NEURAXIS, INC. 2025 ANNUAL REPORT

Neuraxis, Inc. Board of Directors and Executive Officers as of April 28, 2026

BOARD OF DIRECTORS	
Name	**Principal Occupation or Employment**
Brian Carrico	President, Chief Executive Officer, and Director, of Neuraxis, Inc.
Dr. Christopher Robin Brown	Co-founder of Neuraxis, Inc.
Bradley Mitch Watkins	National Sales Manager of Terumo Interventional Systems
Beth Keyser	President Commercial West Region at Anthem Blue Cross and Blue Shield
Kristin Ferge	President and Chief Financial Officer of Capri Communities and Bridges Home Healthcare
Gilad Aharon	Co-founder and Portfolio Manager at Rosalind Advisors, Inc.

EXECUTIVE OFFICERS	
Name	**Principal Occupation or Employment**
Brian Carrico	Chief Executive Officer
Timothy Henrichs	Chief Financial Officer
Dr. Adrian Miranda	Chief Medical Officer, Senior Vice President of Science and Technology
Dr. Thomas Carrico	Chief Regulatory Officer, Compliance Officer and Privacy Officer

This Annual Report contains forward-looking statements. All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. Please read the section of our Annual Report on Form 10-K entitled “Forward-Looking Statements” for a discussion of the limitations and risks regarding forward-looking statements made in this Annual Report. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K included herein, which may cause actual results to differ materially from those contained in any forward-looking statements we may make. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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

FORM 10-K

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

For the fiscal year ended: December 31, 2025

or

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

For the transition period from _____ to _____

Commission File Number: **001-41775**

Neuraxis, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-5079684**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification Number)
11611 N Meridian St, Suite 330 Carmel, IN 46032	**(812) 689-0791**
(Address of principal executive offices and zip code)	(Registrant's telephone number, including area code)

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	NRXS	NYSE American LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's outstanding common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price for the registrant's common stock on that day as reported by the NYSE American, was approximately $20.4 million.

The registrant had 11,187,639 shares of its common stock, par value $0.001, issued and outstanding as of March 12, 2026.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of the federal securities laws. All statements contained in this Annual Report, other than statements of historical fact, including statements regarding our future operating results and financial position, our business strategy and plans, potential growth or growth prospects, future research and development, sales and marketing and general and administrative expenses, and our objectives for future operations, are forward-looking statements. Words such as "believes," "may," "will," "estimates," "potential," "continues," "anticipates," "intends," "expects," "could," "would," "projects," "plans," "targets," and variations of such words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" in this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report and in other documents we file from time to time with the Securities and Exchange Commission (the "SEC") that disclose risks and uncertainties that may affect our business. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance, or achievements. In addition, the forward-looking statements in this Annual Report are made as of the date of this filing, and we do not undertake, and expressly disclaim any duty, to update such statements for any reason after the date of this Annual Report or to conform statements to actual results or revised expectations, except as required by law.

You should read this Annual Report and the documents that we reference herein and have filed with the SEC as exhibits to this Annual Report with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

This Annual Report also contains or may contain estimates, projections and other information concerning our industry, our business and the markets for our products, including data regarding the estimated size of those markets and their projected growth rates. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

PART I

ITEM 1. BUSINESS

Overview

Neuraxis, Inc. ("we", "us", the "Company" or "Neuraxis") is a first-to-market growth-stage medical technology company focused on neuromodulation therapies for chronic and debilitating conditions in gastrointestinal (GI) digestive system, specifically from disorders of the gut-brain interaction (DGBIs) in pediatrics and adults. With several indications in the market and additional clinical trials of Percutaneous Electrical Nerve Field Stimulation (PENFS) in multiple pediatric and adult conditions underway, we are focused on unmet GI healthcare needs in children and adults. We are dedicated to advancing science with our proprietary IB-Stim® therapy, based on our PENFS technology, which was developed internally by the Company. We believe that superior science and evidence-based research are necessary for adoption by the medical and scientific community. Additional clinical trials of PENFS in multiple pediatric and adult conditions are underway, focused on unmet healthcare needs in children and adults. See "*Our Pipeline*" for more information.

Our first product, IB-Stim, is a PENFS technology intended to be used in patients 8 years and older with functional abdominal pain associated with irritable bowel syndrome (IBS), functional dyspepsia (FD) and associated FD nausea symptoms. IB-Stim is a US FDA Class II medical device that has received regulatory clearances: IB-Stim (DEN180057, 2019; K252024, 2025), under the regulation name of "non-implanted nerve stimulator for functional abdominal pain relief."

Our second product, RED™ (Rectal Expulsion Device), is indicated to evaluate the neuromuscular function of a patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity. RED (K242304, 2024) helps identify patients with rectal hypersensitivity who experience a desire or urge to defecate at lower volumes of distension. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

The Company's product portfolio has achieved several key milestones, including:

- Academic Society Guidelines: In May 2025, the leading pediatric academic society, NASPGHAN (North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition), published functional abdominal pain guidelines listing PENFS as the ONLY FDA-approved or FDA-cleared treatment in the guidelines to be recommended.
- AMA Category I CPT Code (64567): In 2024 the AMA confirmed the assignment of a Category I CPT code for PENFS procedures, which takes effect on January 1, 2026. This CPT code brings credibility, streamlined reporting, and relative value units (RVUs) for the physician, allowing credit for their time.
- Federal Supply Schedule (FSS) Contract: In December 2025, NeurAxis was awarded a FSS contract with the United States government which includes the 01-1020 IB-Stim to be sold for the FDA indications of Functional Abdominal Pain with IBS, Functional Dyspepsia (FD), and associated FD Nausea Symptoms.

Our Mission

Our mission is to advance drug-free neuromodulation therapies that improve patient outcomes and reduce medication burden in complex disorders, while expanding access to effective care for populations with significant unmet needs.

Our Corporate History

Neuraxis, Inc. was established in 2011 and incorporated in the state of Indiana in 2012, under the name of Innovative Health Solutions, Inc. The name was changed to Neuraxis, Inc. in 2022 when the Company filed a Certificate of Conversion to become a Delaware corporation. On August 9, 2023, the Company consummated an initial public offering ("IPO") pursuant to a registration statement on Form S-1 (File No. 333- 269179), as amended.

In 2024, the Company's shareholders authorized 5,000,000 shares of preferred stock of which all were designated at $0.001 par value "Series B Preferred Stock" inclusive of cumulative dividends, due and payable quarterly at the Company's discretion either in cash or common stock when declared, at a rate of 8.5% per annum through December 31, 2026. The stated value of the Series B Preferred Stock is $2.38 per share.

We have developed four FDA cleared products: (i) IB-Stim (DEN180057, 2019), (ii) RED (K242304, 2024), (iii) NSS-2 Bridge (DEN170018, 2017), and (iv) the original 510(k) clearance (K140530, 2014), all of which were developed internally by the Company.

- IB-Stim is a PENFS device that is indicated in patients 8 years and older with functional abdominal pain associated with irritable bowel syndrome, functional dyspepsia, and associated FD nausea symptoms.

- RED is indicated to evaluate the neuromuscular function of a patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity patients who experience desire or urge to defecate at lower volumes of distention. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

- NSS-2 Bridge is a percutaneous nerve field stimulator (PNFS) device indicated for use in the reduction of the symptoms of opioid withdrawal and was licensed to Masimo Corporation ("Masimo"). Masimo marketed and sold this product as its Masimo Bridge. On July 1, 2025, The Company terminated the NSS-2 Bridge license with Masimo in exchange for $200,000 of consideration payable of which $100,000 was paid on December 31, 2025 and $100,000 is due on June 30, 2026. The termination agreement allowed the Company to recapture the rights to the trademark (U.S. Registration No. 7,394,465) and two patent applications (Application No. 18/821/255 and Application No. 29/960.608) that were originally licensed to Masimo on April 9, 2020.

- The original 510(k) device was the electroacupuncture device ("EAD"), now called *NeuroStim*. The EAD is no longer being manufactured, sold or distributed but reserved only for research purposes.

Pediatrics Industry Overview

Pediatric providers, as a whole, expressed concern about the lack of attention given to children with functional abdominal pain disorders (including IBS and FD) and the limited treatment options available for a population that suffers from significant disabilities. With 20% of the United States population under age 18, our Company focus began with opportunities in the pediatrics industry. The pediatrics industry has multi-billion-dollar market opportunities. The following points clearly outline the unmet need in children:

- Functional abdominal pain in children is one of the most common conditions seen by pediatricians and pediatric gastroenterologists.
- Children with functional abdominal pain report lower quality of life compared with their healthy peers and equal to those with inflammatory bowel disease.
- Overall, 40-45% of children with functional abdominal pain disorders continue to have symptoms into adulthood, which impacts quality of life and healthcare spending.
- A study published in 2021 demonstrates insufficient evidence for the use of medications in pediatric functional abdominal pain disorders. This lack of evidence for drugs has been supported in by the American Academy of Pediatrics and NASPGHAN.
- IB-Stim is the only medical therapy that has shown to improve pain, global symptoms, and functional disability in children with FAP and IBS.
- IB-Stim is the only currently used medical therapy that is better than placebo in a randomized controlled trial and received FDA clearance for pediatric IBS.

Our Opportunity

For years, physicians and qualified healthcare professionals have resorted to the use of off-label medications without proper evidence of efficacy or safety. This is despite a technical report from the American Academy of Pediatrics and NASPGHAN which found very little evidence to endorse the use of any drugs in the treatment of FAPDs in children. Medications including tricyclic antidepressants, SSRIs and gabapentinoids continue to be used off-label despite lack of evidence to support efficacy or safety. Not only have the most commonly used medications (amitriptyline and citalopram) failed to beat placebo in clinical trials, but new studies also suggest significant risks with the potential for serious side effects with these drugs. The absence of conclusive data to support treatments based on scientific evidence, and the fact no drug therapies have been approved by the FDA for the treatment of FAPDs or IBS in children, presents a unique market opportunity for Neuraxis. Below are the current standard treatments in children with functional abdominal pain and IBS.

Pharmacological Treatment Options for Functional Abdominal Pain Disorders

Mild Pain (No Disability)	Pain (With Disability)	
Peppermint oil	Tricyclic antidepressants (amitriptyline)*	Rifaximin
Iberogast	Selective serotonin reuptake inhibitors (citalopram)*	Constipation
Probiotics	Gabapentin	Linaclotide
Acid suppression with PPIs	Antispasmodics (hyoscyamine, dicyclomine)*	Lubiprostone
	Cyproheptadine*	Plecanatide

* Increased risk of dementia based on anticholinergic burden

Our Solutions

We entered the pediatric market with clinical evidence, key opinion leaders and society endorsement, including a signed letter from the American Academy of Pediatrics and NASPGHAN supporting our request for insurers to provide coverage for PENFS procedures with IB-Stim. IB-Stim is a non-drug alternative to reduce functional abdominal pain in patients with IBS. In June 2019, the FDA cleared IB-Stim, a non-surgical, neuromodulation device for children and adolescents who suffer from IBS, through a de novo process (DEN180057, 2019). Most recently, FDA cleared 510(k) 252024, expanding the indications for use. The FDA created a new classification of PENFS for IB-Stim. This is based on pre-clinical and clinical studies demonstrating the mechanism of action and efficacy. Based on this new class of devices, IB-Stim falls under 21 CFR Part 876, Subpart F – Therapeutic Devices, 876.5340, Product Code QHH. As a PENFS device, it is non-implantable and provides field stimulation to cranial nerves V, VII, IX and X in the ear to access the central nervous system. It stimulates remotely from the source of pain to modulate central pain regions, such as the limbic system, and relieve functional abdominal pain associated with IBS. Studies have demonstrated long-term benefits in functional disability, psychological co-morbidities, and pain. For example, the table below is from a recently published study of IB-Stim in a population of patients with chronic functional abdominal pain. The follow-up was done at 6-12 months post-treatment and shows improvements in validated questionnaires compared to baseline (API), functional disability index (FDI), pain catastrophizing scale (PCS), Screen for Childhood Anxiety Related Disorders (SCARED) and the Promis Anxiety.

Santucci NR, King C, El-Chammas KI, Wongteerasut A, Damrongmanee A, Graham K, Fei L, Sahay R, Jones C, Cunningham NR, Coghill RC. *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.

TABLE 2 Effects on symptoms before, during, and after PENFS

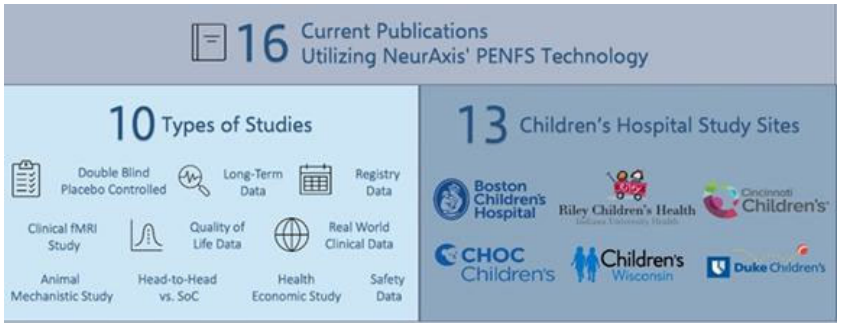
Parameters	Baseline	Penfs				p value[a]	Follow-up	p value[b]
		Week 1	Week 2	Week 3	Week 4			
GI Symptoms								
Resting VAS								
Pain Intensity	2.2 ± 0.52	1.72 ± 0.52	1.75 ± 0.53	1.73 ± 0.53	1.41 ± 0.53	0.06	-	-
Pain Unpleasantness	2.05 ± 0.5	1.21 ± 0.5	1.33 ± 0.51	1.28 ± 0.51	1.28 ± 0.51	0.03	-	-
Nausea	1.07 ± 0.44	0.41 ± 0.44	0.61 ± 0.44	0.74 ± 0.44	0.68 ± 0.44	0.10	-	-
API	2.84 ± 0.25	2.39 ± 0.25	2.08 ± 0.26	2.05 ± 0.26	1.9 ± 0.26	<0.0001	1.39 ± 0.27	<0.0001
NSS	1.78 ± 0.25	1.66 ± 0.25	1.14 ± 0.25	1.36 ± 0.25	1.33 ± 0.25	0.07	0.90 ± 0.27	0.001
Physical Functioning								
FDI	18.95 ± 3.06	15.3 ± 3.06	15.12 ± 3.07	15.07 ± 3.07	15.54 ± 3.07	0.04	10.09 ± 3.14	<0.0001
CSSI (Somatic symptoms)	28.25 ± 3.81	25 ± 3.81	20.61 ± 3.85	20.04 ± 3.85	20.4 ± 3.85	0.01	17.8 ± 4.05	0.002
CSSI (GI symptoms)	9.9 ± 1.1	7.65 ± 1.1	7.4 ± 1.12	6.92 ± 1.12	7.19 ± 1.12	0.01	6.14 ± 1.2	0.002
Psychological Functioning								
PCS-C	23.85 ± 3.24	19.85 ± 3.24	18.08 ± 3.27	16.5 ± 3.27	15.4 ± 3.27	0.0004	14.88 ± 3.42	0.001
SCARED	22.5 ± 4.3	-	-	-	17.5 ± 4.3	0.02	16.9 ± 4.4	0.03
PROMIS Anxiety	51.87 ± 2.27	48.28 ± 2.27	48.85 ± 2.28	48.03 ± 2.28	48.72 ± 2.28	0.03	48.87 ± 2.35	0.05
PROMIS Depression	48.6 ± 2.4	45.1 ± 2.4	46.27 ± 2.42	45.73 ± 2.42	46.78 ± 2.42	0.14	47.85 ± 2.49	0.63

Note: API, Abdominal Pain Index; CSSI, Children's Somatic Symptoms Inventory; FDI, Functional Disability Inventory; NSS, Nausea Severity Scale; PCS-C, Pain Catastrophizing Scale for Children; PENFS, Percutaneous Electrical Nerve Field Stimulation; SCARED, Screen for Child Anxiety-Related Emotional Disorders; VAS, Visual Analog Scale.
All values are LS Means and SE; [a]p for Week 4 vs. Week 0; [b]p for long-term follow-up vs. Week 0

We have submitted one FDA De Novo request and three 510(K) submissions and plan to submit additional 510(k) premarket notifications from our pipeline indications in the future. Most recently, FDA cleared 510(k) 252024, expanding the indications for use.

