

NeurAxis, Inc.



Reimagining an Evidence-Based, Drug Free Alternative For Children

November 12, 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

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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 PENFS¹: First FDA Indicated Treatment for Pediatric FAP/IBS²

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

- Large Global Market with Significant Unmet Need
 - \$23B+ TAM³ for target pipeline indications
 - \$9B+ TAM³ for target pediatric indications (near-tomid term)
 - \$14B+ TAM³ 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

IB-STIN

- Novel treatment targeting the brain-gut-axis
- Differentiated PENFS technology
- 700+ published patients⁴
- 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

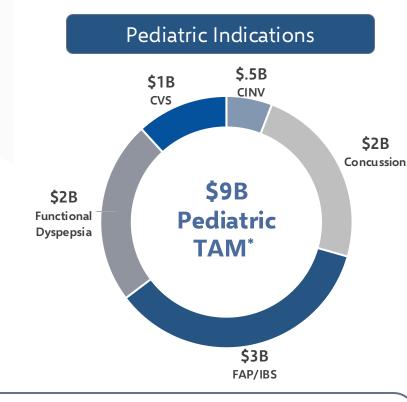


1. Percutaneous Electrical Nerve Field Stimulation

2. FAB/IBS: Functional Abdominal Pain/Irritable Bowel Syndrome

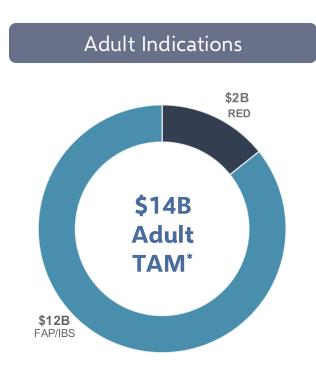
Total Addressable Market (TAM) - Calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient
 Published patient - a patient who went through a study and the study was analyzed and now the study has been published in a peer-reviewed journal

\$23B+ Total Addressable U.S. Market for Pipeline 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

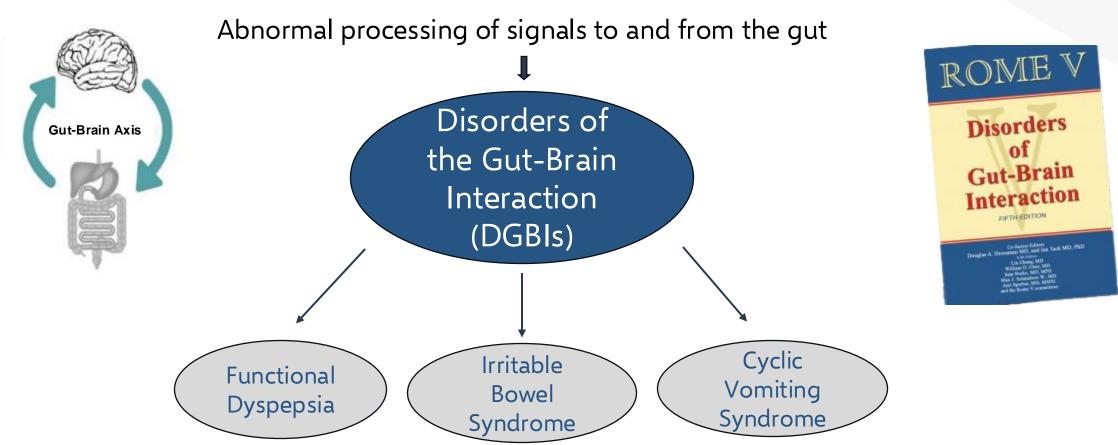
DGBIs: A Problem with an Unmet Need

- 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

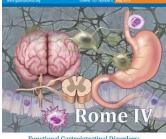


IB-STIN





Gastroenterology



Functional Gastrointestinal Disorders: Disorders of Gut-Brain Interaction **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 RCT¹
- Citalopram (SSRI) did not beat placebo in RCT²

Significant Risk of TCA Side Effects in Children:

