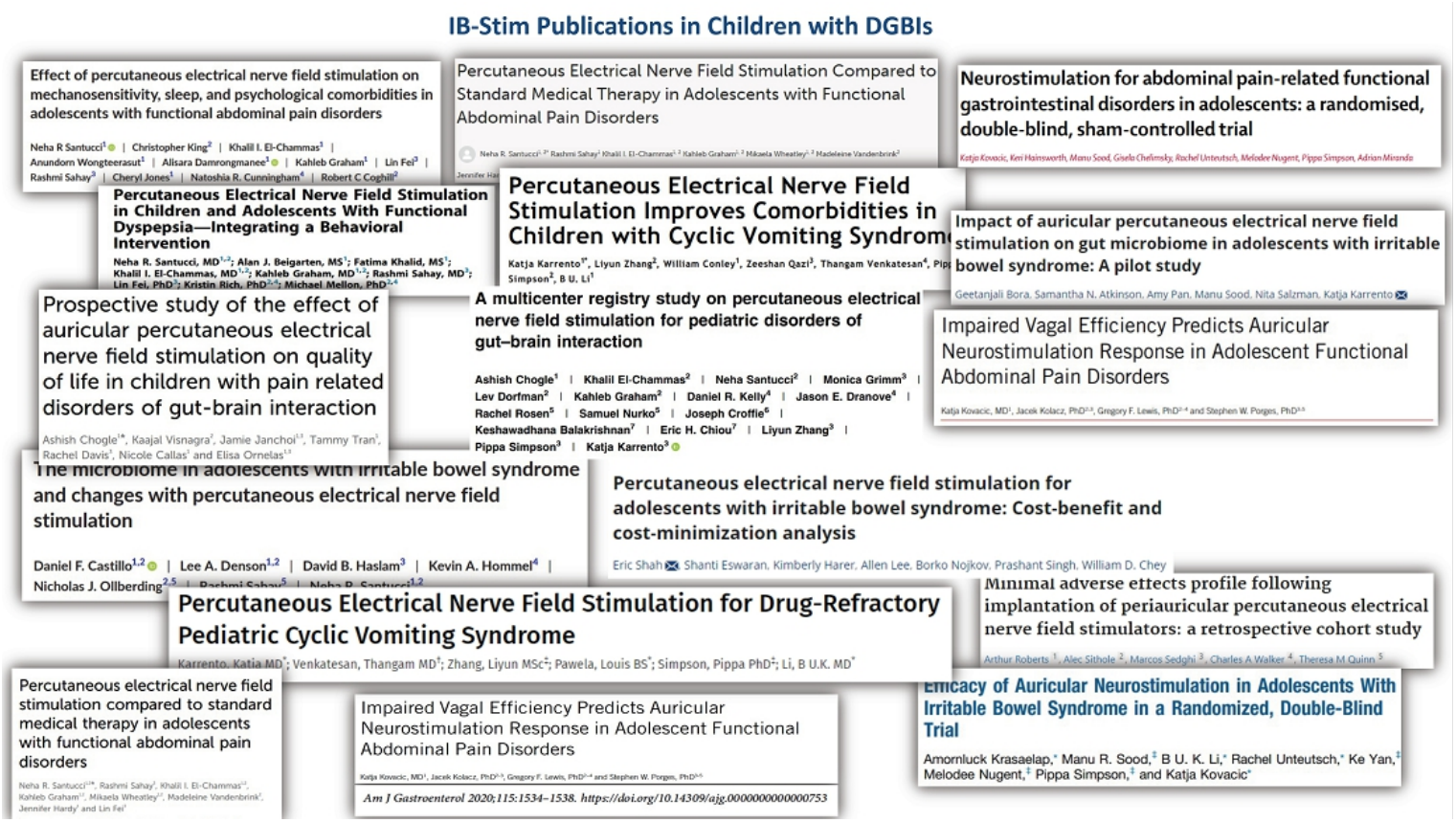
Cincinnati Children's

CHOC Children's

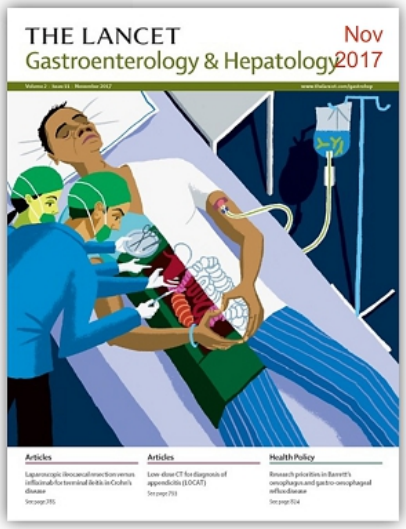
Children's Wisconsin

Duke Children's

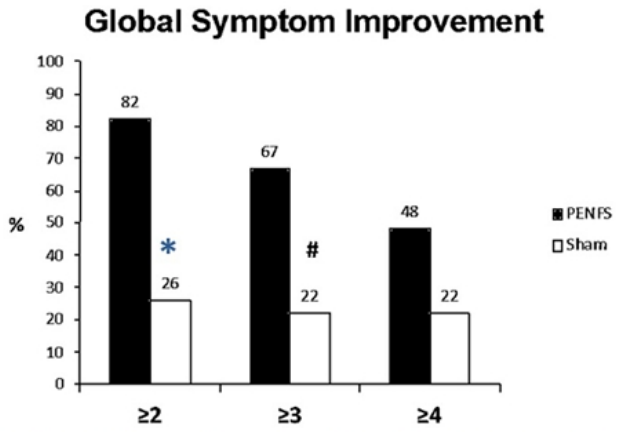
IB-Stim Publications in Children with DGBIs



Growing Body of Clinical Evidence



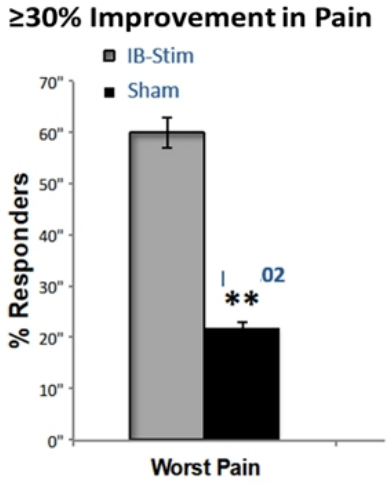
Improvement of Global Symptoms in Patients with Irritable Bowel Syndrome



*Percent of patients reporting improvement of global symptoms using Symptom Response Scale score ≥2 (*p≤0.001), ≥3 (#p=0.002) and ≥4 (p=0.077)

Kovacic K, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomized, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol.* 2017;2(10):727-737.