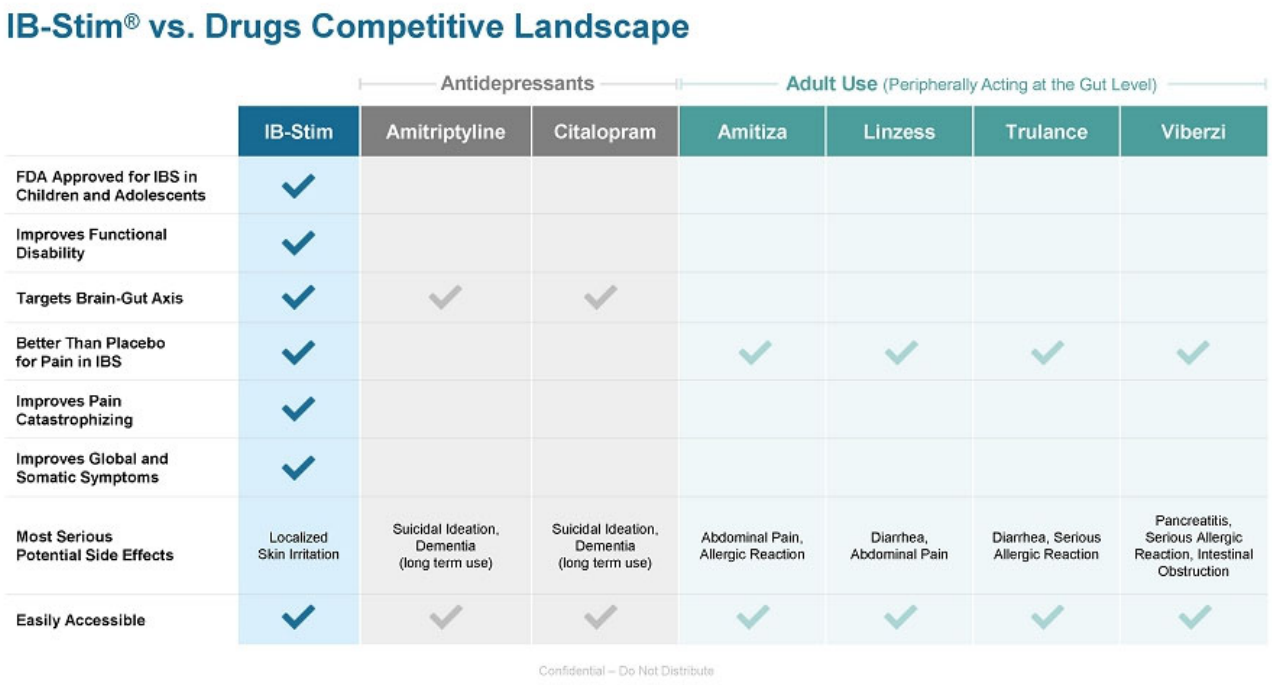
Compliance with treatment so far has been outstanding with the four weeks of therapy required to sustain long-term benefits. Compliance has been an issue with non-pharmacological treatment for children, particularly with some of the psychological approaches such as cognitive behavioral therapy or guided imagery, which sometimes requires 8-12 weeks of treatment. In fact, in a survey included in the randomised, sham controlled trial (Kovacic, K, Hainsworth, M., et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. Lancet Gastroenterol Hepatol. 2017 Oct;2(10):727-737), 95% of adolescents who used IB-Stim said that they would recommend this treatment to family and friends. Many children's hospitals and pediatric providers across the country are currently treating children with IB-Stim due to the safety, efficacy, and patient outcomes with this non-drug alternative.

We have concentrated our marketing focus on the 260 children's hospitals within the United States. To date, IB-Stim is established in approximately 80 children's hospitals within our target market.



Competition

The competitive landscape for therapies includes off-label drugs and drugs with FDA-approved only for adults with IBS while there is no FDA indicated treatments for patients 8-21 years of age with functional abdominal pain associated with IBS and prescriptions often contain FDA black box labels. Psychological treatments such as cognitive behavioral therapy (CBT) or guided imagery have been shown to be some of the most effective treatments for these conditions, however, these are limited by access to trained therapists. As a result, the Company is addressing this challenge by providing access to guided-imagery audio with IB-Stim at a low associated cost to the patient. Competition also includes devices that could theoretically be used, but do not have supporting data or FDA clearance for functional bowel disorders or IBS. Digital therapeutics that offer CBT for IBS have been developed for adults with IBS with limited success in terms of reaching large numbers of patients. Virtual reality could potentially be used in the future to also deliver CBT to patients with IBS. Our method patents limit other devices from targeting IBS through stimulation of cranial nerve branches in the ear.



Approved drugs for children with IBS

1. Linzess: a drug that stimulates fluid secretion from the intestine, approved for IBS-constipation in 7 years of age and older

Approved drugs for adults with IBS

1. Rifaximin: an intraluminal antibiotic approved for IBS-diarrhea
2. Amitiza: a drug that stimulates fluid secretion from the intestine, approved for IBS-diarrhea
3. Linzess**:** a drug that stimulates fluid secretion from the intestine, approved for IBS-constipation
4. Plecanatide: a drug that stimulates fluid secretion from the intestine, approved IBS-constipation
5. Eluxadoline: a schedule IV-controlled substance that is a mixed opioid receptor agonist/antagonist in the intestine approved for IBS-diarrhea

Approved drugs for children or adults with functional dyspepsia

1. None

Devices

1. gammaCore: a transcutaneous, cervical vagal nerve stimulator cleared for cluster and migraine headaches. Recent studies using this device for adults with gastroparesis.
2. Transcranial Magnetic Stimulation: Multiple devices cleared to treat major depressive disorder and obsessive-compulsive disorder. To date, no known gastrointestinal indications.
3. Roo System and Sparrow therapy system: Transcutaneous auricular stimulation devices-cleared for neonatal and adult opioid withdrawal.

The neurostimulation market is predominantly comprised of surgically implanted, invasive technologies that are not directly competitive with our technology. Several neurostimulation companies are large, publicly traded companies that have a history in the market, have significantly easier access to capital and other resources and have an established product pipeline. The combined clinical research and product development done by the industry, including by us and all our competitors, is uncovering the beneficial effects of neurostimulation which now establishes neuromodulation as a valid and scientifically supported approach to the treatment of neurological conditions, and accordingly, we expect for competition in the non-implanted space to grow in the future.

While many companies have joined the neuromodulation space, there are no companies targeting the CNS or the brain-gut axis through auricular nerves for functional bowel disorders or IBS. Currently, the Neuraxis method patents protect access to the brain, particularly the limbic systems through branches of cranial nerves in the ear.

Our Competitive Strengths

We believe that the following competitive strengths will enable us to compete effectively:

- First to market
- Strong portfolio of device and method patents
- Large market opportunities
- Strong pediatric pipeline
- Academic Society guidelines with the only FDA-approved or FDA-cleared recommended treatment
- Category I CPT code (64567) effective January 1, 2026
- Strong clinical data carried out in leading academic institutions in the U.S.

Our Growth Strategies

- List price of our product is $1,195 per device and $4,780 per patient
- Strong gross margin
- Direct sales force
- Target customers are children’s hospitals, adult gastroenterologists in the VA, and adult pain physicians in the VA

Our Pipeline

IB-Stim is to be used for the indication of functional abdominal pain associated with IBS, functional dyspepsia (FD), and associated FD nausea symptoms. The same underlying technology will be used for the remaining pipeline indications, but we may use different branding strategies for marketing and commercialization purposes.

With one FDA indication—functional abdominal pain associated with IBS, functional dyspepsia (FD), and associated FD nausea symptoms for 8 years and older—on the market, additional clinical trials of PENFS in multiple pediatric conditions are underway focused on unmet healthcare needs in children and adults. These indications consist of post-concussion syndrome, cyclic vomiting syndrome, post-operative pain and fibromyalgia pain.

The chart below shows our status in the FDA review process for IB-Stim and each of the following pediatric indications:

1. *Functional dyspepsia* (*nausea*): Sub-analysis of the RCT completed, and data was analyzed and presented to FDA. The data looked only at those patients who met criteria for functional dyspepsia and those that improved in abdominal pain scores by 30% or more as well as improvements in a validated measure of nausea. The sub-analysis was used for FDA purposes and there is no plan to publish in peer reviewed journal since the entire cohort of patients with DGBIs was already published in 2017.

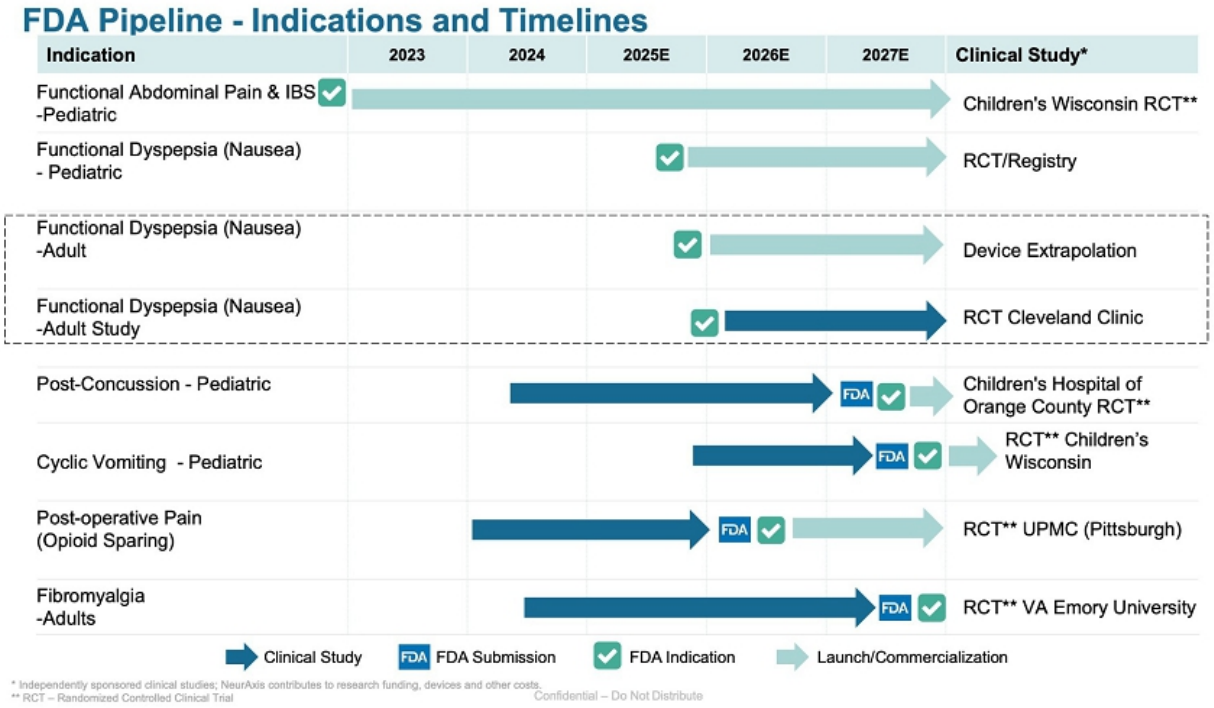
2. *Post-concussion:* RCT currently enrolling patients. ClinicalTrials.gov Identifier: NCT04978571, *A Prospective Study on the Effect of Auricular Percutaneous Electrical Nerve Field Stimulation (PENFS) in Patients with Post-Concussion Syndrome (PCS).* A randomized, double blind, placebo-controlled trial to evaluate the efficacy of IB-Stim in children with post-concussion symptoms. The primary endpoint will be to measure improvements in validated measures, including the Immediate Post-Concussion Assessment, Post-Concussion Symptom Scale, and Balance Error Scoring Symptom compared to placebo. The study will enroll 100 participants and is being conducted at Children's Hospital of Orange County.

3. *Cyclic vomiting:* Successful pilot study completed and published, Karrento K, et.al.. Electrical Nerve Field Stimulation for Drug-Refractory Pediatric Cyclic Vomiting Syndrome. J Pediatr Gastroenterol Nutr. 2023;77:347-353. A new study, *Auricular Neurostimulation for Children with Cyclic Vomiting Syndrome: A randomized, placebo-controlled trial.* RCT anticipated to begin enrolling patients early in 2026. This will be a double blind, placebo-controlled trial to evaluate efficacy of IB-Stim in pediatric patients with cyclic vomiting syndrome. The primary endpoint will be to measure decreases in the frequency and severity of cyclic vomiting episodes compared to a placebo device. The study will include a minimum of 120 patients and is being conducted at Children's Wisconsin/Medical College of Wisconsin.

4. *Post-operative pain (opioid sparing)*: RCT currently enrolling patients and plans to include almost 300 patients total. ClinicalTrials.gov Identifier: NCT05506878. Reduction of Opioid Requirement Associated With Auriculo-Nerve Stimulation Following Open Surgery. The primary outcome measure is opioid consumption. Assess how the use of the NSS-2 BRIDGE Device over a 5 day stimulation period affects the participant's total opioid consumption using morphine equivalent following an open abdominal or pelvic surgery. Other measures will include post-operative pain ratings, sleep, somatization, as well as length of hospital stay. The study is being conducted at University of Pittsburgh Medical Center.

5. *Fibromyalgia in adults*: RCT currently enrolling patients. ClinicalTrials.gov Identifier: NCT06415591. Auricular Neuromodulation in Veterans with Fibromyalgia: The proposed Merit, a randomized, sham-controlled trial of auricular PENFS, evaluates the clinical utility of PENFS for fibromyalgia as compared to sham placebo control, acute and longitudinal PENFS-related neural changes visualized on rs-fcMRI and effects of PENFS on HRV as a potential vagal mechanism of pain relief. For Aim 1, 240 total participants meeting 2016 diagnostic criteria for fibromyalgia (male and female, age 18-60 years old) will be randomized to either true (n=120) or sham (n=120) auricular PENFS. The study is being conducted at Emory University and VA medical center.

Each step in the FDA review process differs in duration and cannot be predicted with accuracy. Timing of FDA review and approval, if ever received, cannot be assured and the process and any approval is within the sole control and discretion of the FDA.



Products

IB-Stim is a PENFS technology intended to be used in patients 8 years and older with functional abdominal pain associated with IBS, functional dyspepsia (FD), and associated FD nausea symptoms. The FDA has classified the non-implanted nerve stimulator for functional abdominal pain relief as a Class II device.

IB-Stim is intended to be used for 120 hours per week, using one (1) device per week, for four (4) consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS (DEN180057, 2019; K252024, 2025). In published studies, patients treated with IB-Stim demonstrated significant improvement in pain, disability and global symptoms with no serious adverse events, and minimal to no side effects, including localized skin irritation. The following table presents a summary of IB-Stim studies performed to date:

Author	DGBI	N=	Ages	# of devices	Outcomes	Major adverse events
Santucci et al.,2025	Functional Abndominal Pain	219	7-21	4	Abdominal pain, nausea, disability	None
Dorfman et.al.,2025	Functional Abdominal Pain	22	11-21	4	Abdominal pain, recurrent treatment	None
Kolacz et.al.,2025	Chronic Nausea	84	11-18	4	Cardiac vagal effeciency	None
Santucci., et.al., 2024	Functional Dyspepsia	84	11-21	4	Abdominal pain and nausea	None
Castillo et.al., 2023	Irritable bowel syndrome	27	11-18	4	Abdominal pain, Microbiome Metabolism	None
Karento et al., 2023	Cyclic Vomiting Syndrome	30	8-18	6	Abdominal pain, nausea, disability	None
Santucci et.al.,2023	Irritable bowel syndrome, functional dyspepsia, FAP	101	11-21	4	Abdominal pain, nausea, disability	None
Chogle et.al., 2023	Irritable bowel syndrome, functional dyspepsia	31	11-18	4	Quality of life, disability, anxiety	None
Chogle et.al., 2023 (Registry)	Irritable bowel syndrome, functional dyspepsia	292	8-18	4	Abdominal pain, nausea, disability	None
Santucci et al., 2023	Functional Dyspepsia	84	11-21	4	Abdominal pain, nausea, anxiety, disability	None
Bora et.al.,2023	Irritable bowel syndrome	20	11-18	4	IBS severity scale, Microbiome diversity	None
Santucci et.al.,2021	Functional abdominal pain	20	11-19	4	Abdominal pain, sleep, nausea, anxiety	None
Krasaelap, et.al., 2020	Irritable bowel syndrome	51	11-18	4	Abdominal pain, global symptoms, disability	None
Kovacic et.al.,2017	IBS, FD, FAP, abdominal migraine	115	11-18	4	Abdominal pain, disability, global symptoms.	Syncope=1 in sham group

The ability of IB-Stim to produce systemic effects by modulating the central nervous system has been demonstrated in a pre-clinical animal model of IBS (see Business—*Pre-Clinical Data*). In patients with IBS, the largest effect on all pain measures, including composite pain scores, worst pain, disability and global symptoms, was seen after completing three consecutive weeks of treatment (see Business—*Clinical Data*). A fourth consecutive week of treatment was included in clinical testing; no safety concerns were identified with this extra consecutive week of treatment. In the trial of 115 subjects, 10 patients reported side-effects and only three discontinued the study because of side-effects. Of such 10 patients, six experienced ear discomfort (three in the PENFS group, three in the sham group), three experienced adhesive allergies (one in the PENFS group, 2 in the sham group), and one experienced syncope due to needle phobia (in the sham group). There were no serious adverse events. Since that study, numerous other studies have confirmed the safety and efficacy in children with chronic DGBIs (see table above).

