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): September 21, 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 2.02 Results of Operations and Financial Condition

On September 21, 2023, Neuraxis, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2023. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

The Company also prepared an investor presentation containing certain information and financial highlights about the Company and its industry. A copy of the presentation materials is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The information contained in Item 2.02 and Item 7.01 (including Exhibits 99.1 and 99.2) 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 September 21, 2023, announcing second quarter 2023 financial results.
99.2	Neuraxis, Inc. Investor Presentation (September 21, 2023).
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: September 21, 2023

NEURAXIS, INC.

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

NeurAxis Reports Second Quarter 2023 Financial Results

Carmel, Ind., September 21, 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 reported financial results for the second quarter ended June 30, 2023.

Recent Highlights:

- Announced a poster presentation titled, "*Percutaneous Electrical Nerve Field Stimulation Saves Cost to Parents and Insurers of Adolescents with Irritable Bowel Syndrome*", from the University of Michigan at the 2023 American Neurogastroenterology and Motility Society (ANMS) Annual Meeting, highlighting the cost-effectiveness of its PENFS or IB-Stim™ therapy in the treatment of irritable bowel syndrome in adolescents. Noting:
    - IB-Stim™ therapy increases the number of healthy days, based on effective treatment of abdominal pain symptoms, in adolescents suffering from IBS;
    - Treatment with IB-Stim™ results in approximately 60% or $4,744 of potential cost-savings to insurers; and
    - IB-Stim™ treatment also offers the potential cost-saving opportunity of approximately 53% or $5,802 to patients' families.
- Highlighted two recently published independent studies showing that IB-Stim™ therapy leads to improvements in abdominal pain and disability in adolescents with IBS and that the gut microbiome may play an important role.
- Announced the publication of *Prospective study of the effect of auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction, a randomized, double-blind, placebo-controlled trial to evaluate the efficacy of IB-Stim™ in children with post-concussion symptoms*, featured in the September 2023 Frontiers in Pain Research. Noting:
    - Patients (n=31) reported significant reductions in abdominal pain, nausea, disability, and anxiety from baseline to week 4 ($p < 0.05$);
    - Parent assessments reported significant improvement in the child's quality of life based on physical function, psychosocial function, and generic core scale scores ($p < 0.05$); and
    - Parents also reported reduced abdominal pain, functional disability, and somatization in their child. The global health scores also significantly improved based on both patient and parent reports ($p < 0.05$).
- Completed initial public offering of common stock which raised net proceeds of approximately $6.1 million.

"We are thrilled with the progress we have made, especially now as a public company, with funds raised to steadily drive our momentum," said Brian Carrico, President and Chief Executive Officer of NeurAxis. "The support we are receiving, including our recently highlighted 10^{th} peer reviewed publication, out of a total 14 publications to-date, demonstrates our continuing commitment to grow our body of clinical evidence. Further, as we approach our target of 16 publications, we believe the foundation of strong clinical evidence we have positions us for expanded payor coverage and the adoption of IB-Stim™. We look forward to our continuing progress to grow our business, in line with our goal to make IB-Stim™ the standard of care for children with abdominal pain related disorders of the gut-brain interactions."

Second Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was $646.0 thousand, representing a decrease of 5% compared to $682.6 thousand in the second quarter of 2022. The decrease was primarily due to ordering patterns of our major customers.

Gross profit for the second quarter of 2023 was $578.2 thousand, representing a decrease of 4% compared to a gross profit of $603.6 thousand in the second quarter of 2022. Gross margin totaled 89.5% in the second quarter of 2023, compared to 88.4% in second quarter of 2022. The increase was primarily due to slightly lower cost of sales.

Selling expenses for the second quarter of 2023 were $78.8 thousand, compared to $127.4 thousand in the second quarter of 2022. The decrease was primarily due to lower commission costs, with the commission rate being lowered at the beginning of 2023.

Second quarter research and development expenses were $109.8 thousand, compared to $13.7 thousand in the second quarter of 2022, reflecting increased spend primarily on new product development.

General and administrative expenses for the second quarter of 2023 were $1,507.2 thousand, compared to $1,132.1 thousand in the second quarter of 2022. The increase was primarily due to higher professional fees.

Second quarter net loss was ($2,235.6) thousand, or ($1.21) per common share, compared to ($1,516.5) thousand, or ($0.87) per common share, for the same period of 2022.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. There are a number of important factors that could cause actual results, developments, business decisions or other events to differ materially from those contemplated by the forward-looking statements in this press release. These factors include, among other things, the conditions in the U.S. and global economy, the trading price and volatility of the Company's stock, public health issues or other events, the Company's compliance with applicable laws, the results of the Company's clinical trials and perceptions thereof, as well as 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.