FDA Benchmark for Clinically Meaningful Endpoint



Treatment for abdominal pain-related functional gastrointestinal disorders in adolescents:

Number Needed to Treat (NNT):
The number of patients that need to be treated for one patient to get the targeted improvement (≥30% improvement).

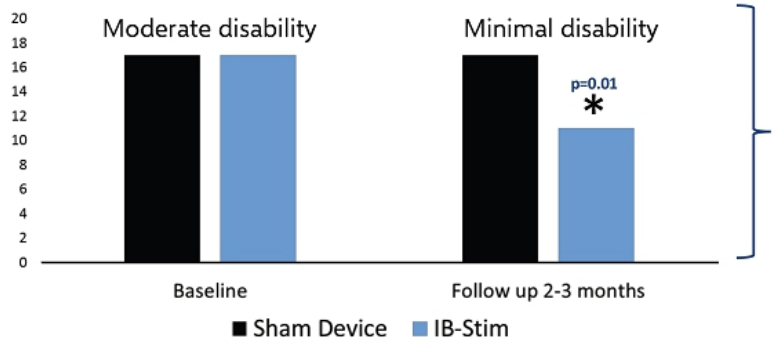
IB-Stim NNT=3

IBS drugs in adults (lubiprostone, linaclotide, and rifaximin) NNT=6 to 14[2]

1.Krasaelap A, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. Clinical Gastroenterology & Hepatology. Clin Gastroenterol Hepatol. 2020;(9):1987-1994
2.Wall GC, et al. Irritable bowel syndrome: a concise review of current treatment concepts. World J Gastroenterol 2014.