- Increased risk of suicidal ideation (black box warning)³
- Mood changes
- EKG disturbance⁴
- Long-term risk of dementia⁵

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

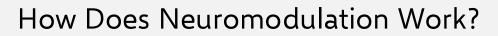
• Growing number of families seeking alternative therapies for pain in children⁶

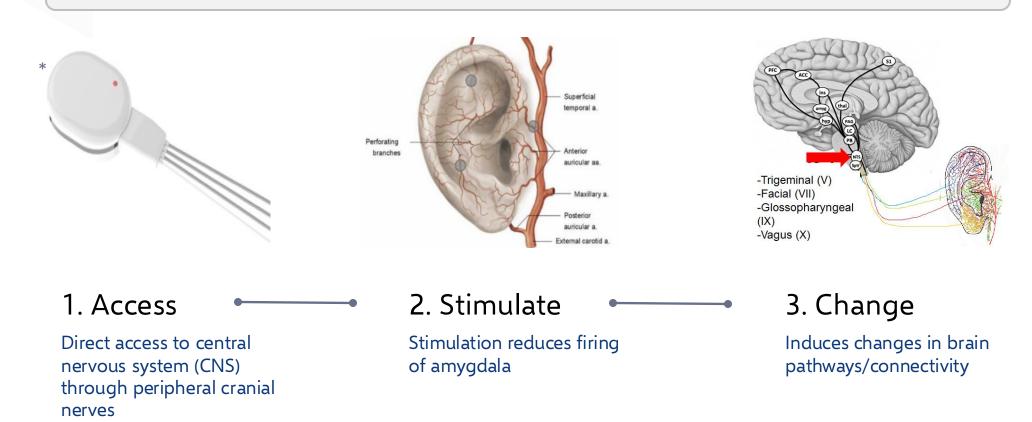
IB-STIN

- . 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.
- Roohafza H, Pourmoghad das Z, Saneian H, Gholamrezaei A. Citalop ram 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. WorldJ 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)







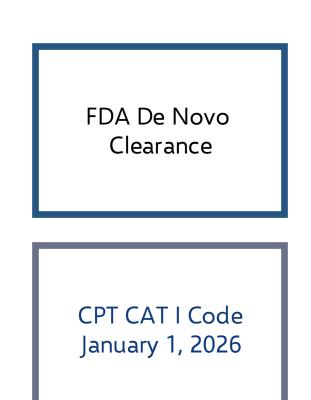
Established Technology with Demonstrated Safety and Efficacy



(IB-STIM

What is IB-Stim[™]

- PENFS system intended for patients 8-21 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 4 consecutive weeks





IB-Stim[™] Advantages Over Traditional Care

IB-Stim [™]	Traditional Care
	No FDA Approved Treatments
	Rx often Containing FDA Black Box Labels
Minimal	Effects Suicidal Ideation, Depression, & Weight Gain
Targets The Brain Gut Axis	ivery and Peripheral





Patient Journey

1. Persistent Pain

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

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

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

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)
- o Cognitive behavioral therapy, where available



4. Use/Care

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

HB-STIM

3. Placement

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



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Families often skip PCP since referral is not required