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.

Contacts:

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Investor Relations
Gilmartin Group
IR@neuraxis.com

NeurAxis, Inc.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Net Sales	**$ 646,021**	$ 682,581	**$ 1,451,131**	$ 1,452,848
Cost of Goods Sold	**67,813**	79,009	**163,713**	154,209
Gross Profit	**578,208**	603,572	**1,287,418**	1,298,639
Selling Expenses	**78,791**	127,424	**186,723**	263,304
Research and Development	**109,789**	13,665	**126,586**	58,063
General and Administrative	**1,507,169**	1,132,065	**2,987,923**	2,160,161
Operating Loss	**(1,117,541)**	(669,582)	**(2,013,814)**	(1,182,889)
Other Income (Expense):				
Financing charges	**—**	(872,763)	**(2,772)**	(872,763)
Interest expense	**(194,690)**	(34,450)	**(356,378)**	(60,550)
Change in fair value of warrant liability	**(36,050)**	61,520	**198,757**	(569,561)
Change in fair value of derivative liability	**860**	—	**192,157**	—
Amortization of debt discount and issuance cost	**(887,937)**	(12,944)	**(3,550,592)**	(12,944)
Extinguishment of debt liabilities	**—**	—	**1,129,498**	—
Other income	**2**	11,689	**1,552**	11,956
Other expense	**(258)**	—	**(7,430)**	—
Total other income (expense), net	**(1,118,073)**	(846,948)	**(2,395,208)**	(1,503,862)
Net Loss	**$ (2,235,614)**	$ (1,516,530)	**$ (4,409,022)**	$ (2,686,751)
Per-share Data				
Basic and diluted loss per share	**$ (1.21)**	$ (0.87)	**$ (2.39)**	$ (1.56)
Weighted Average Shares Outstanding				
Basic and diluted	**2,003,322**	1,970,054	**2,003,322**	1,970,054

NeurAxis, Inc.
Condensed Balance Sheet
(unaudited)

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	**$ 51,440**	$ 253,699
Accounts receivable, net	**237,170**	174,399
Inventories	**44,205**	48,133
Prepaids and other current assets	**21,333**	726
Total current assets	**354,148**	476,957
Property and Equipment, at cost:	**417,912**	405,845
Less - accumulated depreciation	**(332,651)**	(317,834)
Property and equipment, net	**85,261**	88,011
Other Assets:		
Deferred offering costs	**941,143**	736,736
Operating lease right of use asset	**85,823**	101,382
Intangible assets, net	**73,316**	77,558
Total Assets	**$ 1,539,691**	$ 1,480,644
Liabilities		
Current Liabilities:		
Accounts payable	**$ 2,438,117**	$ 1,592,116
Accrued expenses	**1,174,381**	834,062
Notes payable	**249,389**	202,834
Current portion of operating lease payable	**41,261**	33,395
Notes payable - related party	**58,051**	58,051
Notes payable - convertible notes, net of unamortized discount of $4,421,424 and $3,327,213 as of June 30, 2023 and December 31, 2022	**1,217,465**	228,342
Customer deposits	**61,317**	59,174
Derivative liabilities	**2,275,029**	1,735,700
Warrant liabilities	**3,916,884**	2,234,384
Total current liabilities	**11,431,894**	6,978,058
Non-current Liabilities:		
Operating lease payable, net of current portion	**51,635**	76,199
Note payable, net of current portion	**38,797**	—
Total non-current liabilities	**90,432**	76,199
Total liabilities	**11,522,326**	7,054,257
Commitments and contingencies (see note 14)		
Stockholders' Deficit		
Convertible Series A Preferred stock, $0.001 par value; 1,000,000 shares authorized; 506,637 issued and outstanding as of June 30, 2023 and December 31, 2022	507	507
Convertible Series Seed Preferred Stock, $0.001 par value; 120,000 shares authorized; 115,477 issued and outstanding as of June 30, 2023 and December 31, 2022	115	115
Common stock, $0.001 par value; 100,000,000 shares authorized; 1,963,322 issued and outstanding as of June 30, 2023 and December 31, 2022	1,963	1,963
Additional paid in capital	**28,355,230**	28,355,230
Accumulated deficit	**(38,340,450)**	(33,931,428)
Total stockholders' deficit	**(9,982,635)**	(5,573,613)
Total Liabilities and Stockholders' Deficit	**$ 1,539,691**	$ 1,480,644

NeurAxis, Inc.
Condensed Statement of Cash Flows
(unaudited)