Functional Disability Scores at Long-Term Follow-Up

Improvement in Functional Disability in Patients with Irritable Bowel Syndrome



Improving functional disability (attending school and activities) is a marker of overall health and clinically meaningful beyond subjective pain measures

* Based on functional disability index (FDI) developed and validated tool to assess difficulties in daily functioning due to chronic pain.

Kovacic K, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomized, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol*. 2017;2(10):727-737.

Largest Pediatric Registry in Children with DGBI

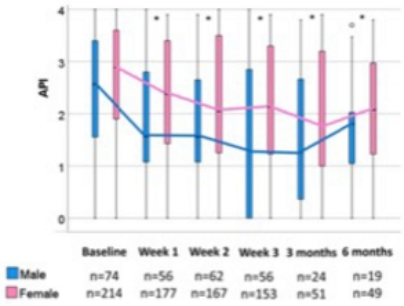
A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut–brain interaction

Ashish Chogle[1] | Khalil El-Chammas[2] | Neha Santucci[2] | Monica Grimm[3] | Lev Dorfman[2] | Kahleb Graham[2] | Daniel R. Kelly[4] | Jason E. Dranove[4] | Rachel Rosen[5] | Samuel Nurko[5] | Joseph Croffie[6] | Keshawadhana Balakrishnan[7] | Eric H. Chiou[7] | Liyun Zhang[3] | Pippa Simpson[3] | Katja Karrento[3]

- **Pediatric registry with "real world" clinical data**
- **61% had failed ≥ 4 medication prior to treatment**
- **Sustained efficacy in abdominal pain up to 6-12 months after 4 weeks of IB-Stim treatment**

TABLE 1 Participating centers

Participating centers	
Center	**Number of patients**
Cincinnati Children's Hospital	89
Children's Hospital of Orange County	75
Children's Wisconsin	65
Atrium Health Levine Children's Hospital	31
Boston Children's Hospital	18
Riley Hospital for Children	11
Texas Children's Hospital	3



A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut-brain interaction. J Pediatr Gastroenterol Nutr. 2024

NeurAxis

Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders

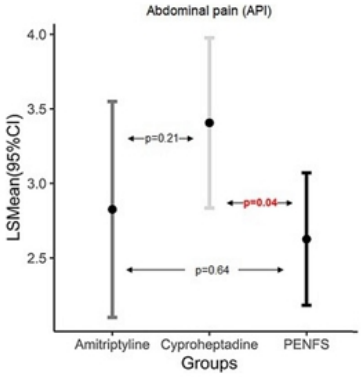
Neha R. Santucci[1,2]*, Rashmi Sahay[3], Khalil I. El-Chammas[1,2], Kahleb Graham[1,2], Mikaela Wheatley[1,2], Madeleine Vandenbrink[2], Jennifer Hardy[1] and Lin Fei[1]

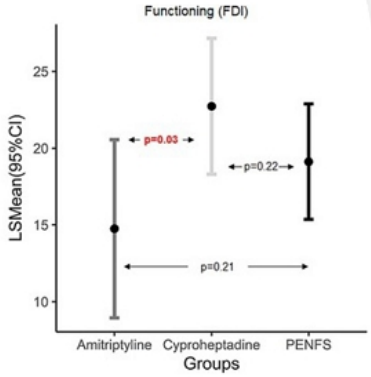
IB-Stim was equivalent or better than standard medications used for FAPDs

TABLE 2 Changes in measures in each group.