IB-STIM

-**(∲IB-STIM**

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

IB-Stim[™] Research – By the Numbers

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



16 Current Publications Utilizing NeurAxis' PENFS Technology





Cincinnati

Duke Children's

Children's

	IB-Stim Publ	ications in Children with DGE	BIS	
Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities adolescents with functional abdominal pain disorders Neha R Santucci ¹ Christopher King ² Khalil I. El-Chammas ¹ Anundorn Wongteerasut ¹ Alisara Damrongmanee ¹ Khalib Graham ¹ Lin Fei ³	in Standard Medical Abdominal Pain [Neha R. Santucci ^{1, 27} Rashmi Sah	ectrical Nerve Field Stimulation Compared Therapy in Adolescents with Functional Disorders ay ¹ Khalil I. El-Chammas ^{1, 2} Kahleb Graham ^{1, 2} Mikaela Wheatley ^{1, 2} Madeleine Vandenbrink ²	d to	Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial Katja Kovacic, Keri Hainsworth, Manu Sood, Gisela Chelimsky, Rachel Unteutsch, Melodee Nugent, Pippa Simpson, Adrian Miranda
Rashmi Sahay ³ Cheryl Jones ¹ Natoshia R. Cunningham ⁴ Robert C Coghill ² Percutaneous Electrical Nerve Field Stin in Children and Adolescents With Funct Dyspepsia—Integrating a Behavioral Intervention Neha R. Santucci, MD ^{1,2} ; Alan J. Beigarten, MS ¹ ; Fatima Khalid Khalil I. El-Chammas, MD ^{1,2} ; Kahleb Graham, MD ^{1,2} ; Rashmi Sa Lin Fei, PhD ³ ; Kristin Rich, PhD ^{2,4} ; Michael Mellon, PhD ^{2,4} Prospective study of the effect of	Jennifer Har nulation tional , MS ¹ ; hay, MD ³ ; A multicenter	Liyun Zhang ² , William Conley ¹ , Zeeshan Qazi ³ , Thangam Venkates	in 'OM(an ⁴ , Pipp al	Geetanjali Bora, Samantha N. Atkinson, Amy Pan, Manu Sood, Nita Salzman, Katja Karrento 🗙
auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction Ashish Chogle ^{1*} , Kaajal Visnagra ² , Jamie Janchoi ^{1,3} , Tammy Tran ¹ , Rachel Davis ³ , Nicole Callas ¹ and Elisa Ornelas ^{1,3}	gut–brain inter Ashish Chogle ¹ K Lev Dorfman ² Ka Rachel Rosen ⁵ Sa Keshawadhana Balak Pippa Simpson ³ I	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 ⁽)		npaired Vagal Efficiency Predicts Auricular eurostimulation Response in Adolescent Functional bdominal Pain Disorders a Kovacic, MD ¹ , Jacek Kolacz, PhD ²⁻³ , Gregory F. Lewis, PhD ²⁻⁴ and Stephen W. Porges, PhD ³⁻⁵
The microbiome in adolescents with irritable and changes with percutaneous electrical ne stimulation		Percutaneous electrical nerve fie adolescents with irritable bowel cost-minimization analysis		
	al Nerve Field S	Eric Shah 🕿 Shanti Eswaran, Kimberly Harer, Allen Lee	_	Minimal adverse effects profile following implantation of periauricular percutaneous electrical
Pediatric Cyclic Vomit	•	a, Louis BS [*] ; Simpson, Pippa PhD [‡] ; Li, B U.K. MD [*]		nerve field stimulators: a retrospective cohort study Arthur Roberts ¹ , Alec Sithole ² , Marcos Sedghi ³ , Charles A Walker ⁴ , Theresa M Quinn ⁵
Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional addeminal pain	d Vagal Efficiency P			cacy of Auricular Neurostimulation in Adolescents With able Bowel Syndrome in a Randomized, Double-Blind I

disorders

Kahleb Graham¹², Mikaela Wheatley¹², Madeleine Vandenbrink², Jennifer Hardy¹ and Lin Fei³

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Amornluck Krasaelap,* Manu R. Sood,[‡] B U. K. Li,* Rachel Unteutsch,* Ke Yan,[‡] Melodee Nugent,[‡] Pippa Simpson,[‡] and Katja Kovacic*