	For the Six Months Ended June 30,	
	2023	**2022**
Cash Flows from Operating Activities		
Net Loss	**$ (4,409,021)**	$ (2,117,190)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization of debt discount and issuance cost	**3,550,592**	12,944
Depreciation and amortization	**20,060**	16,695
Provisions for losses on accounts receivable	**3,927**	29,580
Non-cash lease expense	**15,559**	13,296
Stock based compensation	**—**	24,121
Extinguishment of debt liability	**(1,129,498)**	—
Finance Charges	**2,772**	872,763
Change in fair value of derivative liabilities	**(192,157)**	—
Change in fair value of warrant liabilities	**(198,757)**	569,563
Changes in operating assets and liabilities:		
Accounts receivable	**(66,698)**	(131,764)
Inventory	**3,928**	(13,616)
Prepaids and other current assets	**(20,607)**	(138)
Accounts payable	**846,001**	(118,561)
Accrued expenses	**340,317**	266,486
Customer deposits	**2,143**	(12,720)
Operating lease liability	**(16,698)**	(13,791)
Net cash used by operating activities	**(1,248,137)**	(1,171,895)
Cash Flows from Investing Activities		
Additions to property and equipment	**(12,067)**	—
Additions to intangible assets	**(1,000)**	(49,815)
Net cash used by investing activities	**(13,067)**	(49,815)
Cash Flows from Financing Activities		
Principal payments on notes payable	**(2,724,479)**	(86,453)
Proceeds from notes payable	**159,831**	—
Proceeds from convertible notes, net of fees	**3,828,000**	1,087,500
Offering costs paid	**(204,407)**	(26,549)
Net cash used in financing activities	**1,058,945**	974,498
Net Decrease in Cash and Cash Equivalents	**(202,259)**	(247,212)
Cash and Cash Equivalents at Beginning of Period	**253,699**	320,858
Cash and Cash Equivalents at End of Period	**$ 51,440**	$ 73,646
Supplemental Disclosure of Non-cash Cash Activities		
Cash paid for interest	**$ 57,202**	$ 55,550
Cash paid for income taxes	**—**	—
Supplemental Schedule of Non-cash Investing and Financing Activities		
Fair value of warrant liabilities of warrants from convertible notes	**$ 1,881,257**	$ 884,118
Fair value of derivative liabilities of conversion feature from convertible notes	**1,860,984**	1,075,098

NeurAxis, Inc.

Reimagining an Evidence-Based, Drug Free Alternative For Children

September 21, 2023

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 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.

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

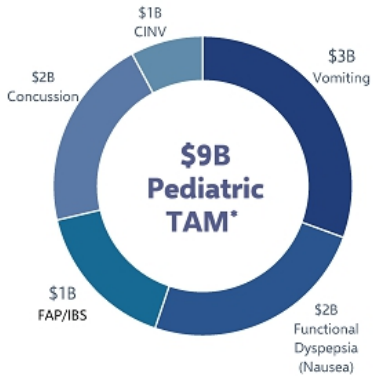
Seasoned Management and Board

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

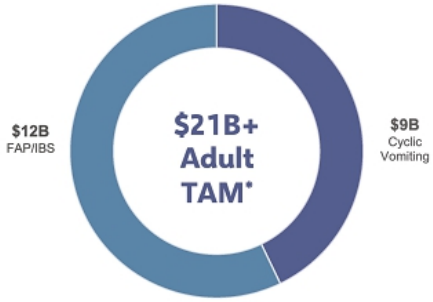
1. Percutaneous Electrical Nerve Field Stimulation
2. FAB/IBS: Functional Abdominal Pain/Irritable Bowel Syndrome
3. Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient
4. Published patient - a patient who 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

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

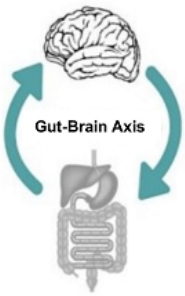
Entering Pediatric markets first with:

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

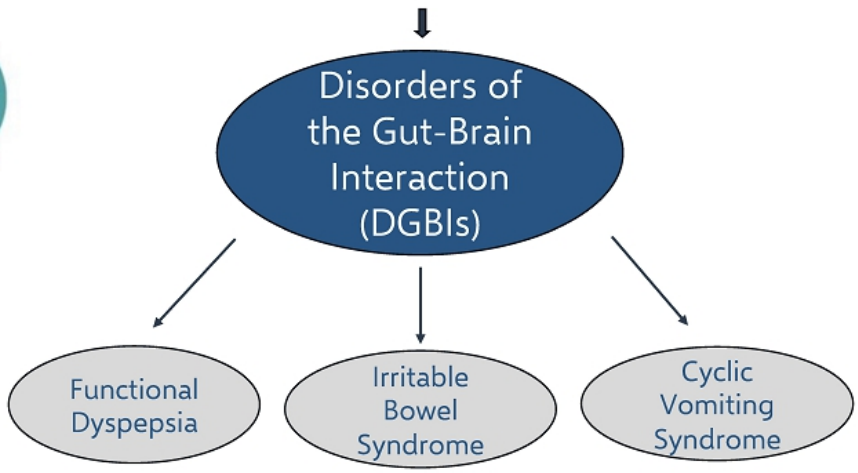
* Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient

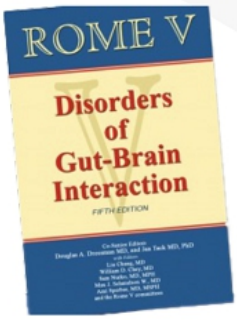
DGBIs: A Problem with an Unmet Need

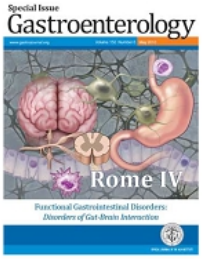
- No approved therapies for children with abdominal pain related disorders of the gut-brain interactions (DGBIs)
- Disorders negatively impacts quality of life and ability to function (attend school, sports, and social activities)
- Insufficient data to support the use of the most prescribed drugs, some 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







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]

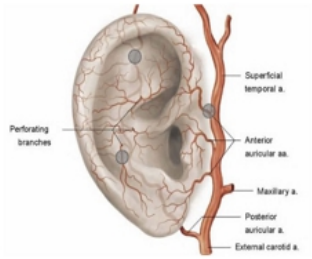
Substantial Patient Need for Safe & Effective, Non-Pharmacological Alternatives:

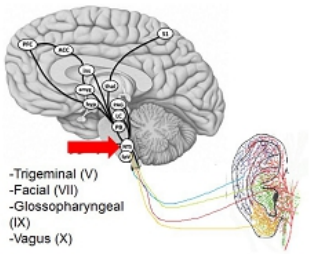
- Growing number of families seeking alternative therapies for pain in children[6]

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, Sanelan 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

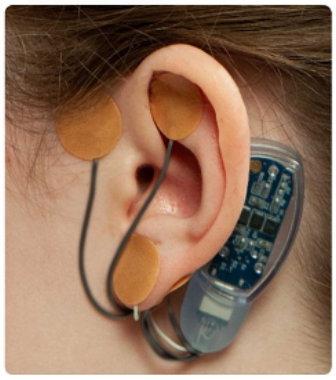
Stimulation reduces firing of amygdala

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*

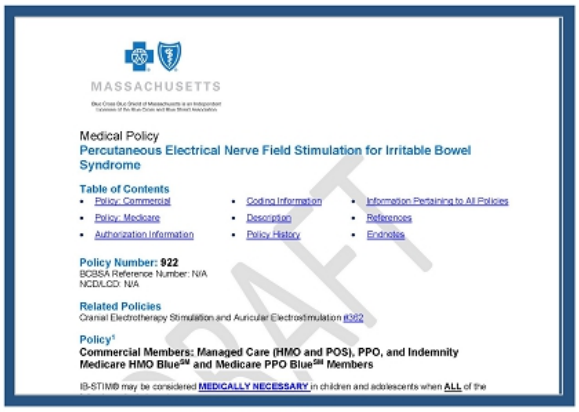
FDA De Novo Clearance

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
NCDL/LCD: N/A

Related Policies
Cranial Electrotherapy Stimulation and Auricular Electrostimulation #362