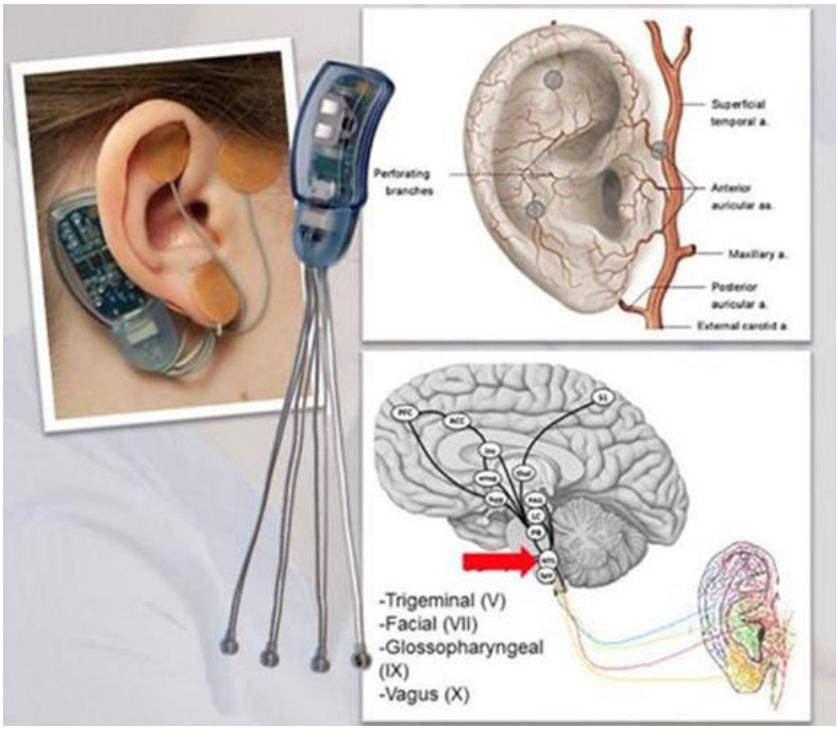
Medical providers are trained to place IB-Stim through NeurAxis' IB-Stim Training and Certification process. Once the provider is trained, the device can be placed in the outpatient clinic and can be removed by the provider in the clinic or by the patient at home. IB-Stim stays on for a total of five-days to allow delivery of gentle electrical pulses to nerves below the skin that access the central nervous system. A study in adolescents showed greater improvement in functional abdominal pain and global symptom improvement with every week of treatment (up to four weeks). At the end of the four-week study, 95% of adolescents stated they would recommend the treatment to family or friends. Safety of percutaneous electrical nerve field stimulation has also been reported in a separate study of over 1200 adult patients with no serious adverse events and minimal to no side-effects.

When wearing IB-Stim and following an easy-to-learn and efficient procedure, patients can still attend school and extracurricular activities, exercise or play non-contact sports, shower, wear earbuds or headphones, and travel.

IB-Stim costs $1,195 per device, and each patient will use four (4) devices. Potential patients with other indications are expected to use six (6) or more devices per patient.

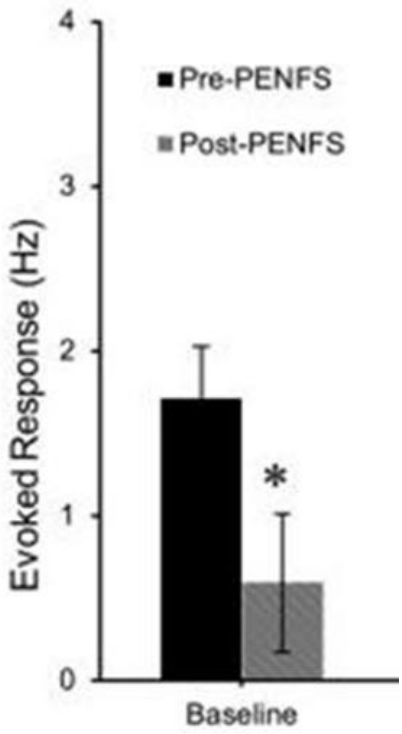
Technology

A maladaptive central nervous system can process pain and emotions differently. This often occurs in children following a traumatic event, viral infections, inflammation or trauma. Changes in brain pathways are known to be involved in the pathophysiology of functional bowel disorders and IBS. IB-Stim works by sending gentle electrical impulses into cranial nerve bundles located in the ear. This stimulation targets brain areas that process pain and helps reduce functional abdominal pain associated with IBS. An animal model of IBS demonstrated that the firing of neurons in the amygdala could be reduced by more than 50% in just 15 minutes of stimulation with IB-Stim. A recent human study in adults with pain related to fibromyalgia suggested that IB-Stim exerts its effect by modulating emotional and executive control centers related to pain processing, see *Feasibility of Auricular Field Stimulation in Fibromyalgia: Evaluation by Functional Magnetic Resonance Imaging, Randomized Trial*, Woodbury et.al., Pain Med. 2021;22:715-726. The field of art pertains to an electrical stimulation device, including a stimulator containing a generator to deliver electrical pulses with defined parameters, and a power supply for supplying the electrical energy through four separate needles, and at least one of which is a needle array.



Pre-Clinical Data

In an animal model of IBS, extracellular, electrophysiologic recordings were performed from neurons in the rat amygdala before and 15 minutes after PENFS treatment. There was a 65% decrease in the spontaneous firing of these neurons after 15 minutes of PENFS. This dampening of neurons in the CNS likely accounts for the modulation of pain responses in a model of post-inflammatory visceral and somatic hyperalgesia.



Clinical Data

There are over 700 published patients specific to our first FDA indication which is functional abdominal pain associated with irritable bowel syndrome in patients 8-21 years of age. A published patient is defined as a patient who went through a study, the study was analyzed, and now the study has been published in a peer-reviewed journal.

A randomized, controlled study in children 11-18 year of age used primary endpoint of improvements in abdominal pain. The Pain Frequency-Severity-Duration ("PFSD") questionnaires was completed at baseline by all subjects and after each week of treatment (weeks 1–3), as well as at extended follow-up occurring in the 8–12 weeks following the end of treatment. The PFSD scale incorporates multiple aspects of the pain experience and was administered weekly during treatment and at extended follow-up appointments. The PFSD scale validated for chronic pain in children (aged 8–18 years). The PFSD was also used to rate weekly worst abdominal pain on a numerical rating scale (0 for no pain, 10 for worst pain). Patients were followed up for a median of 9.2 weeks from the last week of treatment.

For the active PENFS group, median worst pain at follow-up remained lower (baseline: 8.0 vs. follow-up: 6.0), whereas there was no difference at follow-up in the control group (baseline: 7.5 vs. follow-up: 7.0). The between-group differences in worst pain ratings after 3 weeks of treatment showed that the PENFS group improved to a greater extent, with the control group reporting significantly higher worst pain (median 7.0) than the PENFS group (median 5.0).

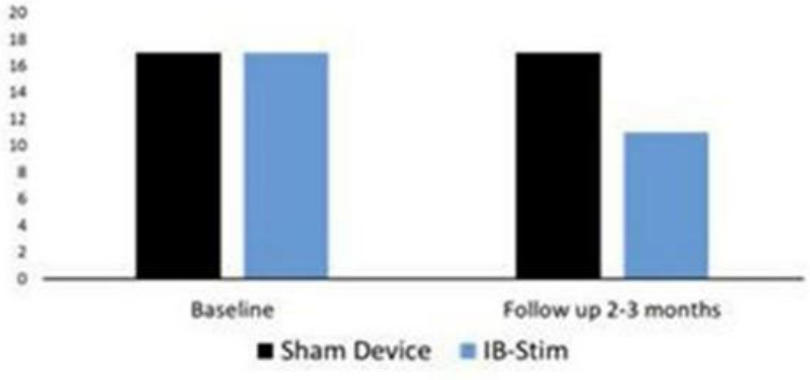
At long-term follow-up, median PFSD composite scores were 12.6 (IQR 3.6–22.5) in the PENFS group and 16.8 (4.8–33.6) in the control group. A comparison of changes in PFSD composite scores (baseline to follow-up) showed that patients in the PENFS group reported significantly greater improvement in pain (median –8.4) than those in the control group (median 0.0). This study was published in the Lancet Gastroenterology Hepatology, (Kovacic K, et.al. Lancet Gastroenterol Hepatol. 2017;2:727-737).

	PFSD worst pain score			PFSD composite pain score		
	Mean (SE)	95% CI	p value	Mean (SE)	95% CI	p value
Week 1	1·09 (0·3855)	0·34–1·85	0·0048	5·75 (2·41)	1·00–10·49	0·018
Week 2	1·21 (0·3924)	0·43–1·98	0·0023	6·41 (2·45)	1·60–11·23	0·0092
Week 3	2·15 (0·3947)	1·37–2·93	<0·0001	11·48 (2·46)	6·63–16·32	<0·0001

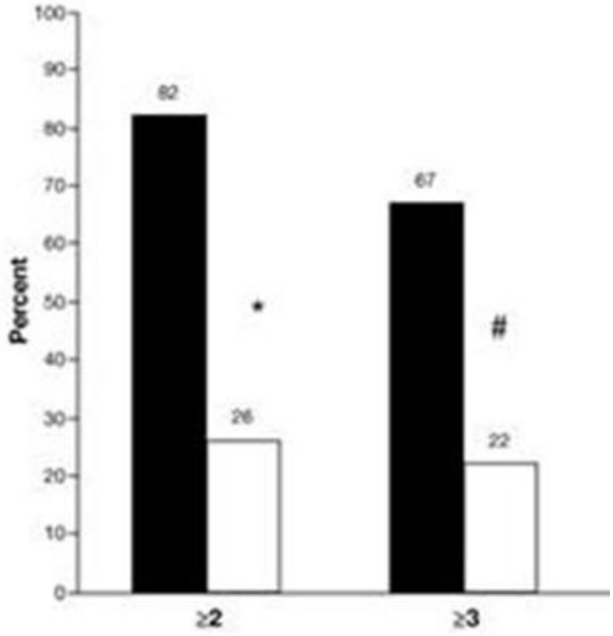
PFSD=Pain-Frequency-Severity-Duration. PENFS=percutaneous electrical nerve field stimulation.

Table 3: **Least squares means estimates of change of worst pain and composite PFSD scores from baseline across weeks 1-3, PENFS versus sham**

A secondary endpoint in the same study used the functional disability index (FDI) to assess functional disability in those treated with PENFS and compared to sham treatment. Those treated with PENFS changed from moderate disability to minimal at the 2–3-month follow-up while the sham device group had no change.



A separate published paper looked at 51 pediatric patients with IBS and used the symptoms response scale (SRS) to assess global symptoms improvement following PENFS treatment compared to sham. Global symptom improvement was assessed with a validated pediatric questionnaire, Symptom Response Scale (SRS). Symptoms were recorded as better, worse, or no change based on a 15-point scale across individual domains for both improvement and deterioration of overall symptoms. Findings from several studies that used the SRS have shown that using 7-point scale response options in disease-specific measures, a change score of 0.5 represents the minimal clinically important difference (Juniper et.al. J Clin Epidemiol 1994; 47: 81–87 and Guyatt GH et.al.1987; 42: 773–78). As previously noted, a minimum change in score of ≥ 2 was chosen for this study as a more stringent criterion for global improvement before and after PENFS treatment and to compare between groups. Patients and providers were blinded in terms of those who received active PENFS or sham. At the end 3 weeks of therapy using the change of ≥ 2, 81% of the PENFS group compared with 26% of the sham group (*p≤ 0.001, #p=0.002) reported overall symptom improvement. When applying an even more stringent criteria with a change ≥ 3 on the SRS, 67% of the PENFS group compared with 22% of the sham group reported symptoms improvement (p=0.002) (Krasaelap A et.al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. Clin Gastroenterol Hepatol. 2020;18:1987-1994).



Recently, the largest, prospective, multicenter registry for any drug or device in pediatric patients with pain associated DGBIs was published. It evaluated outcomes of pediatric patients (8-18 years) following a 4-week course of IB-Stim in a real-world clinical setting. Overall, 292 patients met Rome IV Diagnostic criteria for any pain associated disorder of the gut-brain interaction (DGBIs). In this cohort, 92% had failed medication therapy and 61% of patients had failed 4 or more medications when they entered the study. Patients were asked to fill out several validated pediatric measures, including the abdominal pain index (API) and a validated questionnaire that assesses frequency, duration, and intensity of abdominal pain episodes. Data were collected weekly for the first 3 weeks and at 3, 6, 9 and 12 months. Compared to baseline scores, there were significant improvements in the API after 4 weeks of IB-Stim treatment at every time point, including 6 month ($p<0.001$) and 12 months ($p<0.001$). Although there were many dropouts by the end of the 12 months, the results were still significant and sustained. No serious adverse effects were recorded during the entire 12 month follow-up. (Chogle, A. et. al. A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut-brain interaction. J Pediatr Gastroenterol Nutr. 2024 Mar 7.).

Abdominal Pain Index (API)

Time point	*n*	Median (IQR)	p Value
Baseline	**288**	**2.68(1.84, 3.58)**	**N/A**
3 weeks	**209**	**1.99 (1.13, 3.27)**	**<0.001**
3 months	**75**	**1.81 (0.85, 3.20)**	**<0.001**
6 months	**60**	**1.70 (0.93, 2.72)**	**<0.001**
9 months	**26**	**1.90 (1.33, 2.82)**	**0.002**
12 months	**22**	**220(0.41, 3.21)**	**<0.001**

An open-label study of 20 patients treated with PENFS in a "real-world" clinical setting at Cincinnati Children's Hospital demonstrated that after PENFS, abdominal pain ($p < 0.0001$), nausea ($p=0.001$), pain catastrophizing ($p = 0.001$), functional disability ($p<0.0001$), and anxiety ($p = 0.03$) exhibited significant improvements, and were sustained 6-12 months after treatment (Santucci 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). Validated questionnaires included the abdominal pain index (API), nausea severity scale (NSS), functional disability index (FDI), as well as psychological measures of catastrophizing (PCS-C) and anxiety (SCARED). The table below summarizes the results pre, during and post PENFS results at long-term follow-up (Santucci 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).