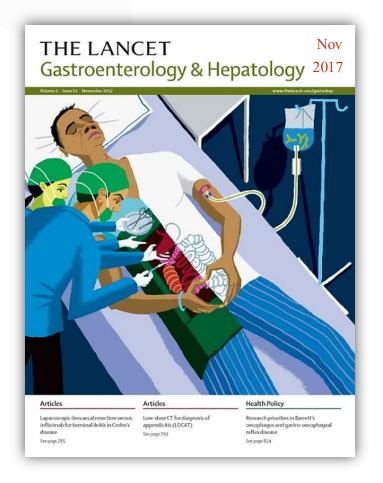
Neha R. Santucci^{12*}, Rashmi Sahay³, Khalil I. El-Chammas¹²,

and Disorders

Katja Kovacic, MD¹, Jacek Kolacz, PhD^{2·3}, Gregory F. Lewis, PhD²⁻⁴ and Stephen W. Porges, PhD^{3·5}

Am J Gastroenterol 2020;115:1534–1538. https://doi.org/10.14309/ajg.000000000000753

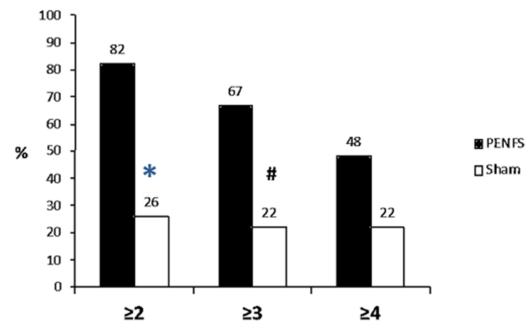
Growing Body of Clinical Evidence



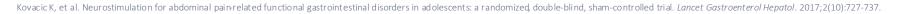
Improvement of Global Symptoms in Patients with Irritable Bowel Syndrome

Global Symptom Improvement

IB-STIN



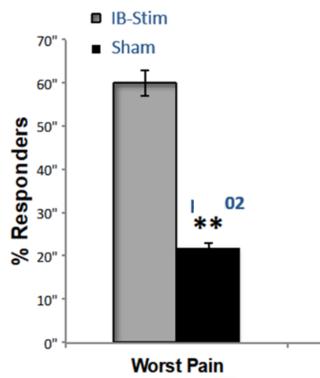
*Percent of patients reporting improvement of global symptoms using Symptom Response Scale score ≥2 (*p≤0.001), ≥3 (#p=0.002) and ≥4 (p=0.077)



Neur/

FDA Benchmark for Clinically Meaningful Endpoint

≥30% Improvement in Pain



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

IB-STIN

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 14²

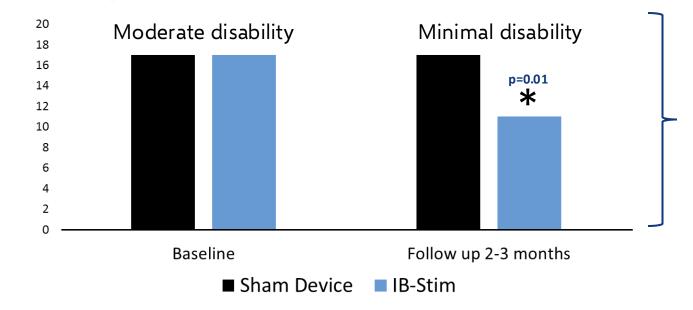
1.Krasaelap A, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. Clinical Gastroenterology & Hepatology. Clin Gastroenterol Hepatol. 2020;(9):1987-1994

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

IB-STIN

* 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.



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Largest Pediatric Registry in Children with DGBI

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

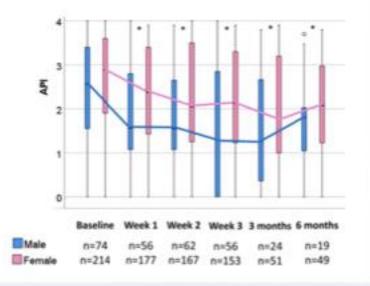
Ashish Chogle¹ | Khalil El-Chammas² | Neha Santucci² | Monica Grimm³ Lev Dorfman² | Kahleb Graham² | Daniel R. Kelly⁴ | Jason E. Dranove⁴ | Rachel Rosen⁵ | Samuel Nurko⁵ | Joseph Croffie⁶ | Keshawadhana Balakrishnan⁷ | Eric H. Chiou⁷ | Liyun Zhang³ | Pippa Simpson³ | Katja Karrento³)

- 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

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

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				



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

Neha R. Santucci^{12*}, Rashmi Sahay³, Khalil I. El-Chammas¹², Kahleb Graham¹², Mikaela Wheatley¹², Madeleine Vandenbrink², Jennifer Hardy¹ and Lin Fei³

TABLE 2 Changes in measures in each group.