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

14 Current Publications

16 Publications Expected by end of 23'

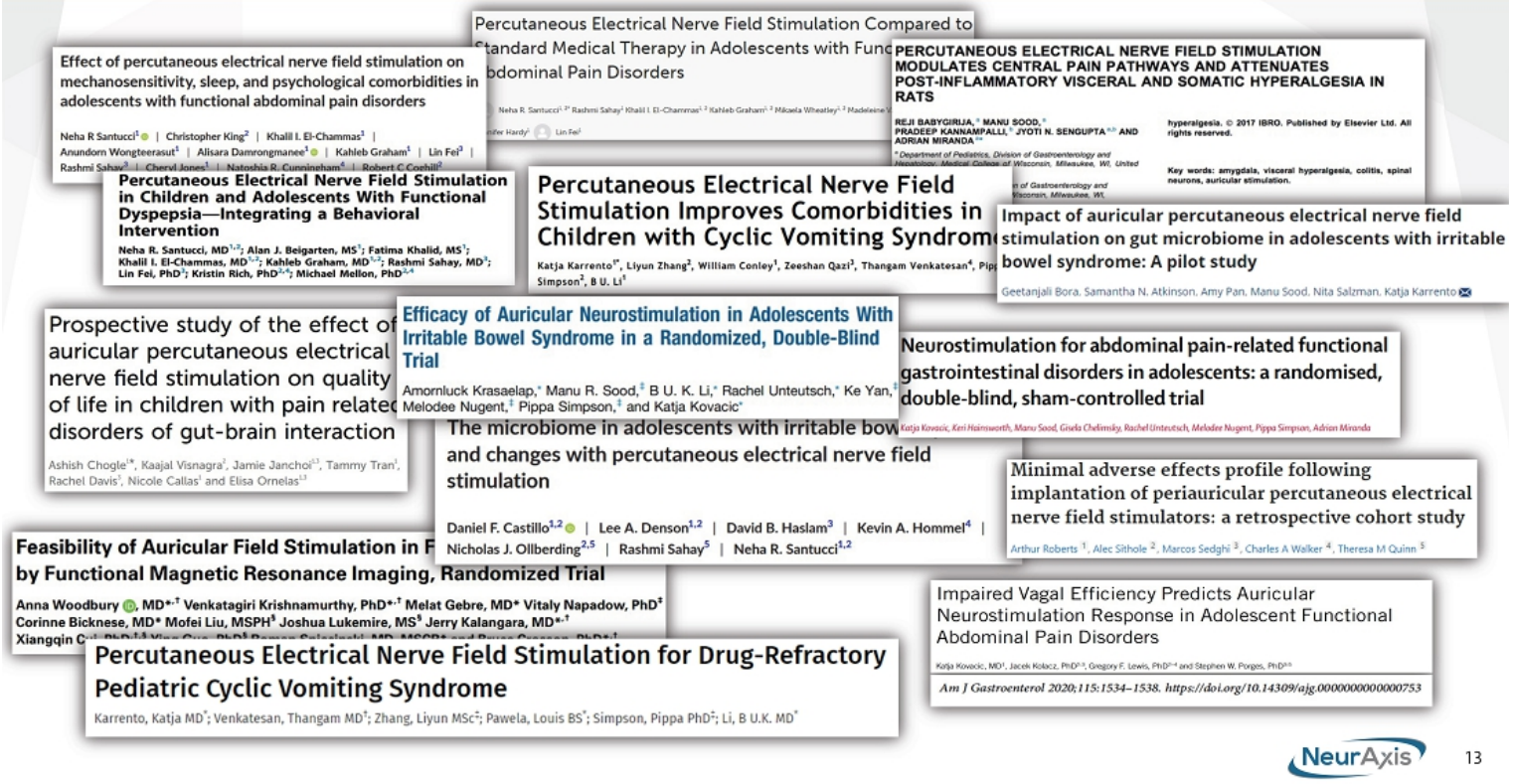
10 Types of Studies

- 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

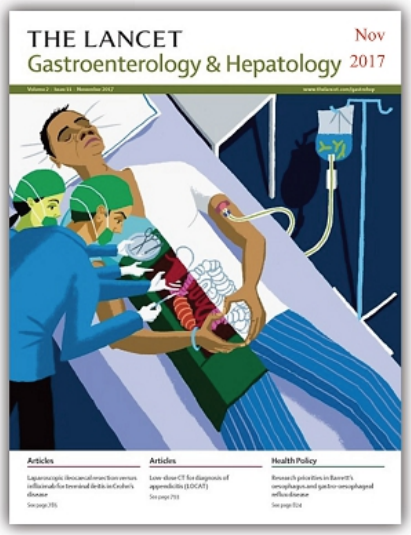
13 Children's Hospital Study Sites

- Boston Children's Hospital
- Riley Children's Health, Indiana University Health
- Cincinnati Children's
- CHOC Children's
- Children's Wisconsin
- Duke Children's

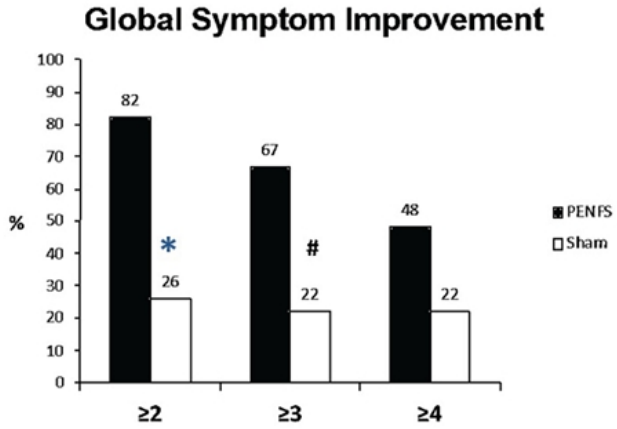
NeurAxis PENFS Technology: 14 Peer-Reviewed Publications To-date