Treatment	Measure	Visit	LS means (LCL, UCL)	Diff LS means (LCL, UCL)[a]	*p*-value
PENFS	API	Baseline	2.776 (2.398, 3.153)		
		3 mFU	2.006 (1.512, 2.499)	−0.77 (−1.169, −0.371)	0.001
	NSS	Baseline	2.45 (2.039, 2.861)		
		3 mFU	1.738 (1.01, 2.466)	−0.712 (−1.456, 0.032)	0.059
	FDI	Baseline	20.244 (16.09, 24.399)		
		3 mFU	14.382 (8.215, 20.55)	−5.862 (−11.652, −0.073)	0.048
Cypro-heptadine	API	Baseline	3.555 (2.77, 4.34)		
		3 mFU	3.252 (2.456, 4.049)	−0.303 (−1.022, 0.416)	0.377
	NSS	Baseline	2.603 (2.026, 3.181)		
		3 mFU	2.054 (1.463, 2.645)	−0.550 (−1.259, 0.160)	0.117
	FDI	Baseline	23.785 (19.161, 28.408)		
		3 mFU	20.604 (15.161, 26.047)	−3.181 (−8.053, 1.691)	0.185
Amitriptyline	API	Baseline	3.113 (2.045, 4.182)		
		3 mFU	2.3 (1.186,3.413)	−0.814 (−1.553, −0.074)	0.034
	NSS	Baseline	2.007 (1.192, 2.822)		
		3 mFU	1.445 (0.579, 2.311)	−0.562 (−1.262, 0.138)	0.101
	FDI	Baseline	15.944 (8.352, 23.537)		
		3 mFU	11.709 (2.597, 20.82)	−4.236 (−12.195, 3.723)	0.259

Examined using Chi square test.
PENFS, percutaneous electrical nerve field stimulation; API, abdominal pain index; NSS, nausea severity scale; FDI, functional disability inventory; LS, least square; LCL, lower control limit; UCL, upper control limit.
[a]negative values indicate reduction in outcome scores from baseline to 3month Follow Up visit.