Treatment	Measure	Visit	LS means (LCL, UCL)	Diff LS means (LCL, UCL) ^a	<i>p</i> -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

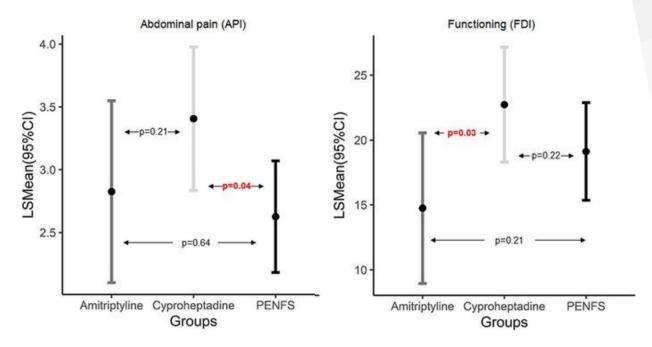
Examined using Chi square test.

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.

"negative values indicate reduction in outcome scores from baseline to 3month Follow Up visit.



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



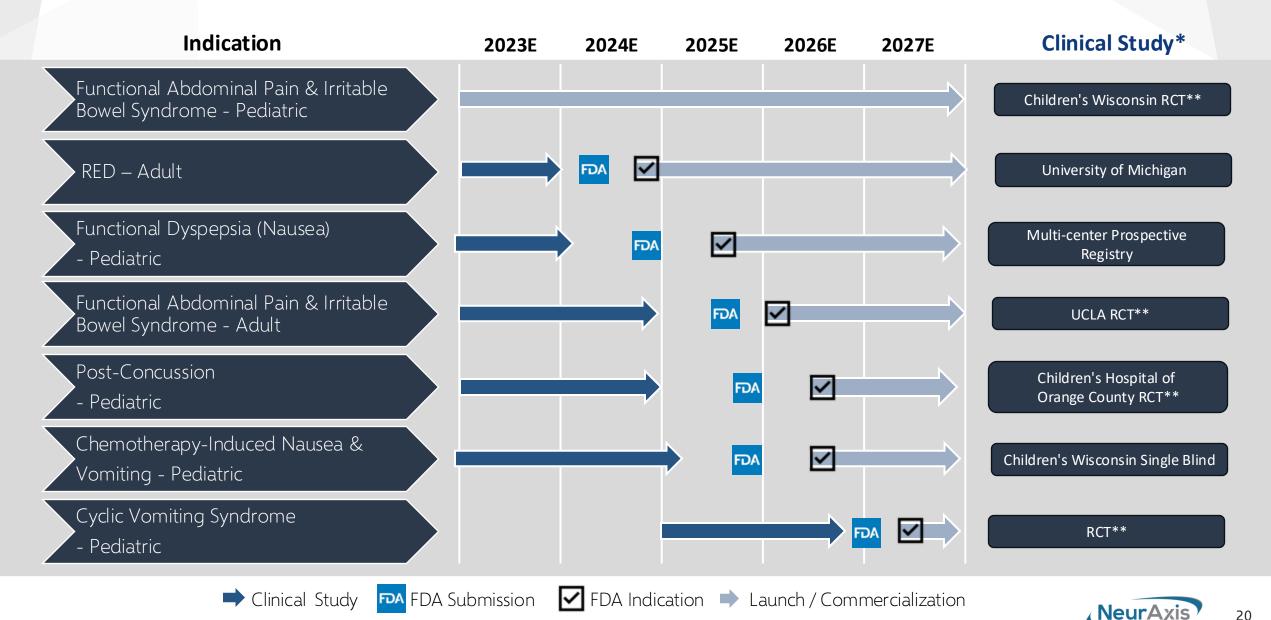


IB-Stim[™] vs. Drugs Competitive Landscape

		Antidepressants		Adult	Use (Peripheral	ly Acting at the	he 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	V	~	~	~	~	~	✓	