TABLE 2 Effects on symptoms before, during, and after PENFS

Parameters	Baseline	Perifs				*p* value[a]	Follow-up	*p* value[b]
		Week 1	Week 2	Week 3	Week 4			
GI Symptoms								
Resting VAS								
Pain Intensity	2.2 ± 0.52	1.72 ± 0.52	1.75 ± 0.53	1.73 ± 0.53	1.41 ± 0.53	0.06	-	-
Pain Unpleasantness	2.05 ± 0.5	1.21 ± 0.5	1.33 ± 0.51	1.26 ± 0.51	1.28 ± 0.51	0.03	-	-
Nausea	1.07 ± 0.44	0.41 ± 0.44	0.61 ± 0.44	0.74 ± 0.44	0.68 ± 0.44	0.10	-	-
API	2.84 ± 0.25	2.39 ± 0.25	2.08 ± 0.26	2.05 ± 0.26	1.9 ± 0.26	<0.0001	1.39 ± 0.27	<0.0001
NSS	1.78 ± 0.25	1.66 ± 0.25	1.14 ± 0.25	1.36 ± 0.25	1.33 ± 0.25	0.07	0.90 ± 0.27	0.001
Physical Functioning								
FDI	18.95 ± 3.06	15.3 ± 3.06	15.12 ± 3.07	15.07 ± 3.07	15.54 ± 3.07	0.04	10.09 ± 3.14	<0.0001
CSSI (Somatic symptoms)	28.25 ± 3.81	21 ± 3.81	20.61 ± 3.85	20.04 ± 3.85	20.4 ± 3.85	0.01	17.8 ± 4.05	0.002
CSSI (GI symptoms)	9.9 ± 1.1	7.65 ± 1.1	7.4 ± 1.12	6.92 ± 1.12	7.19 ± 1.12	0.01	6.14 ± 1.2	0.002
Psychological Functioning								
PCS-C	23.85 ± 3.24	19.85 ± 3.24	18.08 ± 3.27	16.5 ± 3.27	15.4 ± 3.27	0.0004	14.88 ± 3.42	0.001
SCARED	22.5 ± 4.3	-	-	-	17.5 ± 4.3	0.02	16.9 ± 4.4	0.03
PROMIS Anxiety	51.87 ± 2.27	48.28 ± 2.27	48.85 ± 2.28	48.03 ± 2.28	48.72 ± 2.28	0.03	48.87 ± 2.35	0.05
PROMIS Depression	48.6 ± 2.4	45.1 ± 2.4	46.27 ± 2.42	45.73 ± 2.42	46.78 ± 2.42	0.14	47.65 ± 2.49	0.63

Note: API, Abdominal Pain Index; CSSI, Children's Somatic Symptoms Inventory; FDI, Functional Disability Inventory; NSS, Nausea Severity Scale; PCS-C, Pain Catastrophizing Scale for Children; PENFS, Percutaneous Electrical Nerve Field Stimulation; SCARED, Screen for Child Anxiety-Related Emotional Disorders; VAS, Visual Analog Scale.
All values are LS Means and SE. [a]p for Week 4 vs. Week 0; [b]p for long-term follow-up vs. Week 0

PENFS Reimbursement

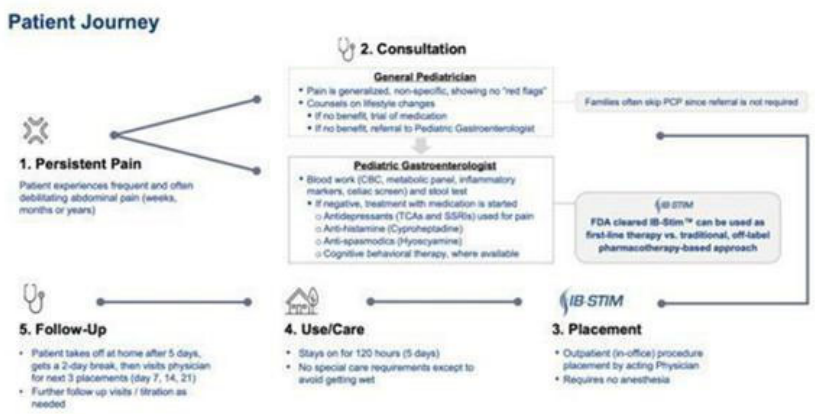
Previously, the American Medical Association (AMA) assigned a procedure-specific Category III CPT Code (0720T) to PENFS, which was published on December 30, 2021 and became effective for utilization on July 1, 2022. Category III CPT Codes are temporary codes issued to define and track the utilization of new procedural technology. To expand patient access to PENFS procedures and IB-Stim technology, we launched our internal Prior Authorization team under our Guidance & Patient Support function in 2023. This continues to address the Prior Authorization process barriers for providers and children's hospitals and streamlines a patient's access to our Patient Advocacy and Financial Assistance offerings, if needed. In September of 2024, the AMA's CPT Editorial Panel accepted addition of Category I CPT Code (placeholder 64X11) for PENFS and deletion of Category III CPT Code 0720T. The finalized Category I CPT Code for PENFS, 64567 and associated valuations, was publicly announced in Q4 of 2025. CPT 64567 became effective for utilization and reporting PENFS procedures on January 1, 2026. Twenty-four (24) commercial health insurers, including certain Blue Cross Blue Shield licensees, have instituted formal medical policy coverage for PENFS. The total membership of these health insurers is approaching 100,000,000 covered lives. Patients who are appropriate clinical candidates may have policy-covered access to PENFS and IB-Stim technology under their specific health plan. We continue to actively leverage clinical evidence, peer-reviewed publications, and academic medical society clinical practice guidelines to expand patient access to IB-Stim technology. The finalized CPT code (1/1/2026) will strengthen PENFS access as Fee Schedules and claim payments become more transparent, allowing both commercial and Medicaid payer entities to more-effectively process covered claims.

Marketing

NeurAxis markets its products through a direct sales team, online channels, and to clinicians via affiliated academic societies. Our main goal is to raise educational awareness among clinicians and hospitals about the unmet needs of patients with functional abdominal pain and NeurAxis' FDA-cleared, drug-free product solutions. Our primary focus is with the 260 children's hospitals within the United States. As our FDA-indications expand, so will our outreach and education to adult gastroenterology providers. Direct-to-patient marketing efforts will be considered in the future.

Patients/Customers

IB-Stim is indicated for patients 8 years and older suffering from functional abdominal pain, functional dyspepsia (FD),and associated FD nausea symptoms. Customers are currently primarily children's hospitals who serve these patients, but is currently expanding to adult gastroenterologists and adult pain physicians.



RED™ (Rectal Expulsion Device)

RED enables comprehensive constipation for every gastroenterology practice. The mission is for every gastroenterology practice to be able to safely and confidently differentially screen root causes of chronic constipation with the patient and physician in mind. RED can be implemented in a GI practice with minimal impact to clinical workflow and does not require a large capital expense. Eight (8) million patients each year present with constipation. Of those eight million patients, 700,000 patients present to the Emergency Room.

Clinical Background

Constipation is one of the most encountered gastrointestinal complaints in clinical practice. A recent systematic review reported that the prevalence of chronic constipation (CC) in North America is between 10-15%. This condition causes significantly reduced quality of life, reduced work-related productivity and billions of dollars in health expenditures. Clinical practice guidelines recommend empiric treatment of chronically constipated patients with fiber supplements or laxative therapies. Approximately 40% of patients do not adequately respond to empiric laxative therapy. In these patients, anorectal physiology testing is essential.

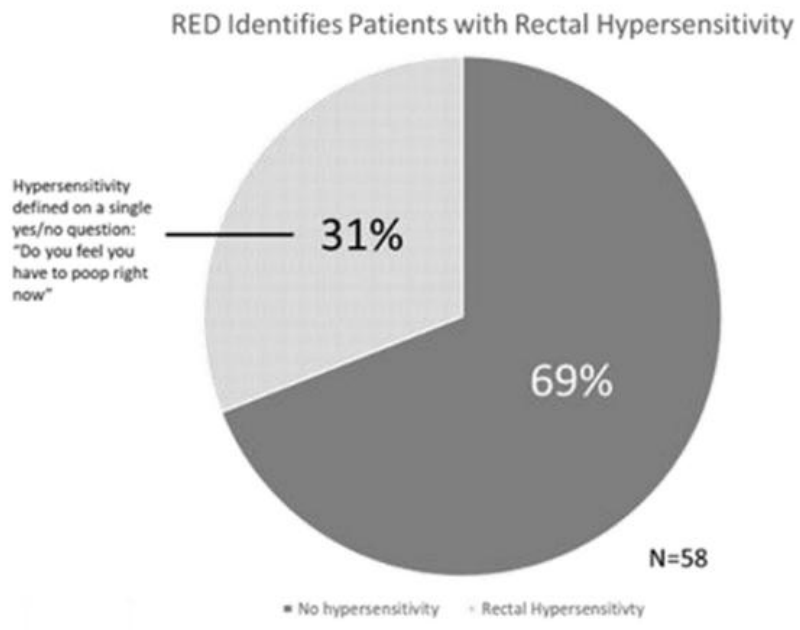
There is a clinical need for an easy-to-use, office-based, point-of-care, anorectal function test that can measure rectal sensitivity and be used as a rectal expulsion device to assess pelvic floor dysfunction. Current testing methods typically require elaborate volumetric testing equipment to assess sensation and expulsion, which makes them not practical in the clinical setting. The current standard is to refer patients to specialized motility centers for evaluation, resulting in sub-optimal number of patients with constipation undergoing anal-rectal testing. In the current clinical setting, only about 2% of all patients with constipation are referred for anal-rectal testing and thus, a large number with pelvic floor dysfunction and rectal hypersensitivity are missed and/or fail to get proper treatment. The design of RED allows for it to be used as a self-inflating expulsion device and as a balloon to assess patients who experience rectal hypersensitivity. When it is opened to atmospheric pressure, RED safely self inflates and contains a proprietary foam technology that mimics the "feel" of stool. This provides an alternative to sensation and expulsion testing in the office without affecting clinical workflow.

Rectal Sensation Testing

Rectal sensation is an important metric to guide clinical care, particularly rectal hypersensitivity. For example, a patient that reports an immediate perceived immediate need to defecate or discomfort (max tolerated) to low volumes of distension would have rectal hypersensitivity. This diagnosis is important because it would impact how a patient is treated. Rectal hypersensitivity is addressed by pelvic floor physical therapists who deliver education and re-training to help the patient align the desire to defecate according to the actual volume of stool contained within the rectal vault. The basis of sensory re-training during physical therapy involves inflating a balloon in the rectum until urge threshold is reached. With repeated inflations, the patient learns to associate a given sensory intensity with the inflated volume. Over time, the balloon is inflated with decreasing volumes and the patient is asked to closely monitor and attend to sensations experienced. Eventually, new sensory thresholds are established. Unfortunately, because of the difficulty in performing hypersensitivity testing in routine clinical care, only a small percentage of all patients with constipation undergo anorectal testing in the clinical setting.

In a recent study, 60 adult patients (mean±standard deviation age of 46.4±17.6 years; 93.3% women) that underwent evaluation with RED and answered the questions were included in the analysis. One patient did not undergo rectal sensation testing due to suspected anal fissure and overall, 58 patients were included in the analysis.

As outlined in the figure below, 18 of 58 patients, or 31%, had rectal hypersensitivity on RED when defined on a single yes/no question of "do you feel you have to poop right now" that evaluates the patient perception to defecate.



These data suggest that approximately 31% of patients with chronic constipation reported urge to defecate with RED baseline distension volume, thus meeting the London criteria for hypersensitivity.

Balloon Expulsion Testing

RED can be used as a rectal expulsion device and in a recent prospective trial of 60 adults with functional constipation (defined by Rome IV criteria), it was demonstrated to be safe in a clinical setting. It can be quickly performed in the left lateral position (i.e., the patient lying on their left side) immediately after a rectal examination. Further, it proved to be effective for patients who fail a trial of laxative therapy. In those patients with constipation who failed laxative treatment, RED was able to reliably identify patients for whom pelvic floor physical therapy was unlikely to provide substantial benefit (i.e, patients who might be more likely to benefit from intensifying medical therapy). Patients with an abnormal RED in the left lateral position or commode were likely to respond to pelvic floor therapy (48.8% to 71.4%, respectively). Also, RED showed very high sensitivity (>95%) to broadly detect evacuation disorders as a simple screening tool as noted in the table below.

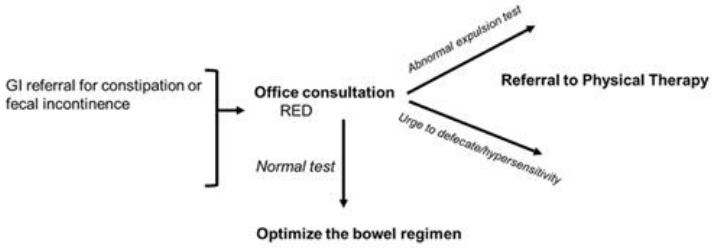
Definition of an abnormal RED	Patients who test positive based on the chosen definition	Sensitivity	Specificity	Likelihood of clinical response among patients with an abnormal test (PPV)	Likelihood of clinical response among patients with a normal test (1-NPV)	*P* value
Left lateral position Expulsion time <5 s or >120 s (ie, weak pelvic floor or dyssynergia)	78.8% likelihood of testing positive (41/52 patients)	95.2% sensitivity (20/21 patients)	32.2% specificity (10/31 patients)	48.8% expected likelihood of response (20/41 patients)	8.9% expected likelihood of response (1/11 patients)	.042

Accuracy of Predicted Clinical Response to Pelvic Floor Physical Therapy and Expected Clinical Response Rates at Optimal Cut-Off Values Using RED at Baseline in Left Lateral and Seated Positions. Values derived from,Shah ED, Pelletier EA, Greeley C, Sieglinger EE, Sanchez JD, Northam KA, Perrone JA, Curley MA, Navas CM, Ostler TL, Burnett Greeley AR, Martinez-Camblor P, Baker JR, Harris A, Siegel CA, Chey WD. An Office-Based, Point-of-Care Test Predicts Treatment Outcomes With Community-Based Pelvic Floor Physical Therapy in Patients With Chronic Constipation. Clin Gastroenterol Hepatol. 2023;21:1082-1090.

RED Benefits Over Predicates

1. Prompt point of care test allows assessment of patients and potentially changes clinical management.
2. Identifies those who would benefit from physical therapy or who would require optimization of laxatives or addition of secretagogues.
3. Identifies many patients with rectal hypersensitivity that otherwise would never get tested.
4. Easily integrates with clinical workflow

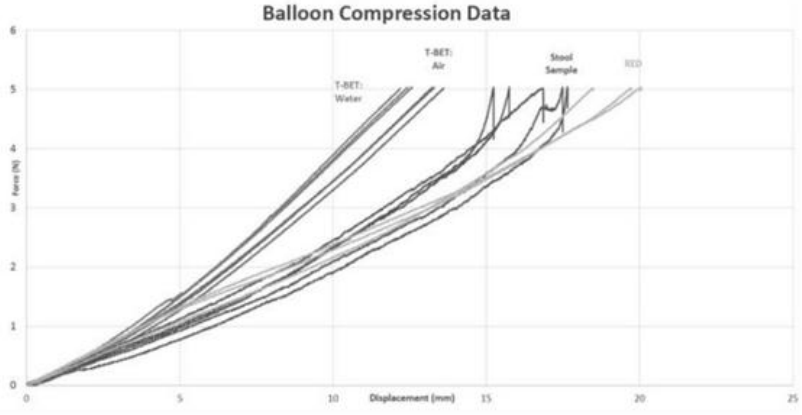
There is an urgent need to better identify patients with pelvic floor abnormalities and/or rectal hypersensitivity. Making the right diagnosis can impact care and ensure that patients are properly assessed and treated. The figure below demonstrates how RED can impact clinical decision making.



Overall, RED is a point-of-care device designed to be used in the office. Rectal sensation is an important component of evaluating pelvic floor function among patients with chronic constipation. Currently, 98% of clinically appropriate patients do not receive anorectal testing. The study findings demonstrate that RED impacts clinical decision making by identifying patients who would benefit from physical therapy or who would require optimization of laxatives. Shah et.al., An Office-Based, Point-of-Care Test Predicts Treatment Outcomes With Community-Based Pelvic Floor Physical Therapy in Patients With Chronic Constipation. Clin Gastroenterol Hepatol. 2023;21:1082-1090.It is also sufficient to qualitatively assess for rectal hypersensitivity which was evident in almost one-third of patients with chronic constipation failing a trial of fiber/laxatives. It is critical to assess rectal sensation and balloon expulsion in patients with constipation and/or fecal incontinence.

RED Safety

- The tube for RED remains open to room air as the patient defecates. The pressure is therefore never greater than room air.
- The predicate device uses manual inflation with a syringe against resistance. The predicate device is re-capped so that the patient must defecate an air-filled balloon with low compliance. The resistance with defecating the predicate is therefore greater than RED, because RED is more compliant than an air-filled balloon. RED is therefore safer with regard to patients with decreased compliance.
- There have been no safety events reported to compliance in MAUDE with the predicate in the last 10 years.
- RED is more compliant than air or water based on balloon compression data as demonstrated in the graph below.



- RED CPT coding changed effective January 1, 2026, and we are currently waiting on the AMA CPT Knowledge Base to give an opinion on the coding going forward.