Growing Body of Clinical Evidence



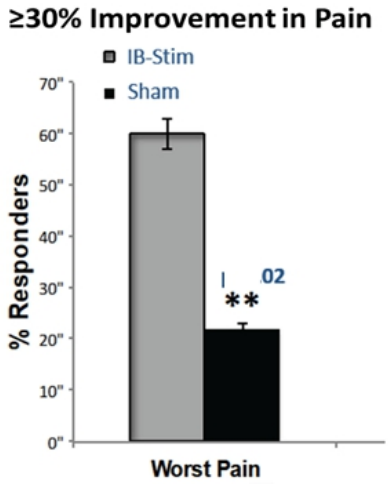
Improvement of Global Symptoms in Patients with Irritable Bowel Syndrome



*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).

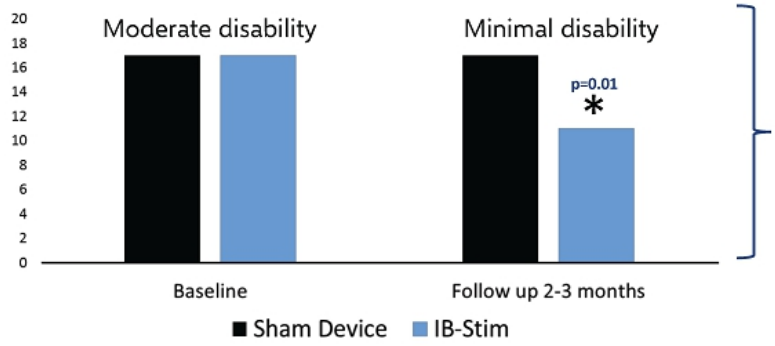
IB-Stim NNT=3

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

1. 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.
2. Kashikar-Zuck S, Flowers SR, Claar RL, et al. Clinical utility and validity of the Functional Disability Inventory among a multicenter sample of youth with chronic pain. Pain. 2011;152:1600-1607.

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.

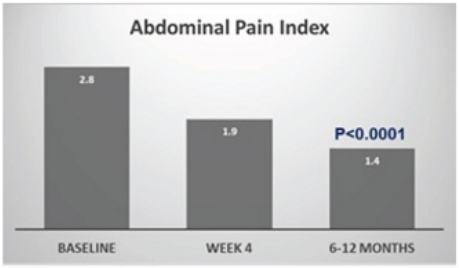
Kovacic K, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomized, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol.* 2017;2(10):727-737.

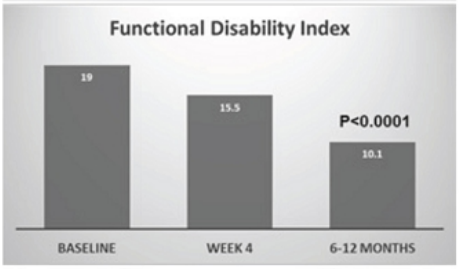
IB-Stim™ Long Term Data: Cincinnati Children's Hospital Cont.

Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders

Neha R Santucci[1] | Christopher King[2] | Khalil I. El-Chammas[1] | Anundorn Wongteerasut[1] | Alisara Damrongmanee[1] | Kahleb Graham[1] | Lin Fei[3] | Rashmi Sahay[3] | Cheryl Jones[1] | Natoshia R. Cunningham[4] | Robert C Coghill[2]

- Used validated measures with short and long-term follow-up.
- Symptoms continued to be significantly improved from baseline at 6-12 months post- treatment.





*Santucci NR et. al. Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders. Neurogastroenterol Motil. 2022;34:e14358.

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

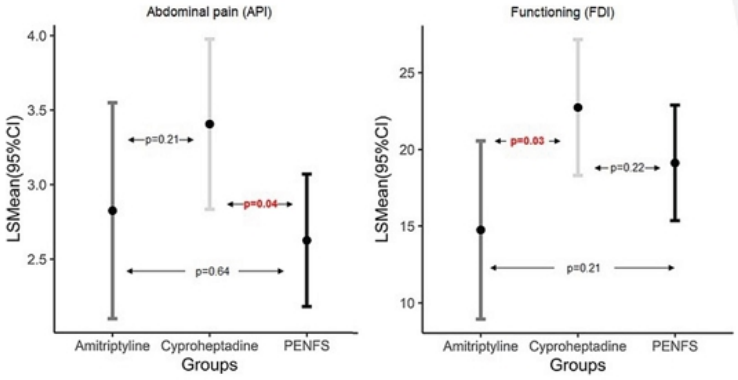
Neha R. Santucci[1,2]*, Rashmi Sahay[3], Khalil I. El-Chammas[1,2], Kahleb Graham[1,2], Mikaela Wheatley[1,2], Madeleine Vandenbrink[2], Jennifer Hardy[2] and Lin Fei[3]