FDA Pipeline - Indications and Timelines



* 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 June 2024 with expected clearance in Q4 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

UNIQUE FEATURES

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

MARKET



~\$2B market opportunity
Current balloon expulsion testing requires a separate visit to a GI physiology laboratory

IB-STIN

 Anorectal manometry is too expensive to be practical

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

IB-STIN

Key Publications	> Academic Society Support	\geq	Successful Cov	verage Policies		CPT Billing Code
• Versus Placebo	NASPGHAN Written Support		• CareFirst BCBS	• BCBS Kansas City	• (CPT CAT I Code
• Long-term Data x 2	AAP Written Support		• BSBS Nebraska	 Highmark BCBS 		• (Effective January 1, 2026)
• Comparison vs. Soc Rx			• Quartz Wisconsin	• FL Blue		
• Multi-center Registry			BCBS South Carolina	a • BCBS VT		
 ~300 patients 			• BCBS Massachusetts	_s • Geisenger		
• Positive Health Economic Da	ata		 CS HealthVine 	 BCBS of North Dakot 	a	

	2023E		2024	E		2025E	2(026E	2027E
ory/Clinical			700+ Published Patients 16 Published Studies	FDA In R	dication: ED		FDA FDA Indication: Adult FAP/IBS	FDA FDA Indication: Post-Concussion Syndrome	
Regulato						FDA FDA Indication: Functional Dyspepsia		FDA Indication: CINV	FDA FDA Indication: Cyclic Vomiting Syndrome
ient	APC Payment Effective January		CAT I Code Su June 20		12	25M+ Covered Lives	CAT I CPT Effectiv January 1, 2026	e	
Irsem	1,2023	8M+ Covered	50M+ Cove	red Lives			:	200M+ Covered Lives	
Reimbu		Lives							NeurAxis 22

IB-Stim Go-to-Market Strategy

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

2024 Policy Coverage

Total Plans	Total # Lives covered
14 plans	~35M
Insurance Plans	# 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
Florida Blue	6M
BCBS VT	200К
Geisenger	600K
BCBS North Dakota	310К

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Commercialization Strategy

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

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 Sp	ecific CPT coding					
CPT CAT I code*	Effective 1/1/26					
List Price	• \$1,195					
Cus	tomers					
	~33k					
	U.S. Pediatricians					
Children's Hospitals ~260 in the U.S.	~10k U.S. Adult Gastroenterologists					



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* CPT Code Effective July 1^{st} , 2022