Intellectual Property

Our intellectual property consists of patents, trademarks, and trade secrets. Our trade secrets consist of product formulas, research, and development, and unpatentable know-how, all of which we seek to protect, in part, by confidentiality agreements. To protect our intellectual property, we rely on a combination of laws and regulations, as well as contractual restrictions. Federal trademark law protects our registered trademarks. We also rely on the protection of laws regarding unregistered copyrights for certain content we create and trade secret laws to protect our proprietary technology. To further protect our intellectual property, we enter into confidentiality agreements with our executive officers and directors.

Trademarks

The Company has nine (9) registered trademarks, and three (3) pending applications for registration:

Country	Trademark	Reg. No.	Reg. Date	Class/Goods	Status
US	NEURO-STIM and Design	5105257	20-Dec-2016	10 Int. nerve stimulator apparatus	Registered
US	NSS THE NEUROSTIM SYSTEM and Design	4905470	23-Feb-2016	10 Int. nerve stimulator apparatus	Registered
US	NSS	4852008	10-Nov-2015	10 Int. medical apparatus, namely, electrical nerve stimulators; medical device, namely, a non- implantable neurological pain management generator, with percutaneously-implantable needle arrays; medical system and apparatus consisting of a non-implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; medical system and apparatus consisting of implantable arrays for transmitting current into auricular and peri-auricular tissue; medical device for peripheral nerve and nerve field stimulation; medical system and apparatus consisting of a non-implantable modulating frequency generator and implantable needle arrays for transmitting current into auricular and peri-auricular tissue for use in pain management, namely, patient stimulators for auricular and peri-auricular peripheral nerve field neuromodulation therapy; medical apparatus, appliances and instruments for peripheral nerve field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, headache control, control of phantom limb pain, stump pain, reflex sympathetic dystrophy (RSD), peripheral neuropathies and other types of sympathetically mediated pain	Registered
US	IB-STIM	5926831	03-Dec-2019	10 Int. medical apparatus, namely, electrical nerve stimulators; medical device, namely, a non- implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; medical apparatus consisting of percutaneously implantable arrays for transmitting current into auricular and peri-auricular tissue; medical device for peripheral nerve and nerve field stimulation; medical device consisting of a non-implantable modulating frequency generator and percutaneously implantable needle arrays for transmitting current into auricular and peri-auricular tissue for use in pain management and FGID (functional gastrointestinal disorders), namely, patient stimulator for auricular and peri-auricular peripheral nerve field neuromodulation therapy; medical apparatus, for peripheral nerve field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co-morbidities, sleep disturbances, psychological disorders, including mood and anxiety, satiety and changes in autonomic nervous system and other types of sympathetically mediated pain	Registered

US	IB-STIM and Design	5926832	03-Dec-2019	10 Int. medical apparatus, namely, electrical nerve stimulators; medical device, namely, a non- implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; medical apparatus consisting of percutaneously implantable arrays for transmitting current into auricular and peri-auricular tissue; medical device for peripheral nerve and nerve field stimulation; medical device consisting of a non-implantable modulating frequency generator and percutaneously implantable needle arrays for transmitting current into auricular and peri-auricular tissue for use in pain management and FGID (functional gastrointestinal disorders), namely, patient stimulator for auricular and peri-auricular peripheral nerve field neuromodulation therapy; Medical apparatus, for peripheral nerve field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co-morbidities, sleep disturbances, psychological disorders, including mood and anxiety, satiety and changes in autonomic nervous system and other types of sympathetically mediated pain	Registered
US	IB-STIM AURICULAR STIMULATOR	5978411	04-Feb-2020	10 Int. medical apparatus, namely, electrical nerve stimulators; Medical device, namely, a non- implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; Medical apparatus consisting of percutaneously implantable arrays for transmitting current into auricular and peri-auricular tissue; Medical device for peripheral nerve and nerve field stimulation; Medical device consisting of a non-implantable modulating frequency generator and percutaneously implantable needle arrays for transmitting current into auricular and peri-auricular tissue for use in pain management and FGID (functional gastrointestinal disorders), namely, patient stimulator for auricular and peri-auricular peripheral nerve field neuromodulation therapy; Medical apparatus, for peripheral nerve field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co-morbidities, sleep disturbances, psychological disorders, including mood and anxiety, satiety and changes in autonomic nervous system and other types of sympathetically mediated pain	Registered
US	IB-STIM AURICULAR STIMULATOR and Design	5978412	04-Feb-2020	10 Int. medical apparatus, namely, electrical nerve stimulators; medical device, namely, a non- implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; medical apparatus consisting of percutaneously implantable arrays for transmitting current into auricular and peri-auricular tissue; medical device for peripheral nerve and nerve field stimulation; medical device consisting of a non-implantable modulating frequency generator and percutaneously implantable needle arrays for transmitting current into auricular and peri-auricular tissue for use in pain management and FGID (functional gastrointestinal disorders), namely, patient stimulator for auricular and peri-auricular peripheral nerve field neuromodulation therapy; medical apparatus, for peripheral nerve field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co-morbidities, sleep disturbances, psychological disorders, including mood and anxiety, satiety and changes in autonomic nervous system and other types of sympathetically mediated pain	Registered

Country	Trademark	App. No.	App. Date	Class/Goods	Status
US	NEURAXIS	97/327951	24-Mar-2022	10 Int. nerve stimulator apparatus; nerve stimulator apparatus for FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co- morbidities, sleep disturbances, psychological disorders, including mood, anxiety, and satiety, pain control, headache control, control of phantom limb pain, stump pain, reflex sympathetic dystrophy (RSD), peripheral neuropathies and other types of sympathetically mediated pain	Registered
US	NEURAXIS (STYLIZED)	97/356330	11-Apr-2022	10 Int. nerve stimulator apparatus; nerve stimulator apparatus for FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, changes in FGID co- morbidities, sleep disturbances, psychological disorders, including mood, anxiety, and satiety, pain control, headache control, control of phantom limb pain, stump pain, reflex sympathetic dystrophy (RSD), peripheral neuropathies and other types of sympathetically mediated pain	Registered
US	RECTAL EXPULSION DEVICE	99/249573	24-Jun-2025	10 Int. medical devices, namely, devices for measuring pelvic floor dysfunction and rectal hypersensitivity for use in the diagnosis and treatment of chronic constipation; medical diagnostic apparatus for testing pelvic floor dysfunction and rectal hypersensitivity in the field of chronic constipation; medical devices and apparatus for medical screening testing of individuals with chronic constipation; medical apparatus and instrument for diagnostic use, namely, apparatus for medical diagnostic testing in the field of chronic constipation; disposable medical devices for diagnosing and treating constipation	Filed
US	RED – RECTAL EXPULSION DEVICE (word)	99/249859	24-Jun-2025	10 Int. medical devices, namely, devices for measuring pelvic floor dysfunction and rectal hypersensitivity for use in the diagnosis and treatment of chronic constipation; medical diagnostic apparatus for testing pelvic floor dysfunction and rectal hypersensitivity in the field of chronic constipation; medical devices and apparatus for medical screening testing of individuals with chronic constipation; medical apparatus and instrument for diagnostic use, namely, apparatus for medical diagnostic testing in the field of chronic constipation; disposable medical devices for diagnosing and treating constipation	Filed
US	RED & Design	99/249570	24-Jun-2025	10 Int. medical devices, namely, devices for measuring pelvic floor dysfunction and rectal hypersensitivity for use in the diagnosis and treatment of chronic constipation; medical diagnostic apparatus for testing pelvic floor dysfunction and rectal hypersensitivity in the field of chronic constipation; medical devices and apparatus for medical screening testing of individuals with chronic constipation; medical apparatus and instrument for diagnostic use, namely, apparatus for medical diagnostic testing in the field of chronic constipation; disposable medical devices for diagnosing and treating constipation	Filed
US	AXI-STIM	99/507683	20-Nov-2025	10 Int. Medical apparatus, namely, electrical nerve stimulators; medical device, namely, a non-implantable modulating frequency generator, providing neuromodulation therapy to cranial and peripheral nerves; medical apparatus consisting of percutaneously implantable arrays for transmitting current into auricular and per-auricular tissue; medical device for peripheral nerve and nerve field stimulation; medical device consisting of a non-implantable modulating frequency generator and percutaneously implantable needle arrays for transmitting current into auricular and per-auricular tissue for us in pain management and FGID (functional gastrointestinal disorders), namely, patient stimulator for auricular and peri-auricular peripheral nerve filed neuromodulation therapy; medical apparatus, for peripheral never field stimulation in cranial and peripheral nerves and occipital nerve branches, for pain control, FGID, irritable bowel, functional dyspepsia, functional abdominal pain, nausea, functional nausea, abdominal migraine, Crohn's Disease, visceral hypersensitivity, chronic inflammatory bowel disease, change in FGID co-morbidities, sleep disturbances, psychological disorders, including mood and anxiety, satiety and changes in autonomic nervous system and other types of sympathetically mediated pain.	

Patents

The Company has fifteen (15) granted patents in the United States and one (1) applied for patent application in the United States and one (1) granted foreign patent and two (2) applied for foreign patent applications.

Country	Owner	Serial No.	Actual Filing Date	Patent No.	Issue Date	Anticipated Expiration Date	Title	Application Status	Licensing Status
CA	Neuraxis, Inc.	3096494	25-Apr-2019				AURICULAR NERVE FIELD STIMULATION DEVICE	Applied for	
JP	Neuraxis, Inc.	2021-509961	23-Oct-2020	7252319	27-Mar-2023	25-Apr-2039	AURICULAR NERVE FIELD STIMULATION DEVICE	Granted	
US	Neuraxis, Inc.	17/040766	23-Sep-2020	11369791	28-Jun-2022	21-Jun-2039	AURICULAR NERVE FIELD STIMULATION DEVICE	Granted	
US	Neuraxis, Inc.	17/715121	07-Apr-2022	12097371	24-Sep-2024	04-Jan-2040	AURICULAR NERVE FIELD STIMULATION DEVICE	Granted	

US	Neuraxis, Inc.	16/014169	21-Jun-2018	10322062	18-Jun-2019	14-May-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	Granted
US	Neuraxis, Inc.	16/408004	09-May-2019	11077019	03-Aug-2021	16-Jul-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	Granted
US	Neuraxis, Inc.	17/363620	30-Jun-2021	11654082	23-May-2023	29-Jul-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	Granted
US	Neuraxis, Inc.	17/830411	02-Jun-2022				DEVICE AND METHOD FOR ERADICATING PATHOGENS IN NASAL PASSAGES	Applied for
US	Neuraxis, Inc.	17/589082	31-Jan-2022				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION AND AUDIO THERAPY DEVICE	Applied for

US	Neuraxis, Inc.	17/861646	11-Jul-2022				EXTERNAL AUDITORY CANAL THERAPY DEVICE	Applied for
US	Neuraxis, Inc.	17/617364	08-Dec-2021				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION DEVICE	Applied for
US	Neuraxis, Inc.	15/488416	14-Apr-2017	10413719	17-Sep-2019	14-Apr-2037	METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION	Granted
US	Neuraxis, Inc.	16/534159	07-Aug-2019	11331473	17-May-2022	14-Apr-2037	METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION	Granted
US	Neuraxis, Inc.	15/595185	15-May-2017	9839577	12-Dec-2017	14-May-2034	SYSTEM AND METHOD FOR AURICULAR PERIPHERAL NERVE FIELD STIMULATION	Granted
US	Neuraxis, Inc.	15/811278	13-Nov-2017	10010479	03-Jul-2018	14-May-2034	SYSTEM AND METHOD FOR AURICULAR PERIPHERAL NERVE FIELD STIMULATION	Granted
US	Neuraxis, Inc.	14/277158	14-May-2014	9662269	30-May-2017	14-May-2034	SYSTEMS AND METHODS FOR AURICULAR PERIPHERAL NERVE FIELD STIMULATION	Granted
US	Neuraxis, Inc.	17/725,761	21-Apr-2022	11813448	14-Nov-2023	14-Apr-2037	AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	Granted
US	Neuraxis, Inc.	18/154,375	13-Jan-2023	12029701	09-Jul-2024	14-May-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	Granted
US	Neuraxis, Inc.	18/736,834	07-June-2024	12383461	12-Aug-2025	14-May-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	Granted
US	Neuraxis, Inc.	18/173,893	24-Feb-2023	12447332	21-Oct-2025	01-May-2035	AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	Granted
US	Neuraxis, Inc.	18/377,968	09-Oct-2023	12285602	24-Apr-2025	14-Apr-2037	AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	Granted
US	Neuraxis, Inc.	19173434	08-Apr-2025				AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	Applied for
CA	Neuraxis, Inc.	3243826	07-Aug-2024				AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	Applied for

License Agreements

TKBMN Exclusive License Agreement

On May 7, 2020, the Company entered into an exclusive license agreement with TKBMN, LLC to obtain an exclusive license under certain patent rights (the "Patent Rights") owned by TKBMN. Dr. Thomas Carrico, our Chief Regulatory Officer, is the manager of TKBMN. Brian Carrico, our Chief Executive Officer, and Matt Carrico, our National Sales Director, are members of TKBMN. TKBMN owns the Patent Rights set forth in the patents listed in the following table (the "TKBMN Patents") by virtue of an assignment from Dr. Carrico, who is the sole inventor listed on the TKBMN Patents. TKBMN has assigned the auricular portion of the TKBMN Patent Rights to the Company.

Licensed TKBMN Patents

Country	Owner	Application No.	Patent No.	Issue Date	Anticipated Expiration Date*	Title
US	TKBMN, LLC	15/981,082	10,792,500	October 2, 2020	October 18, 2037	Systems and methods for electro-therapy treatment
US	TKBMN, LLC	17/014,450	11,684,782	June 7, 2023	October 18, 2037	Systems and methods for electro-therapy treatment

* If all maintenance fees remain paid

Pursuant to the exclusive license agreement, TKBMN agreed to grant an exclusive, worldwide, non-transferable, royalty-free license under Patent Rights, which including three patents applications filed by TKBMN in connection with systems and methods for elector-therapy treatment, to the Company to develop, market, and sell licensed products, in the field of electro-therapy treatment by stimulation of cranial nerves, cranial nerve branches, auricular nerves, auricular nerve branches, auricular nerve bundles, and/or auricular anatomical structures in human patients (the "Field"), in consideration of a one-time license fee of $1.00. The Company has the right to grant sublicenses to the Patents Rights in the Field. The exclusive license agreement expires upon the expiration of the last to expire valid claim within the Patent Rights and may be terminated by the Company upon 60 days prior written notice. Upon expiration or termination of the exclusive license agreement, all rights in the Patent Rights will revert to TKBMN. There are no royalties or any other form of committed revenue to TKBMN or any of its members Under the agreement, the Company has agreed to cover fees and expenses associated with maintenance, prosecution, and additional associated/continuation patent filings for the TKBMN Patents.

Masimo License and Collaboration Agreement

On April 9, 2020, the Company entered into a license and collaboration agreement with Masimo. As consideration, in part, Masimo entered into a Series A Preferred Stock purchase agreement with the Company. Under the license and collaboration agreement, the Company grants an exclusive, fully paid-up, royalty-free license to specifically identified patents and trademarks in a limited Field of use. At all times, the Company remains the owner of all licensed intellectual property rights, and there is a possibility of joint ownership of collaboratively developed products and methods. The licensed patents are generally directed to a device and the treatment of opioid withdrawal symptoms. The licensed trademarks are generally directed to the NSS-2 Bridge mark. The license agreement includes a collaboration component to efficiently develop, obtain regulatory approval, and commercialize products for the limited field of use. The term of the agreement is in effect until the expiration or lapse of the last intellectual property rights. Masimo paid a one-time fee of $250,000. The license and collaboration agreement may not be terminated by the Company for any reason, and the sole remedy for any breach or default by Masimo shall be to seek monetary damages and equitable remedies. The license and collaboration agreement may be terminated by Masimo if there is material breach by the Company that remain uncured for thirty (30) days or without cause by providing thirty (30) days prior written notice.