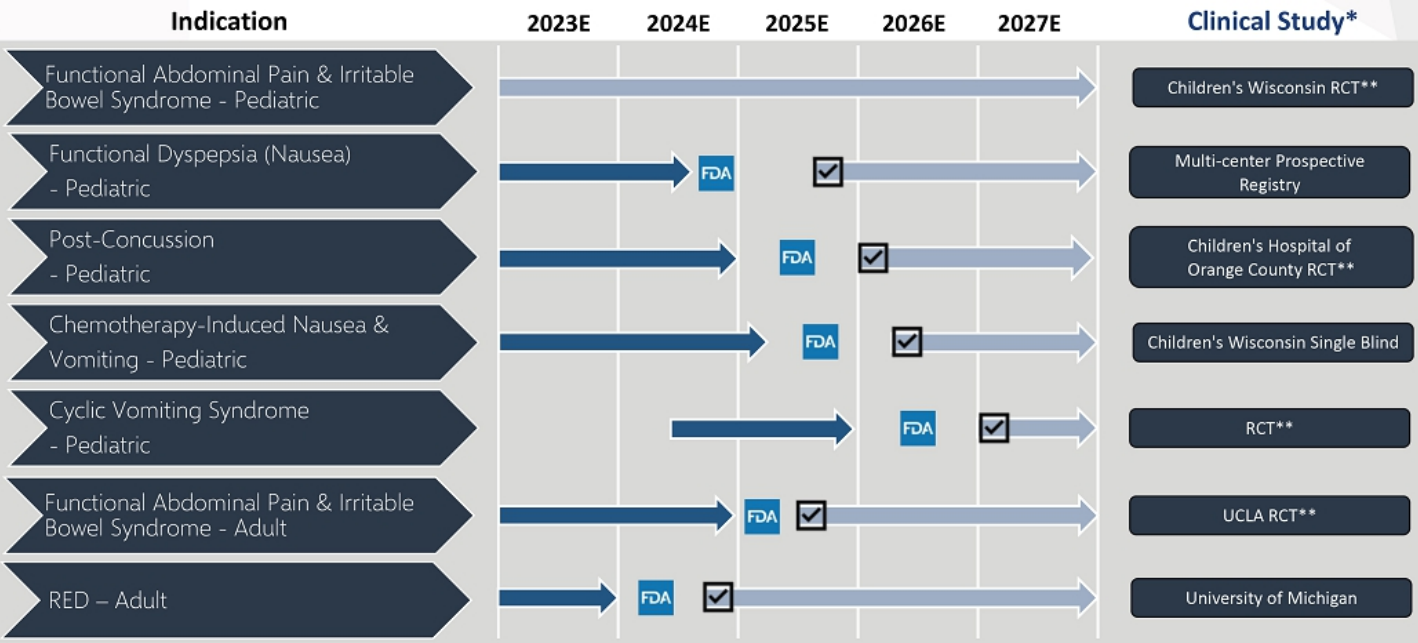




IB-Stim™ vs. Drugs Competitive Landscape

		Antidepressants		Adult Use (Peripherally Acting at the Gut Level)			
	IB-Stim™	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	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	✓	✓	✓	✓	✓	✓	✓

FDA Pipeline - Indications and Timelines



Clinical Study | FDA FDA Submission | FDA Indication | Launch / Commercialization

* Independently sponsored clinical studies; NeurAxis contributes to research funding, devices and other costs. **RCT – Randomized Controlled Clinical Trial

Expanding Portfolio of Next Generation Devices for Disorders of Gut-Brain Interaction

RECTAL EXPULSION DEVICE [RED]

- Developed at the University of Michigan enabling comprehensive constipation care for every adult gastroenterology practice
- RED is a self-inflating balloon expulsion test that allows for point-of-care testing to effectively identify patients with an evacuation disorder
- FDA 510(k) submission on track for May 2024 with expected clearance in October 2024

RESPONSIVE DESIGN

Designed to meet a specific need in the office as a point of care decision and fit into the workflow and time available of the physician

MARKET

- ~$2B market opportunity
- Current balloon expulsion testing requires a separate visit to a GI physiology laboratory
- Anorectal manometry is too expensive to be practical

UNIQUE FEATURES

- Self-inflating
- Enables point-of-care testing (In-office use)
- Provides immediately actionable binary test results

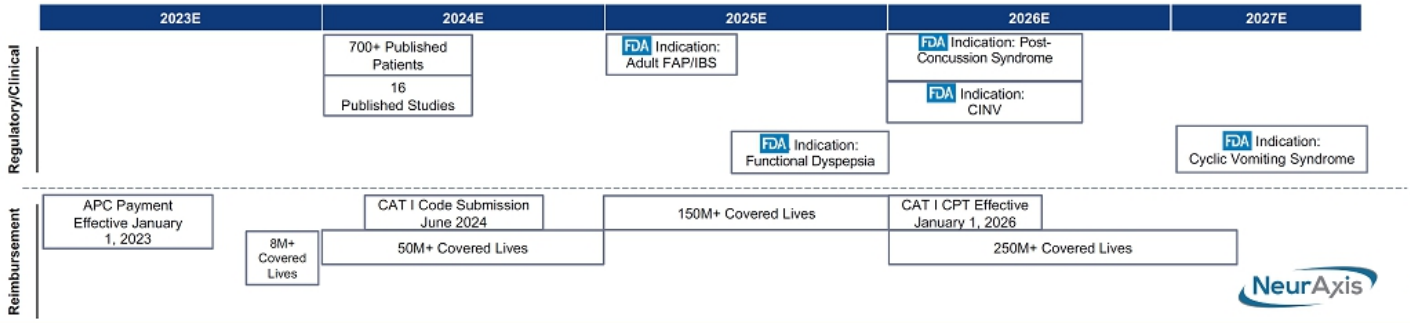
REIMBURSEMENT

- Current CAT I CPT Code 91120
- Medicare reimbursement: $519.15

IB-Stim Reimbursement Market Access Plan Established

Strong Data = Strong Policy Coverage & Reimbursement = Strong Revenue Growth

Key Publications	Academic Society Support	Successful Coverage Policies	CPT Billing Code
• Versus Placebo	• NASPGHAN Written Support	• CareFirst BCBS	• CAT III (Effective July 2022)
• Long-term Data x 2	• AAP Written Support	• BSBS Nebraska	• CAT I Application (June 2024)
• Comparison vs. Soc Rx		• Quartz Wisconsin	• CAT I Code (Effective January 2026)
• Multi-center Registry		• BCBS South Carolina	
○ ~300 patients		• BCBS Massachusetts	
• Positive Health Economic Data		• CareSource HealthVine (SW Ohio)	
		• BCBS Kanass City	
		• Highmark BCBS	