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

	(12) United States Patent Brown et al.	(10) Patent No.: US 10,010,479 B2 (45) Date of Patent: *Jul. 3, 2018	
	US010413719B2	1	US010322062B2
(12) United States Patent Brown et al.	(10) Patent No.: US 10,413,719 B2 (45) Date of Patent: Sep. 17, 2019	(12) United States Patent Brown et al.	(10) Patent No.: US 10,322,062 B2 (45) Date of Patent: *Jun. 18, 2019
 (54) METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION (71) Applicant: Innovative Health Solutions, Inc., Versuilles, IN (US) 	References Cited U.S. PUTERT DOCUMENTS 4.666/744 A* 3/1997 Capit 4.865/84 A* 3/1997 Externa A01N 1/328 4.865/84 A* 3/1997 Externa	 (54) AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME (71) Applicat: Inavority Health Solutions, Inc., Versailles, IN (US) 	(56) References Cited U.S. PATEINT DOCUMENTS 5488.625 A 101995 Kendall 6.212.433 Bi 4 42001 Bell (Continued)
 (72) Inventors: Christopher R. Brown, Greensburg, IN (US); Gary M. Peterson, Versailles, IN (US) (73) Assignee: Innovative Health Solutions, Inc., 	60745 (Continued) FOREIGN PATENT DOCUMENTS AT 35106 B 91992	 (72) Inventors: Christopher R. Brown, Greensburg, IN (US); Gary M. Peterson, Versailles, IN (US) (73) Assignce: Innovative Health Solutions, Inc., 	FOREIGN PATENT DOCUMENTS AT 395106 B 9/1992 EP 2247339 A1 11/2012 (Cominued)
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.	OTHER PUBLICATIONS Non-Final Office Action dated Mar. 19, 2018 filed in U.S. Appl. No.	 Versailles, IN (US) (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 6 days. This patent is subject to a terminal dis- 	COMMING OTHER PUBLICATIONS Non-Final Office Action dated Mar. 19, 2018 filed in U.S. Pat. No. 10010,479 issued Jul. 3, 2018. (Continued)
Pile Appl. No.: 15/488,416 Piled: Apr. 14, 2017 (65) Prior Publication Data US 2017/0296807 A1 Oct. 19, 2017	10010.479 issued Iul. 3. (Continued) Primary Examiner — Catherine M Voorhees (74) Antorney, Agent, or Firm — Barnes & Thomburg LP	claimer. (21) Appl. No.: 16/014,169 (22) Filed: Jun. 21, 2018	Primary Examiner - Nadia A Mahmood (74) Attorney, Agent, or Firm - Barnes & Thornburg LLP
Related U.S. Application Data (60) Provisional application No. 62/323,369, filed on Apr. 15, 2016, provisional application No. 62/324,598, filed on Apr. 19, 2016.	(57) ABSTRACT A method for treating pain or disconfort in a patient is disclosed. The method comprises stimulating a canaial nerve with an electrical signal. The patin or disconfort may be a	(65) Prior Publication Data US 2018/0296435 A1 Oct. 18, 2018 Related U.S. Application Data (63) Continuation of application No. 15/811,278, filed on Nov. 15, 2017, nov Pat. No. 10,001/479, which is a	(57) ABSTRACT An auricular peripheral nerve field stimulator includes an electrical stimulation device for generating electrical stimu- lation signals, at least one therapy electrode electrically coupled to the stimulation device and configured for pereu-
51) Int. CL AGIN 1/05 (2006.01) AGIN 1/05 (2005.01) AGIN 1/05 (2006.01) SUS, CL CPC	withdrawal symptom. The cranial nerve may be auricular area of the patient. The cranial nerve may be cranial nerve V, cranial nerve VII, cranial nerve IX, cranial nerve X, or branches of greater and lesser occipital nerve thereof and their associated neurowaseutor bundle	(Continued)	taneous intertion into an antricle of a human cert near at least one neurowatcalb bundle, a processor, and a memory with software executable by the processor to (i) control the stimulation device to generate and deliver to the inserted at least one therapy electrode the stimulation signals at a selected frequency with one of a positive and a negative
(2013.01); <i>A6IN 1/36071</i> (2013.01); <i>A6IN</i> 3//45 (2013.01) (58) Field of Classification Search CPC	addiction. The secondary drug may be one day to about one week after initi step.	01301; .46111 39/02 V 1/0551 (201301);	pulse relative to a reference to stimulate at least one aurieu- lar peripheral nerve field within the auricle, (ii) continually repeat (i) for a first duration, (iii) following copriation of the first duration, centrol the stimulation device to generate no stimulation isguals for a second duration, and (iv) repeat (i) through (iii) with the stimulation signals having a modulated frequency.
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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

IB-STIN

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











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Collective Experience





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Key Investment Highlights

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



Large Global Market with Significant Unmet Need

- \$23B+ TAM³ for target pipeline indications
- \$9B+ TAM³ for target pediatric indications (near-to-mid term)
- \$14B+ TAM³ 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 patients⁴
- 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