On July 1, 2025, The Company terminated the NSS-2 Bridge license with Masimo in exchange for $200,000 of consideration payable in equal installments on December 31, 2025 and June 30, 2026. The termination agreement allowed the Company to recapture the rights to the trademark (U.S. Registration No. 7,394,465) and two patent applications (Application No. 18/821/255 and Application No. 29/960.608) that were originally licensed to Masimo on April 9, 2020. See *"—Our Corporate History*" for more information.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company" as defined in Rule 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our shares held by non-affiliates equals or exceeds $250 million as of the prior June 30th, or (2) our annual revenues equal or exceed $100 million during such completed fiscal year and the market value of our shares held by non-affiliates equals or exceeds $700 million as of the prior June 30th. Such reduced disclosure and corporate governance obligations may make it more challenging for investors to analyze our results of operations and financial prospects.

For additional information, see "*Risk Factors – Because the Company is a 'smaller reporting company,' we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company" and "As a smaller reporting company," we may at some time in the future choose to exempt our Company from certain corporate governance requirements that could have an adverse effect on our public stockholders."*

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) December 31, 2028, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur on the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company, we may:

- present only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related management's discussion and analysis of financial condition and results of operations in this prospectus;
- avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- provide reduced disclosure about our executive compensation arrangements; and
- not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

In addition, under the JOBS Act, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to take advantage of the extended transition period for complying with new or revised accounting standards provided to emerging growth companies under the JOBS Act.

Government Regulation

Our products and our operations are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other federal, state, and local authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations.

United States Regulation

The FDA regulates, among other things, the development, design, non-clinical and clinical testing, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export and post-marketing surveillance of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each new or significantly modified medical device commercially distributed in the United States requires FDA clearance of a 510(k) premarket notification. The 510(k) clearance can be resource intensive, expensive, and lengthy.

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of FDA's current good manufacturing practices for devices, as reflected in the Quality System Regulation, or QSR, establishment registration and device listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I devices are exempt from the premarket notification requirements.

Class II devices are subject to the FDA's general controls, and any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, special labeling requirements, post-market surveillance, patient registries and FDA guidance documents.

Most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance.

If a new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed.

Investigational Device Process

Clinical trials are sometimes required to support a 510(k) submission. In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval or to determine safety and effectiveness of a device for an investigational use must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective thirty (30) days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including the following:

- The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- Patients do not enroll in clinical trials at the rate expected;
- Patients do not comply with trial protocols;
- Patient follow-up is not at the rate expected;
- Patients experience serious adverse events;
- Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- Device malfunctions occur with unexpected frequency or potential adverse consequences;
- Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of result in the imposition of new requirements or testing;

- Institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- Third-party investigators are disqualified by the FDA;
- We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- Changes in government regulations or administrative actions;
- The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

510(k) Clearance Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent," as defined in the FDCA, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. A device is considered to be substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics; or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise different questions of safety or effectiveness than the predicate device.

Before the FDA will accept a 510(k) premarket notification for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission lacks necessary information for substantive review, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. If a 510(k) submission is accepted for substantive review, the Medical Device User Fee Amendments sets a performance goal of 90 days for FDA review of a 510(k) submission, but the review time can be delayed if FDA raises questions or requests additional information during the review process. As a practical matter, clearance often takes longer, and clearance is never assured. Thus, as a practical matter, clearance often takes longer than 90 days. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is substantially equivalent to a predicate device, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous requirements of the PMA approval process, or can request a risk-based classification determination for the device in accordance with the "*de novo*" process, which is a route to market for certain novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

Medical devices can only be marketed for the indications for use for which they are cleared or approved. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained or a *de novo* request is granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

In September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible.

PMA Approval Process

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective for its intended use, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If FDA accepts the application for substantive review, it has 180 days under the FDCA to complete its review of a filed PMA application, although in practice, the FDA's review often takes significantly longer, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA application, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA may or may not accept the panel's recommendation. Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as conduct inspections of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to, among other things, ensure compliance with the QSR. NeurAxis, Inc. is a designated small business with the FDA and enjoys discounted fees. NeurAxis, Inc. PENFS technology is a Class II medical device and typically pursues De Novo or 510K clearances.

- Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA's satisfaction;

- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

Certain changes to an approved medical device, such as changes in manufacturing facilities, methods, quality control procedures, sterilization (if applicable), packaging, expiration date, labeling, device specifications, materials, or design of a device, or other changes which affect the safety or effectiveness of the device that has been approved through the PMA process require submission of a new PMA or PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original, approved PMA and may not require as extensive clinical data or the convening of an advisory panel, depending on the nature of the proposed change. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Ongoing Regulation by the FDA

Even after the FDA permits a device to be marketed, numerous and pervasive regulatory requirements continue to apply. These include:

- Establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, supplier/contractor selection, compliant handling, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- Labeling regulations, advertising and promotion requirements, restrictions on sale, distribution or sale of a device, each including the FDA prohibition against the promotion of products for any uses other than those authorized by the FDA, which are commonly known as "off-label" uses;
- The Medical Device Reporting, or MDR, regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- Medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- Recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- An order of repair, replacement, or refund;
- Device tracking requirements; and
- Post-market study and surveillance requirements.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k). The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination not to seek a new 510(k) clearance, the FDA may retroactively require it to seek 510(k) clearance. The FDA could also require the manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines and penalties.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, some states also require medical device manufacturers and/or distributors doing business within the state to register with the state or apply for a state license, which could subject our facility to state inspection as well as FDA inspection on a routine basis for compliance with the QSR and any applicable state requirements. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- Warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- Recalls, withdrawals, or administrative detention or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing or delays in processing, clearing, or approving submissions or applications for new products or modifications to existing products;
- Suspension or withdrawal of 510(k) clearances or PMA approvals that have already been granted;
- FDA refusal to issue certification to foreign governments needed to export our products for sale in other countries; or
- Criminal prosecution.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

Regulation of Medical Devices in the European Union

The European Union, or EU, has adopted specific directives regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices. EU directives must be implemented into the national laws of the EU member states and national laws may vary from one member state to another.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in the Council Directive 93/42/EEC, or the Medical Devices Directive, and the Council Directive 90/385/EEC, or the Active Implantable Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are independent organizations designated by EU countries to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (which must, in particular, comply with ISO 13485:2016 related to Medical Devices Quality Management Systems). If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

Notified Body certificates of conformity are valid for a fixed duration (which shall not exceed five years). Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the Notified Body before it will renew the relevant certificate(s).

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

The advertising and promotion of medical devices is subject to some general principles set forth by EU directives. According to the Medical Devices Directive, only devices that are CE-marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à -vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

On May 25, 2017, Regulation 2017/745, or the EU Medical Devices Regulation, entered into force, which repeals and replaces the Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable, without the need for adoption of EU member state laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation was originally intended to become applicable three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year – until May 26, 2021. Devices lawfully placed on the market pursuant to the Medical Devices Directive and the Active Implantable Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025. Once applicable, the new regulations will among other things:

- Strengthen the rules on placing devices on the market and reinforce surveillance once they are available;

- Establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- Improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- Set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union, or EU; and
- Strengthen the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet EU requirements.

The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in the UK will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the Medical Devices Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU recognized Notified Bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the UK market after this period, the UK Conformity Assessment, or UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK Notified Bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the "rules of origin" criteria will need to be reviewed. Depending on which countries products will ultimately be sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

Healthcare Fraud and Abuse Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, transparency and other healthcare fraud and abuse laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced-price items and services. Among other things, the Anti-Kickback Statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand and prescribers and purchasers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. The government can exercise enforcement discretion in taking action against unprotected activities. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The majority of states also have anti-kickback laws, which establish similar prohibitions, and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers and self-pay patients.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996 created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to additional healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

In the United States, our currently cleared products are not separately reimbursed by any third-party payors and if covered, are paid for as part of the procedure in which the product is used. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures in which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain coverage and adequate reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies, may adversely impact demand for our products.

Based on our experience to date, third-party payors generally reimburse for the procedures in which our products are used if medical necessity is met and a prior approval is completed with a favorable response. Some payors are moving toward a managed care system and control their healthcare costs by establishing coverage policies that categorically restrict coverage of certain procedures, or by limiting authorization for procedures, including elective procedures using our devices. No uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor. Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for our product unless reimbursement approval can be obtained and/or maintained from governmental and private third-party payors.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, and exploration of more cost-effective methods of delivering healthcare. In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the European Union, member states are facing increased pressure to limit public healthcare spending. There can be no assurance that procedures using our products will be covered for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act (the "ACA") in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been judicial, executive and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the law or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the CCPA, the CPRA and the GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

In Europe, the GDPR went into effect on May 25, 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the preceding financial year of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom General Data Protection Regulation, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is also unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four- to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, while the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions.

Environmental Matters

Based on our current operations, environmental protection requirements do not have a significant financial and operational effect on the capital expenditures, earnings and competitive position of our Company in the current financial year and are not expected to have a significant effect in the reasonably foreseeable future.

Manufacturing Services Agreements

The Company is party to two separate manufacturing services agreements for the manufacture and supply of the Company's IB-Stim and RED devices based on the Company's product specifications that automatically renew annually unless either party provides a written termination notice to the other party within 180 days prior to the end of the then-current term. The Company's IB-Stim and RED devices are manufactured in Indiana and Michigan, respectively. The Company provides the necessary equipment to the manufacturers and retains ownership. The manufacturers bear the risk of loss of and damage to the equipment and consigned materials. Performance under the agreement is initiated by orders issued by the Company and accepted by the manufacturers. The Company also entered into quality agreements with the manufacturers to perform quality assurance services on product provided by the Company.

Employees

As of December 31, 2025, we had 24 full-time employees.

ITEM 1A. RISK FACTORS

Risks Relating to Our Business and Our Product

Our business and prospects depend entirely on our current products, IB-Stim and RED. Even though we have received FDA clearance for our products, it will remain subject to ongoing regulatory review. If we are unable to maintain regulatory clearance and commercialize our product or are significantly delayed or limited in our commercialization efforts, our business and prospects will be materially harmed.

Almost all of our revenues have been derived from sales and royalties from sales of IB-Stim, and we expect to develop, market, and sell other neuromodulation therapy devices for the treatment of chronic and debilitating conditions in children and adults. The commercial success of our products and our ability to generate and maintain revenues from the sale of our products will depend on a number of factors, including:

- our ability to develop and obtain additional regulatory clearances and further commercialize our products for additional indications;
- our ability to expand into new markets and future indications;
- the acceptance of our products by patients and the healthcare community, including physicians and third-party payers (both private and governmental), as therapeutically effective and safe;
- the accomplishment of various scientific, engineering, clinical, regulatory and other goals, which we sometimes refer to as milestones, on our anticipated timeline;

- the relative cost, safety and efficacy of alternative therapies;
- our ability to obtain and maintain sufficient coverage or reimbursement by private and governmental third-party payers and to comply with applicable health care laws and regulations;
- the ability of our third-party manufacturers to manufacture our products in sufficient quantities with acceptable quality;
- our ability to provide marketing, distribution and customer support for our products;
- the potential presence of competitive products in our active indications;
- results of future clinical studies relating to our products or other competitor products for similar indications;
- compliance with applicable laws and regulatory requirements;
- the maintenance of our existing regulatory clearance; and
- the consequences of any reportable adverse events involving our products.

In addition, the promotion of our products is limited to approved indications, which vary by geography. The labelling for our device in the U.S. is limited in certain respects, which may limit the number of patients to whom it is prescribed.

Our ability to generate future revenues will also depend on achieving regulatory approval of, and eventual commercialization of, our products for additional indications and in additional geographies, which is not guaranteed. Our near-term prospects are substantially dependent on our ability to obtain regulatory approvals on the timetable we have anticipated, and thereafter to further successfully commercialize our products for additional indications. Regulatory changes or actions in areas in which we operate or propose to operate may further affect our ability to obtain regulatory clearances on our anticipated timetable. If we are not able to receive such approvals, meet other anticipated milestones, or further commercialize our products, or are significantly delayed or limited in doing so, our business and prospects will be materially harmed and we may need to reduce expenses by delaying, reducing or curtailing the development of our products and we may need to raise additional capital to fund our operations, which we may not be able to obtain on favorable terms, if at all.

To date, we have not generated any operating profits, and due to our long-term research and development efforts, we have a history of incurring substantial operating losses.

We were founded in 2011 and have a history of incurring substantial operating losses. We anticipate continuing to incur significant costs associated with developing and commercializing our products for approved indications including signal development, device hardware and software development, product sales, marketing, manufacturing, and distribution expenses. We expect our research, development, and clinical study expenses to increase in connection with our ongoing activities and as additional indications enter clinical development and as we advance our product development. Our expenses could increase beyond expectations if, for example, we are required by the FDA, or other regulatory agencies or similar governing bodies, to change manufacturing processes for our products or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. Our revenues are dependent, in part, upon the size of the markets in the jurisdictions in which we receive regulatory approval, the accepted price for our products and the ability to obtain reimbursement at the accepted applicable price. If the number of addressable patients is not as significant as we or our strategic partners and licensees estimate, the indications approved by regulatory authorities are narrower than we expect or the eligible population for treatment is narrowed by competition, regulatory approvals, physician choice or treatment guidelines, we may not generate significant revenues. If we are not able to generate significant revenues, we may never be sustainably profitable.

Our clinical studies could be delayed or otherwise adversely affected by many factors, including difficulties in enrolling patients.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. Moreover, success in pre-clinical and early clinical studies does not ensure that large-scale studies will be successful or predict final results. Acceptable results in early studies may not be replicable in later studies. A number of companies in therapeutics industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. Negative or inconclusive results or adverse events or incidents during a clinical study could cause the clinical study to be redone or terminated. In addition, failure to appropriately construct clinical studies could result in high rates of adverse events or incidents, which could cause a clinical study to be suspended, redone or terminated. Our failure or the failure of third-party participants in our studies to comply with their obligations to follow protocols and/or legal requirements may also result in our inability to use the affected data in our submissions to regulatory authorities.

The timely completion of clinical studies depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical studies for a variety of reasons, including:

- the severity of the disease under investigation;
- the limited size and nature of the patient population;
- the patient eligibility criteria defined in our protocol and other clinical study protocols;
- the nature of the study protocol, including the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects;
- the ability to obtain IRB approval at clinical study locations;
- clinicians' and patients' perceptions as to the potential advantages, disadvantages and side effects of our products in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are pursuing;
- availability of other clinical studies that exclude use of our products;
- the possibility or perception that enrolling in a product's clinical study may limit the patient's ability to enroll in future clinical studies for other therapies due to protocol restrictions;
- the possibility or perception that our software is not secure enough to maintain patient privacy;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the availability of appropriate clinical study investigators, support staff, drugs and other therapeutic supplies and proximity of patients to clinical sites;
- physicians' or our ability to obtain and maintain patient consents; and
- the risk that when we collaborate with a third-party for research of a product in a particular institution, we can expect to relinquish some or all of the control over the future success of that study to the third-party.

If we have difficulty enrolling and retaining a sufficient number or diversity of patients to conduct our clinical studies as planned, or encounter other difficulties, we may need to delay, terminate or modify ongoing or planned clinical studies, any of which would have an adverse effect on our business.

If we are unable to develop an adequate sales and marketing organization or contract with third parties to assist us, we may not be able to successfully commercialize our products for current and future indications.

To achieve commercial success for our products, we must compliantly develop and grow our sales and marketing organization and, as necessary, enter into sales and distribution relationships with third parties to market and sell our products. Developing and managing a sales and marketing organization is a difficult, expensive and time consuming process. We may not be able to successfully develop adequate sales and marketing capabilities to achieve our growth objectives. We compete with other medical device, pharmaceutical and life sciences companies to recruit, hire, train and retain the sales and marketing personnel that we anticipate we will need, and the nature of our products may make it more difficult to compete for sales and marketing personnel. In addition, because our current products require, and we anticipate our future products will require, physician training and education, our sales and marketing organization may need to grow substantially as we expand our approved indications and markets. As a consequence, our expenses associated with building up and maintaining our sales force and marketing capabilities may be disproportionate to the revenues we may be able to generate on sales of our products.

If we are unable to establish adequate sales and marketing capabilities or successful sales and distribution relationships, we may fail to realize the full revenue potential of our products for current and future indications, and we may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. In our future sales and distribution agreements with other companies, we generally may not have control over the resources or degree of effort that any of these third parties may devote to our products, and if they fail to devote sufficient time and resources to the marketing of our products, or if their performance is substandard, our revenues may be adversely affected.

The success of our business may be dependent on the actions of our collaborative partners.

Our business strategy includes, in part, the consummation of collaborative arrangements with companies who will support the development and commercialization of our products and technology. We may also enter into clinical collaborations with third parties to test our products and technology together with other products and technologies.