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

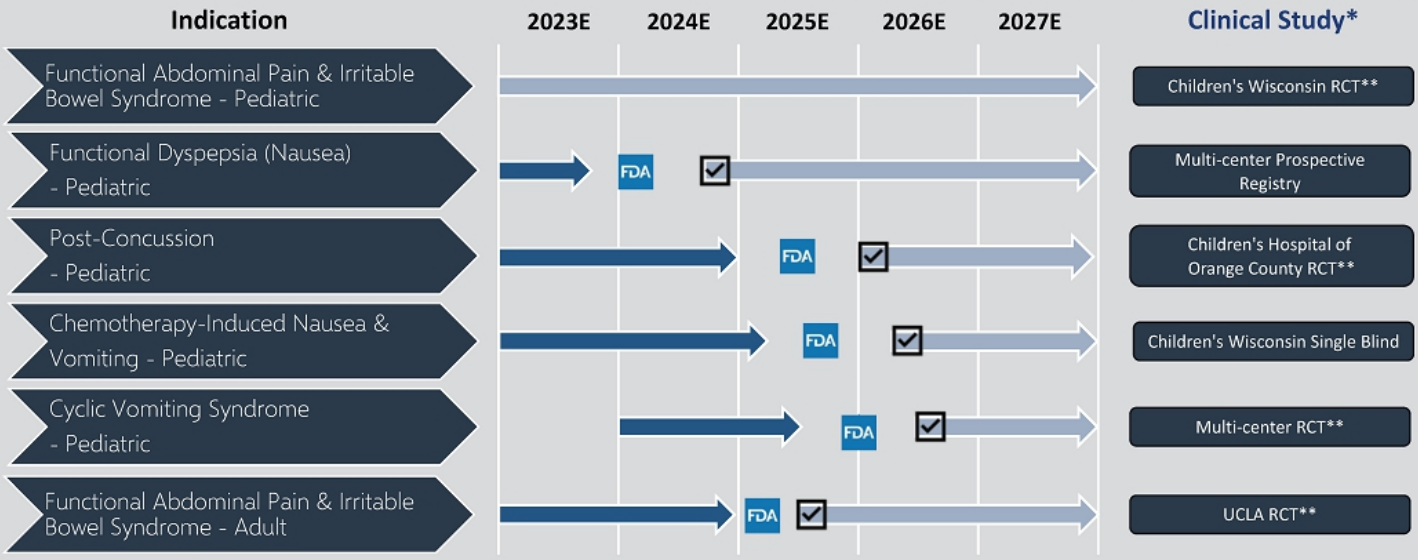
Examined using Chi square test.
PENFS, percutaneous electrical nerve field stimulation; API, abdominal pain index; NSS, nausea severity scale; FDI, functional disability inventory; LS, least square; LCL, lower control limit; UCL, upper control limit.
[a]negative values indicate reduction in outcome scores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



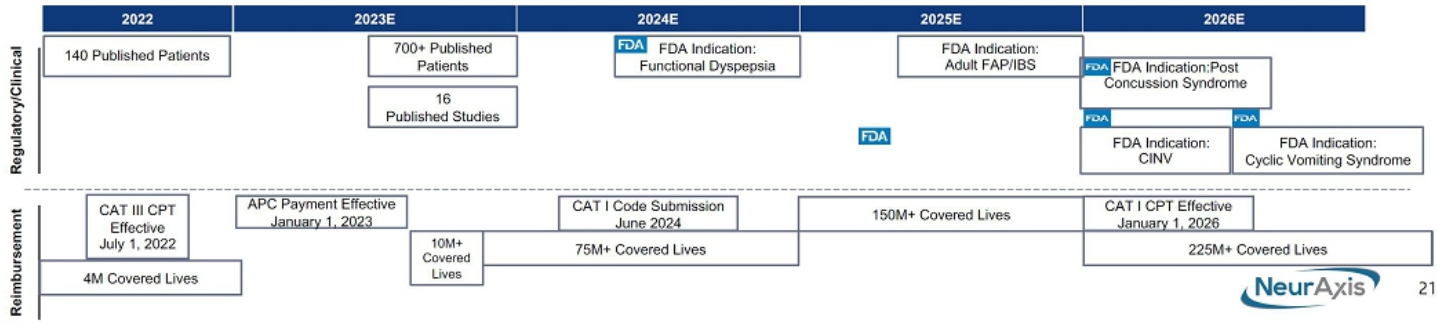
Clinical Study | FDA FDA Submission | FDA Indication | Launch / Commercialization