IB-Stim Go-to-Market Strategy

Strong Data = Strong Policy Coverage & Reimbursement = Strong Revenue Growth

2024 Policy Coverage

Total Plans	Total # Lives covered
8 plans	16M+

Insurance Plan	# Lives covered
CareFirst BCBS	3.5M
BCBS of MA	3M
BCBS of SC	770k
BCBS of Nebraska	340k
Quartz Wisconsin	335k
CareSource HealthVine	120k
BCBS Kansas City	1M
Highmark BCBS	7M

Developed ROI Calculator for Payers

On strength of clinical evidence, targeting guideline changes that support IB-Stim™ as standard of care

* CPT Code Effective July 1st, 2022

Commercialization Strategy

Developed ROI Calculator for Accounts

Launched internal Prior Authorization Team

Increasing D2C Marketing in States with Policy Coverage

Hiring W-2 Reps in States with Policy Coverage

Direct Sales Force

Reimbursement Strategy

Technology Specific CPT coding

CPT code*	• CAT III code (0720T)
List Price	• $1,195

Engaging with AAP and NASPGHAN to apply for CAT I CPT code in 2024

Customers

Children's Hospitals
~260 in the U.S.

~33k
U.S. Pediatricians

~10k
U.S. Adult Gastroenterologists

NeurAxis IP Portfolio

- 11 issued and 9 pending patents
  - Device
  - Method
- U.S. IP runs through 2039 as of now
- International IP in process
- Freedom to operate completed

Collaborative Contract Manufacturing Partner

In-House Capabilities

- Office and factory in Indiana
- 69,000 square foot facility
  - Offices, factory, environmentally controlled room, warehouse, parts processing, assembly, quality control
- Medical device focused manufacturing established in 1990

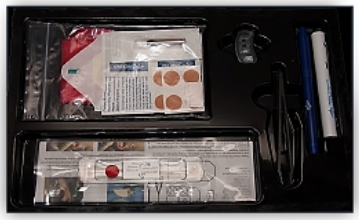
Manufacturing Capacity

- Controlled, repeatable, monitored production process
- Kit production capacity sufficient for all NeurAxis projected needs
- New dedicated room built in 2022 for NeurAxis equipment and production
  - All NeurAxis materials now maintained in the room
  - Environmentally controlled build room

Quality Management System

- ISO 13485:2016 Certified
- FDA registered
- ITAR Registered





Medical Advisory Board

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Boston Children's Hospital
Until every child is well

Dr. Carlo Di Lorenzo

Nationwide Children's
When your child needs a hospital, everything matters.

Dr. Rachel Rosen

Boston Children's Hospital
Until every child is well

Dr. Kahlil El-Chammas

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changing the outcome together

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Brian Carrico
Chief Executive Officer, Board Member

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

Collective Experience

Anthem BlueCross BlueShield · TERUMO · capri COMMUNITIES · ST. JUDE MEDICAL · sharecare · BRIGHTON healthplan SOLUTIONS · BROOKDALE SENIOR LIVING · BARD

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

Timothy Henrichs
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Chief Regulatory Officer

INTEGRATIVE HEALTH CARE PARTNERS

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

NeurAxis

Key Investment Highlights

Strong Data = Strong Policy Coverage & Reimbursement = Strong Revenue Growth

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

Unique, Innovative Product Supported by Clinical Evidence

- Novel treatment targeting the brain-gut-axis
- Differentiated PENFS technology
- 700+ published patients[4] by Q1 2024
- Easy-to-learn and efficient procedure

Clear Commercial Pathway

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

Seasoned Management and Board

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

1. Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient
2. 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