When we collaborate with a third party for commercialization of a product in a particular territory, we can expect to relinquish some or all of the control over the future success of that product to the third party in that territory. In addition, our collaborative partners may have the right to terminate applicable agreements, including payment obligations, prior to or upon the expiration of the agreed-upon terms. We may not be successful in establishing or maintaining collaborative arrangements on acceptable terms or at all, collaborative partners may terminate funding before completion of projects, our products may not achieve the criteria for milestone payments, our collaborative arrangements may not result in successful product commercialization, our products may not receive acceptable pricing and we may not derive any revenue from such arrangements. Additionally, our collaborators may not perform their obligations as expected or in compliance with study protocols or applicable laws. Acts or omissions by collaborators may disqualify study data for use in regulatory submissions and/or create liability for us in the jurisdictions in which we operate. Any disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of commercialization, might cause delays or termination of the commercialization of products, might lead to additional responsibilities for us with respect to commercializing products, or might result in litigation or arbitration, any of which would be time-consuming and expensive. To the extent that we are not able to develop and maintain collaborative arrangements, we would need to devote substantial capital to undertake commercialization activities on our own in order to further expand our reach, and we may be forced to limit the territories in which we commercialize our products.

We may not be successful in achieving market acceptance of our products by healthcare professionals, patients and/or third-party payers in the timeframes we anticipate, or at all, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not achieve market acceptance of our products for current or future indications within the timeframes we have anticipated, or at all, for a number of different reasons, including the following factors:

- it may be difficult to gain broad acceptance of our products because they are new technologies and involve a novel or derivative mechanism of action and, as such, physicians may be reluctant to prescribe our products without prior experience or additional data or training;
- physicians may be reluctant to prescribe our products due to their perception that the supporting clinical study designs have limitations, as they are, for example, unblinded;
- physicians at large academic universities and medical centers may prefer to enroll patients into clinical studies instead of prescribing our products;
- it may be difficult to gain broad acceptance at community hospitals where the number of patients seeking treatment may be more limited than at larger medical centers, and such community hospitals may not be willing to invest in the resources necessary for their physicians to become trained to use our products, which could lead to reluctance to prescribe our products;
- patients may be reluctant to use our products for various reasons, including a perception that the treatment is untested or difficult to use or a perception that our software is not secure;
- our products may have side effects and our products cannot be worn in all circumstances; and
- each patient will use more than one device and therefore, as the duration of the treatment course increases, the overall price will increase correspondingly and, when used in combination with other treatments, the overall cost of treatment will be greater than using a single type of treatment.

In particular, our products may not achieve market acceptance for current or future indications because of the following additional factors:

- achieving patient acceptance could be difficult because not all patients are willing to comply with requirements of treatment with our products, and other patients may forego our products for financial, privacy, cosmetic, visibility or mobility reasons;

- achieving patient compliance may be difficult because the recommended use of our products is 120 hours per week for four (4) consecutive weeks, which to some extent restricts physical mobility because our products cannot be worn in all circumstances, and the patient or a caregiver must ensure that it remains continuously operable and this may also impact the pool of patients to whom physicians may be willing to prescribe our products;
- there may be certain perceived limitations to our study designs or data obtained from our clinical studies;
- efficacy may also be limited in instances where patients take a break from the device when experiencing skin rashes, or while bathing or swimming (because our products should not be immersed in water); and
- patients may decline therapy or prescribers may be unwilling to prescribe our products due to certain adverse events attributable to the device reported in clinical studies by patients treated with our products.

In addition, even if we are successful in achieving market acceptance of our products for IBS or other indications, we may be unsuccessful in achieving market acceptance of our products for other indications.

There may be other factors that are presently unknown to us that also may negatively impact our ability to achieve market acceptance of our products. If we do not achieve market acceptance of our products in the timeframes we anticipate, or are unable to achieve market acceptance at all, our business, prospects, financial condition and results of operations could be materially adversely affected.

Failure to secure and maintain adequate coverage and reimbursement from third-party payers could adversely affect acceptance of our products and reduce our revenues.

We expect that the majority of our revenues will come from third-party payers, primarily children's hospitals, either directly to us in markets where we provide our products or plan to provide our device candidates to patients or indirectly via payments made to hospitals or other entities providing our products or which may in the future provide our device candidates to patients.

In the U.S., private payers cover the largest segment of the population, with the remainder either uninsured or covered by governmental payers. The majority of the third-party payers outside the U.S. are government agencies, government sponsored entities or other payers operating under significant regulatory requirements from national or regional governments.

Third-party payers may decline to cover and reimburse certain procedures, supplies or services. Additionally, some third-party payers may decline to cover and reimburse our products for a particular patient even if the payer has a favorable coverage policy addressing our products or previously approved reimbursement for our products. Additionally, private and government payers may consider the cost of a treatment in approving coverage or in setting reimbursement for the treatment.

Private and government payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of governments. Adoption of additional price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenues and operating results. If third-party payers do not consider our products or the combination of our products with additional treatments to be cost-justified under a required cost-testing model, they may not cover our products for their populations or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Reimbursement for the treatment of patients with medical devices is governed by complex mechanisms. These mechanisms vary widely among countries, can be informal, somewhat unpredictable, and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining and maintaining reimbursement for the treatment of patients with medical devices has become more challenging. We cannot guarantee that the use of our products will receive reimbursement approvals and cannot guarantee that our existing reimbursement approvals will be maintained in any country.

Our failure to secure or maintain adequate coverage or reimbursement for our products by third-party payers in the U.S. or in the other jurisdictions in which we market our products could have a material adverse effect on our business, revenues and results of operations and cause our stock price to decline.

We may not be successful in maintaining reimbursement codes necessary to facilitate accurate and timely billing for our products or physician services attendant to our products.

Third-party payers, healthcare systems, government agencies or other groups often issue reimbursement codes to facilitate billing for products and physician services used in the delivery of healthcare. Our IB-Stim technology-specific CAT III CPT Code (0720T) was published on December 30, 2021 and effective on July 1, 2022. In September of 2024, the AMA's CPT Editorial Panel accepted the addition of Category I CPT Code (64567) for PENFS and deletion of Category III CPT Code 0720T. The finalized Category I CPT Code for PENFS, and associated valuations, were announced publicly in Q4 of 2025. The new code became effective for utilization on January 1, 2026. RED CAT I CPT codes changed on January 1, 2026. We may not be able to maintain the CPT code for physician services related to our products. Our future revenues and results may be affected by the absence of CPT codes, as physicians may be less likely to prescribe the therapy when there is no certainty that adequate reimbursement will be available for the time, effort, skill, practice expense and malpractice costs required to provide the therapy to patients.

Outside the U.S., we have not secured codes to describe our products or to document physician services related to the delivery of therapy using our products. The failure to obtain and maintain these codes could affect the future growth of our business.

We may depend on single-source suppliers for some of our components. The loss of these suppliers could prevent or delay shipments of our products, delay our clinical studies or otherwise adversely affect our business.

In certain jurisdictions, we may source some of the components of our products from only a single vendor. If any one of these single-source suppliers were to fail to continue to provide components to us on a timely basis, or at all, our business and reputation could be harmed. We will seek and maintain second-source suppliers, but we can provide no assurance that we will secure or maintain such suppliers. We have developed or are in the process of developing and obtaining regulatory approval for second sources for components in all jurisdictions. Various steps must be taken before securing these suppliers, including qualifying these suppliers in accordance with regulatory requirements, but we may never receive such approvals. The risks associated with the failure of our suppliers to comply with strictly enforced regulatory requirements as described below are exacerbated by our dependence on single-source suppliers.

If we experience any deficiency in the quality of, delay in or loss of availability of any components supplied to us by third-party suppliers, or if we switch suppliers or components, we may face additional regulatory delays and the manufacture and delivery of our products would be interrupted for an extended period of time, which could materially adversely affect our business, prospects, financial condition and results of operations. If we are required to obtain prior regulatory approval from the FDA or regulatory authorities or similar governing bodies in other jurisdictions or to conduct a new conformity assessment procedure for our products, regulatory approval for our products may not be received on a timely basis, or at all, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Quality control problems with respect to devices and components supplied by third-party suppliers could have a material adverse effect on our reputation, our clinical studies or the commercialization of our products and, as a result, a material adverse effect on our business, prospects, financial condition and results of operations.

Our products, which are manufactured by third parties, are highly technical and are required to meet exacting specifications. Any quality control problems that we experience with respect to the devices and components supplied by third-party suppliers could have a material adverse effect on our reputation, our attempts to complete our clinical studies, our operating expenses or the commercialization of our products. The failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action, including warning letters, product recalls, suspension or termination of distribution, product seizures or civil penalties. If we experience any delay in the receipt or deficiency in the quality of products supplied to us by third-party suppliers, or if we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of our products would be interrupted for an extended period of time, which would materially adversely affect our business, prospects, financial condition and results of operations.

We currently do not own a manufacturing facility and rely on contract manufacturers for the production of our products. Any significant disruption to the contract manufacturer's operations or facilities could have a material adverse effect on our business, financial condition and results of operations.

We rely on two manufacturers for the production of our products. We do not have control over the operations of the facilities of the third-party manufacturers that we use. A significant disruption to our manufacturers could have a material adverse effect on our business, financial condition and results of operations. Our reliance on our manufacturers poses a number of risks, including lack of control over the manufacturing process and ultimately over the quality and timing of delivery of our product. A change in our relationship with our manufacturers could result in a material adverse effect on our business, financial condition and results of operations. A decision to change manufacturers would result in longer times for design and production as we secure any necessary licenses or clearances, develop quality control measures, and implement manufacturing processes.

Continued testing of our products may not yield successful results and could reveal currently unknown aspects or safety hazards associated with our products.

Our research and development programs are designed to test the safety and efficacy of our products through extensive pre-clinical and clinical testing. Even if our ongoing and future pre-clinical and clinical studies are completed as planned, we cannot be certain that their results will support our claims or that the FDA and other regulatory authorities will agree with our conclusions. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the later studies will replicate the results of prior studies and pre-clinical studies. The clinical study process may fail to demonstrate that our device candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a device candidate and may delay development of others. It is also possible that patients enrolled in clinical studies will experience adverse side effects that have not been previously observed. In addition, our pre-clinical and clinical studies for our device candidates involve a relatively small patient population and, as a result, these studies may not be indicative of future results.

We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent further commercialization of our products, including the following:

- pre-clinical and clinical testing for our products may not produce the desired effect, may be inconclusive or may not be predictive of safety or efficacy results obtained in future clinical studies, following long-term use or in much larger populations;
- unanticipated adverse events or other side effects that are not currently known may occur during our clinical studies that may preclude additional regulatory approval or result in additional limitations to commercial use if approved; and
- the data collected from our clinical studies may not reach statistical significance or otherwise not be sufficient to support FDA or other regulatory approval.

If unacceptable side effects arise in the development of our products for future indications, we could suspend or terminate our clinical studies or the FDA or other regulatory authorities could order us to cease clinical studies or deny approval of our device candidates for any or all targeted indications, narrow the approved indications for use or otherwise require restrictive product labeling or marketing or require further clinical studies, which may be time-consuming and expensive and may not produce results supporting FDA or other regulatory approval of our products in a specific indication. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have a need to train medical personnel using our devices for clinical studies and upon any commercialization of our products for future indications. Inadequate training in recognizing or managing the potential side effects of our products could result in patient injury or death. Any of these occurrences may harm our business, prospects and financial condition significantly.

Any delay or termination of our clinical studies will delay the filing of submissions for regulatory approvals of our products and ultimately our ability to commercialize our products and generate revenues. Furthermore, we may abandon our products for indications that we previously believed to be promising. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

As we expand, we may experience difficulties managing our growth.

Our anticipated growth will place a significant strain on our management and on our operational and financial resources and systems. We could face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Failure to manage our growth effectively could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our third-party suppliers, resulting in an increased need to carefully monitor the available supply of components and services and to scale up our quality assurance programs. There is no guarantee that our suppliers will be able to support our anticipated growth. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

The size and expected growth of our available market has not been established with precision and may be smaller than we estimate.

Our data on the available market for our current products and future products is based on a number of internal and third-party research reports, estimates and assumptions. While we believe that such research, our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. In addition, the statements in this document relating to, among other things, the expected growth in the market for IB-Stim are based on a number of internal and third-party data, estimates and assumptions, and may prove to be inaccurate. If the actual number of consumers who would benefit from our products, the price at which we can sell future products or the available market for our products is smaller than we estimate, it could have a material adverse effect on our business, financial condition and results of operations.

If physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even when any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Physicians may decide not to recommend our treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the device;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of its products.

If any of our product candidates is approved but fails to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from successfully operating our business, including developing our products, conducting clinical studies, commercializing our products and obtaining any necessary financing.

We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our key executives, any of them could leave our employment at any time. We do not have “key person” insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our business objectives.

The competition for qualified personnel in the medical device fields is intense, and we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of research and development and clinical studies, sales and marketing and supply chain management. These activities will require the addition of new personnel and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms or at all. Failure to do so could materially harm our business.

Customer or third-party complaints or negative reviews or publicity about our company or our products could harm our reputation and brand.

We are heavily dependent on customers who use IB-Stim to provide good reviews and word-of-mouth recommendations to contribute to our growth. Customers who are dissatisfied with their experiences with our products or services may post negative reviews. We may also be the subject of blog, forum or other media postings that include inaccurate statements and/or create negative publicity. In addition, any negative news regarding similar products may adversely impact our business. Any negative reviews or publicity, whether real or perceived, disseminated by word-of-mouth, by the general media, by electronic or social networking means or by other methods, could harm our reputation and brand and could severely diminish consumer confidence in our products.

Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity.

A general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U.S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross profit and expenses, and may make it more difficult to raise or refinance debt. Sustained uncertainty about, or worsening of, current global economic conditions and further escalation of trade tensions between the U.S. and its trading partners, could result in a global economic slowdown and long-term changes to global trade. Such events may also (i) cause our customers and consumers to reduce, delay or forgo spending, (ii) result in customers sourcing products from other suppliers not subject to such restrictions or tariffs, (iii) lead to the insolvency or consolidation of key suppliers and customers, and (iv) intensify pricing pressures. Any or all of these factors could negatively affect demand for our products and our business, financial condition and results of operations.

Additionally, economic conditions in certain regions may also be affected by natural disasters and public health emergencies, such as extreme weather events, and could have a significant adverse effect on our business, including interruption of our commercial and clinical operations, supply chain disruption, endangerment of our personnel, fewer patient visits, increased patient drop-out rates, delays in recruitment of new patients, and other delays or losses of materials and results.

A pandemic could materially adversely impact our business.

A pandemic could disruption and impact our business and clinical studies, which could include:

- delays and/or difficulties in onboarding active patients and enrolling patients in our clinical studies;
- delays and/or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- declines in prescriptions written due to a perception that our products are difficult to administer remotely or if patients are unwilling to travel to treatment sites or receive in-home treatment assistance from us or other caregivers;
- reductions in third-party reimbursements, which could materially affect our revenue, as most of our patients rely on third-party payers to cover the cost of our products and a material number of our patients could lose access to their private health insurance plan if they or someone in their family lose their job;
- diversion of healthcare resources away from conducting clinical studies, including the diversion of hospitals serving as our clinical study sites and hospital staff supporting the conduct of our clinical studies;

- interruption of key clinical study activities, such as clinical study site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- staff disruptions and turnover internally and at treatment sites and third-party providers who provide support, either directly as a result of illness or indirectly as a result of vaccine mandates and other changes in terms of employment;
- delays in receiving approval from local regulatory authorities or IRBs to initiate our planned clinical studies;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical studies;
- interruption in shipping that may affect the transport of active patient and clinical study materials;
- changes in local regulations as part of a response to a pandemic that may require us to change the ways in which our clinical studies are conducted, which may result in unexpected costs, or to discontinue the clinical studies altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- disruption of our supply chain as our suppliers and common carriers are unable to meet our requirements to provide us the materials we need for clinical study and active patient care needs;
- indirect consequences of a pandemic on the economy in general, such as an increase in bankruptcies of our key suppliers, or the inability of our third-party payers to meet their obligations reimburse us in a timely fashion or at all;
- postponements and cancellations of key conferences and meetings and travel restrictions could interfere with our ability to interact with key thought leaders in the field, leading to a disruption in the rate of adoption of our technology;
- access restrictions at offices, hospitals, and treatment centers, and stakeholder illness could interfere with the ability of our sales force to engage in face-to-face visits with providers, leading to a disruption in the rate of adoption of our technology;
- increases in expenditures for technology and other tools necessary to provide patient care in an environment where both patient and care-giver travel is restricted and access to in-person interaction is limited;
- refusal of the FDA to accept data from clinical studies in affected geographies outside the United States; and
- patient delays in seeking or receiving treatment, either due to fear of infection or lack of access to treatment and study sites, leading to fewer diagnoses of the indications our products are approved to treat or more advanced procession of the disease, which may contraindicate the use of our products or disqualify the patient from participating in a given study.