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

IB-Stim Reimbursement Market Access Plan Established

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

Publications	Academic Society Support	Successful Proof-of-Concept Coverage Policies	CPT Billing Code
• Versus Placebo (Completed)	• NASPGHAN Written Support	• BCBS Massachusetts	• CAT III (Effective July 2022)
• Long-term Study (Completed)	• AAP Written Support	• BSBS Nebraska	• CAT I Application (June 2024)
• Health Economic Study (Completed)		• Quartz Wisconsin	• CAT I Code (Effective January 2026)
• Registry Data (Completed)		• BCBS South Carolina	
• Quality of Life Study (Completed)			
• Head-to-Head Study (Completed)			



Go-to-Market Strategy

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

2023 Policy Coverage

Total Plans	Total # Lives covered
4 plans	4.75M

Insurance plans (% of Comm Lives in State)	# Lives covered
BCBS of MA (45%)	3M
BCBS of SC (49%)	750k
BCBS of Nebraska (47%)	700k
Quartz Wisconsin (10%)	300k

Hiring Senior Market Access Director to Leverage Data and Lead Policy Coverage

Developed ROI Calculator for Payers

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

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

* 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 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

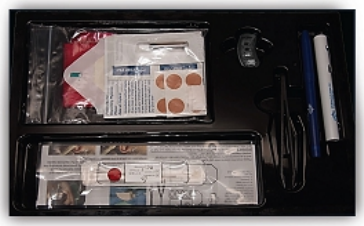
Manufacturing Capacity

- 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

Dr. Samuel Nurko

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

Cincinnati Children's
changing the outcome together

Dr. Miranda van Tilburg

UNC School of Medicine

Dr. Leonel Rodriguez

Yale University
School of Medicine

Board of Directors

Beth Keyser
Board Member

Mitch Watkins
Board Member

Timothy Henrichs
Board Member

Brian Carrico
Chief Executive Officer, Board Member

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

Collective Experience

Anthem BlueCross BlueShield · TERUMO · RENOVO HOME PARTNERS · ST. JUDE MEDICAL · sharecare · BRIGHTON healthplan SOLUTIONS · Follett · BARD

Management Team

Brian Carrico
Chief Executive Officer, Board Member

Dr. Adrian Miranda
Chief Medical Officer

John Seale
Chief Financial Officer

Dan Clarence
Chief Operating Officer

Dr. Tom Carrico
Chief Regulatory Officer

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

NeurAxis Milestones

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

2022

- •CAT III CPT Code Effective - July 1, 2022
- •6 Publications
- •135 Published Patients
- •BCBS MA Policy Coverage
- •4.75M Covered Lives

2023E

- 16 Publications (end 2023)
  - Long-Term Study
  - Health Economic Study
  - Registry Data
  - Quality of Life Study
  - Head-to-Head Study
- 700+ Published Patients
- 10M+Covered Lives (end 2023E)

2024E

- CPT CAT 1 Code Application Submission
- FDA Indication:
  - Functional Dyspepsia (Nausea); 1Q 2024
- 75M+ Covered Lives
- 18 Publications
- 1000+ Published Patients

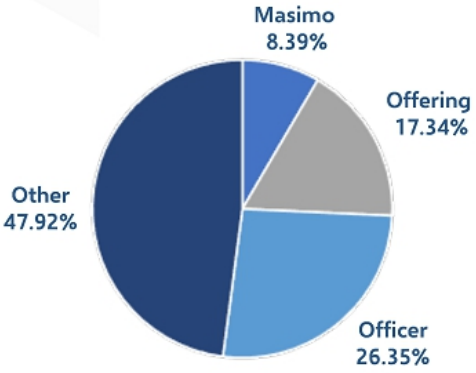
2025E

- FDA Indications:
  - Adult FAP/IBS; 1Q 2025
- 150M+ Covered Lives

2026E

- •CPT CAT 1 Code Effective (Jan 1)
- •225M+ Covered Lives
- •FDA Indication:
  - •Cyclic Vomiting Syndrome; Mid-2026
  - •Post-concussion Syndrome; Q1 2026
  - •CINV; Q3 2025

Capital Structure & Financial Snapshot



Financial Snapshot

Revenue

- ~$1.45 million YTD June 2023
- ~$2.7 million in 2022

Gross Margin

- 88.7% YTD June 2023
- 88.9% in 2022

1. Gross Margin includes research devices sold for development/expansion

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