The extent to which a pandemic may impact our business and clinical studies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing guidelines, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease. The response to a pandemic may result in permanent changes to the environment in which we operate as described above in ways we are unable to predict. A pandemic may also have the effect of heightening many of the other risks described herein.

Developing medical technology entails significant technical, regulatory and business risks.

We may fail to adapt our technology to user requirements or emerging treatment standards. Neuromodulation therapies are not currently considered standard of care for IBS and may not ever be considered standard of care. Treatment standards may not evolve to incorporate our product. New industry standards for the development, manufacture and marketing of medical devices may evolve and we may not be able to conform to the changes, meet new standards in a timely fashion or maintain a competitive position in the market. In particular, regulatory standards for electrical treatments of medical conditions are evolving. If we face material delays in introducing our products and new technology, we may fail to attract new customers.

Our Company has an evolving business strategy and investors must be willing to accept a substantial degree of uncertainty.

The Company's strategic focus is on the development of developing neuromodulation therapies to address chronic and debilitating conditions in children. The Company may engage in ongoing discussions with potential licensees, other strategic partners and institutional or private financing sources, the result of which could add to or alter its current strategic focus, cash needs or ownership structure. Investors must be willing to accept a substantial degree of uncertainty and must be willing to rely upon the Company's board of directors and management to complete an appropriate business strategy to commercially exploit targeted business opportunities.

We may not be able to compete with treatments now being marketed and developed, or which may be developed and marketed in the future by other companies.

Our products will compete with existing and new therapies and treatments for chronic and debilitating conditions in children. We are aware of a number of companies currently seeking to develop alternative therapies or treatment for such diseases and conditions at least in part. Numerous pharmaceutical, biotechnology, drug delivery and medical device companies, hospitals, research organizations, individual scientists, and nonprofit organizations are engaged in the development of alternatives to our technology. Some of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial, and managerial resources than we do. Collaborations or mergers between large pharmaceutical or biotechnology companies with competing treatment technologies could enhance our competitors' financial, marketing, and other resources. Developments by other medical device companies could make our products or technologies uncompetitive or obsolete. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA clearances and/or approval for products or gaining market acceptance more rapidly than we can.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, and/or we may be unable to pursue the clinical trials that we would like to pursue.

We have limited technical, managerial, and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. Due to our limited available financial resources, we may have curtailed clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes.

We may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. Furthermore, we cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. Our decisions to allocate our research, management, and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also cause us to miss valuable opportunities.

We had material weaknesses in our internal control over financing reporting during the years ended December 31, 2025 and 2024, that are unremediated as of December 31, 2025. If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles.

We document, review and improve our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting. To comply with the requirements of being a public company, the Company has undertaken various actions to implement internal controls and procedures. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating internal controls over financial reporting, the Company may identify material weaknesses that it may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. If the Company identifies any additional material weaknesses in its internal control over financial reporting or is unable to remediate the material weakness described above or comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or if the Company's independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting once it is no longer an emerging growth company, or if the Company is unable to conclude in our quarterly and annual reports that our disclosure controls and procedures are effective, investors may lose confidence in the accuracy and completeness of the Company's financial reports and the market price of our common stock could be negatively affected, and the Company could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

In addition, if the Company fails to remediate any identified material weakness, our financial statements could be inaccurate and the Company could face restricted access to capital markets. Our small size and internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. Moreover, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

Management has developed, documented and implemented controls over each of the Company's material weaknesses and successfully tested the design and operating effectiveness of three deficiencies during the year ended December 31, 2025. However, the material weaknesses were not considered remediated as of December 31, 2025, because the new controls were not operational for a sustained period of a full financial reporting cycle. These remediation efforts are subject to ongoing management evaluation and will continue into fiscal year 2026.

Risks Related to Legal and Regulatory Matters

Product liability suits, whether or not meritorious, could be brought against us due to alleged defective devices or for the misuse of our products, which could result in expensive and time-consuming litigation, payment of substantial damages and/or expenses and an increase in our insurance rates.

If our current or future devices are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. This may occur if our products are misused or damaged, have a sudden failure or malfunction (including with respect to safety features) or are otherwise impaired due to wear and tear. Even absent a product liability suit, malfunctions of our products or misuse by physicians or patients would need to be remedied swiftly in order to maintain continuous use and ensure efficacy of our products.

Any product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the device, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even successful defense may require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical study participants and inability to continue clinical studies;
- initiation of investigations by regulators;

- costs to prepare for and defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any device candidate; and
- a decline in our share price.

Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, if any, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Even if our agreements with our third-party manufacturers and suppliers entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Other future litigation and regulatory actions could have a material adverse impact on the Company.

From time to time, we may be subject to litigation and other legal and regulatory proceedings relating to our business or investigations or other actions by governmental agencies. No assurances can be given that the results of these or new matters will be favorable to us. An adverse resolution of lawsuits, arbitrations, investigations or other proceedings or actions could have a material adverse effect on our financial condition and results of operations, including as a result of non-monetary remedies. Defending ourselves in these matters may be time-consuming, expensive and disruptive to normal business operations and may result in significant expense and a diversion of management's time and attention from the operation of our business, which could impede our ability to achieve our business objectives. Additionally, any amount that we may be required to pay to satisfy a judgment, settlement, fine or penalty may not be covered by insurance. Subject to the Delaware General Corporation Law, our certificate of incorporation permit us to indemnify any director against any liability, to purchase and maintain insurance against any liability for any director and to provide any director with funds (whether by loan or otherwise) to meet expenditures incurred or to be incurred by such director in defending any criminal, regulatory or civil proceedings or in connection with an application for relief (or to enable any such director to avoid incurring such expenditure). In addition, under our Articles of Incorporation and bylaws (the "Bylaws") we are obligated to indemnify each of our directors and officers against certain liabilities and expenses arising from their being a director or officer to the maximum extent permitted by Delaware law. In the event we are required to make such payments to our directors and officers, there can be no assurance that any of these payments will not be material.

We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts.

In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements.

If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations.

We are increasingly dependent on information technology systems and are subject to privacy and security laws. Our products and our systems and infrastructure face certain risks, including cyber security breaches and data leakage.

We increasingly rely upon technology systems and infrastructure. Our technology systems, including our products, are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with both permitted and unauthorized access to our products and our systems may pose a risk that protected patient information ("PI") may be exposed to unauthorized persons or to the public, or may be permanently lost. The increasing use and evolution of technology, including cloud-based computing, creates additional opportunities for the unintentional dissemination of information, intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices. We could also experience a business interruption, information theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber incidents, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party service providers or other business partners.

The size and complexity of our computer systems, and scope of our geographic reach, make us potentially vulnerable to information technology system breakdowns, internal and external malicious intrusion, cyberattacks and computer viruses. Because the techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure or properly manage third-party contractors who perform data management services on our behalf, then a security breach could subject us to, among other things, transaction errors, business process inefficiencies, the loss of customers, damage to our reputation, business disruptions or the loss of or damage to intellectual property. Such security breaches could expose us to a risk of loss of information, litigation, penalties, remediation costs and potentially significant liability to customers, employees, business partners and regulatory authorities, including, for example, under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in the United States and Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data under GDPR in the EU. If our data management systems (including third party data management systems) do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired. Any such impairment could materially and adversely affect our financial condition and results of operations.

While we have invested heavily in the protection of data and information technology and in related training, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents or ensure compliance with all applicable security and privacy laws, regulations, and standards, including with respect to third-party service providers that utilize sensitive personal information, including PI, on our behalf.

A security breach, whether of our products, systems or third-party hosting services we utilize, could disrupt treatments being provided by our products, disrupt access to our customers' stored information, such as patient treatment data and health information, and could lead to the loss of, damage to or public disclosure of such data and information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and damages, reduced demand for our products, an unwillingness of customers to use our products, harm to our reputation and brand and time-consuming and expensive litigation, any of which could have a material adverse effect on our financial results. We currently carry cyber and privacy liability insurance with an aggregate limit of $5,000,000, but the amount of insurance coverage that we purchased and may purchase in the future may be inadequate. In the future, our insurance coverage may be expensive or not be available on acceptable terms or in sufficient amounts, if at all.

We may choose to, or may be required to, suspend, repeat or terminate our clinical studies if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the studies are not well designed.

Clinical studies must be conducted in accordance with the FDA's cGCPs and the equivalent laws and regulations applicable in other jurisdictions in which the clinical studies are conducted. The clinical studies are subject to oversight by the FDA, regulatory agencies in other jurisdictions, ethics committees and institutional review boards at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with device candidates produced under the FDA's QSR and in accordance with the applicable regulatory requirements in the other jurisdictions in which the clinical studies are conducted. The conduct of clinical studies may require large numbers of test patients.

The FDA or regulatory agencies in other jurisdictions might delay or terminate our clinical studies of a device candidate for various reasons, including:

- the device candidate may have unforeseen adverse side effects or may not appear to be more effective than current therapies;
- we may not agree with the FDA, a regulatory authority in another jurisdiction or an ethics committee regarding the protocol for the conduct of a clinical study;
- new therapies may become the standard of care while we are conducting our clinical studies, which may require us to revise or amend our clinical study protocols or terminate a clinical study; or
- fatalities may occur during a clinical study due to medical problems that may or may not be related to clinical study treatments.

Furthermore, the process of obtaining and maintaining regulatory approvals in the U.S. and other jurisdictions is lengthy, expensive and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, any of our device candidates could take a significantly longer time than we expect to, or may never, gain regulatory approval, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Legislative and regulatory changes in the U.S. and in other countries regarding healthcare insurance and government-sponsored reimbursement programs (such as Medicare in the United States) may adversely affect our business and financial results.

We rely to a material degree on highly regulated private and government-run health insurance programs for our revenue in most of the countries in which we operate. The laws and regulations regarding health care programs, both public and private, are driven by public policy considerations that may be unrelated to the direct provision of patient care, such as lowering costs or requiring or limiting access to healthcare options. These laws and regulations are very complicated and there are many requirements we must satisfy in order for our products to become and remain eligible for reimbursement under these programs. In many cases we may have limited negotiating power when negotiating reimbursement rates for our products.

In the future, lawmakers and regulators could also pass additional healthcare laws and implement other regulatory changes at both the national and local levels. These laws and regulations could potentially affect coverage and reimbursement for our products. However, we cannot predict the ultimate content, timing or effect of any future healthcare initiatives or the impact any future legislation or regulation will have on us.

With respect to countries outside the U.S., the national competent authorities in the EU member states, the UK, Switzerland, Israel, Japan, and other jurisdictions are also increasingly active in their goal of reducing public spending on healthcare. We cannot, therefore, guarantee that the treatment of patients with our products would be reimbursed in any particular country or, if successfully included on reimbursement lists, whether we will remain on such lists.

We are subject to extensive post-marketing regulation by the FDA and comparable authorities in other jurisdictions, which could impact the sales and marketing of our products and could cause us to incur significant costs to maintain compliance. In addition, we may become subject to additional regulation in other jurisdictions if we market and sell our products outside of the U.S.

We market and sell our products subject to extensive regulation by the FDA and numerous other federal, state and governmental authorities in other jurisdictions. These regulations are broad and relate to, among other things, the conduct of pre-clinical and clinical studies, product design, development, manufacturing, labeling, testing, product storage and shipping, premarket clearance and approval, conformity assessment procedures, premarket clearance and approval of modifications introduced in marketed products, post-market surveillance and monitoring, reporting of adverse events and incidents, pricing and reimbursement, interactions with healthcare professionals, interactions with patients, information security, advertising and promotion and product sales and distribution. Although IB-Stim already has market clearance from FDA for functional abdominal pain associated with IBS in children, we will require additional FDA clearances to market our products for treating other indications.

In addition, before our products can be marketed in the EU, our products must obtain a CE Certificate from a notified body. New intended uses of CE marked medical devices falling outside the scope of the current CE Certificate require a completely new conformity assessment before the device can be CE marked and marketed in the EU for the new intended use. The process required to gather necessary information and draw up documentation in order to obtain CE Certification of a medical device in the EU can be expensive and lengthy and its outcome can be uncertain. We may make modifications to our products in the future that we believe do not or will not require notifications to our notified body or new conformity assessments to permit the maintenance of our current CE Certificate. If the competent authorities of the EU member states or our notified body disagree and require the conduct of a new conformity assessment, the modification of the existing CE Certificate or the issuance of a new CE Certificate, we may be required to recall or suspend the marketing of the modified versions of our products.

In Japan, new medical devices or new therapeutic uses of medical devices falling outside the scope of the existing approval by the MHLW require a new assessment and approval for each such new device or use. Accordingly, we may be required to obtain a new approval from MHLW before we launch a modified version of our products or the use of our products for additional indications. Approval time frames from the MHLW vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to "Quality Management System (QMS) Ordinance," which includes the equivalent of "Good Import" regulations in the U.S. As with any highly regulated market, significant changes in the regulatory environment could adversely affect our ability to commercialize our products in Japan.

In the U.S. and other jurisdictions, we also are subject to numerous post-marketing regulatory requirements, which include regulations under the QSR related to the manufacturing of our products, labeling regulations and medical device reporting regulations, which require us to report to the FDA or comparable regulatory authorities in other jurisdictions and our notified body if our products cause or contributes to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may in the future change in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA or comparable regulatory authorities in other jurisdictions and notified bodies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- patient notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall, withdrawal or seizure of our current or future devices;
- administrative detention by the FDA or other regulatory authority in another jurisdiction of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusal or delay of our requests for approval for new intended uses for or modifications to our products or for approval of new devices;
- refusal or delay in obtaining CE Certificates for new intended uses for or modifications to our products;
- suspension, variation or withdrawal of the CE Certificates granted by our notified body in the EU;
- prohibition or restriction of products being placed on the market;
- operating restrictions;
- suspension or withdrawal of approvals that have already been granted;
- refusal to grant export approval for our products or any device candidates; or
- criminal prosecution.

The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Over time, we expect to make modifications to our products that are designed to improve efficacy, reduce side effects, enhance the user experience or for other purposes. Modifications to our products may require approvals, modified or new CE Certificates and analogous regulatory approvals in other jurisdictions or even require us to cease promoting or to recall the modified versions of our products until such clearances, approvals or modified or new CE Certificates are obtained, and the FDA, comparable regulatory authorities in other jurisdictions or our notified body may not agree with our conclusions regarding whether new approvals are required.

In addition, any substantial change introduced to a medical device or to the quality system certified by our notified body requires a new conformity assessment of the device and can lead to changes to the CE Certificates or the preparation of a new CE Certificate of Conformity. Substantial changes may include, among others, the introduction of a new intended use of the device, a change in its design or a change in the Company's suppliers. Responsibility for determination that a modification constitutes a substantial change lies with the manufacturer of the medical device. We must inform the notified body that conducted the conformity assessment of the products we market or sell in the EU of any planned substantial changes to our quality system or changes to our products that could, among other things, affect compliance with the MDR or the devices' intended use. The notified body will then assess the changes and verify whether they affect the product's conformity with the Essential Requirements laid down in Annex I to the MDD or the conditions for the use of the device. If the assessment is favorable, the notified body will issue a new CE Certificate or an addendum to the existing CE Certificate attesting compliance with the Essential Requirements laid down in Annex I to the MDD. There is a risk that the competent authorities of the EU member states or our notified body may disagree with our assessment of the changes introduced to our products. The competent authorities of the EU member states or our notified body also may come to a different conclusion than the FDA on any given product modification.

In addition, medical devices that have obtained a CE Certification under the MDD may in principle continue to be marketed under such CE Certificate until the CE Certificate expires and at the latest until May 27, 2024, provided that the manufacturer complies with the MDR's additional requirements related to post-marketing surveillance, market surveillance, vigilance, and registration of economic operators and of devices. However, if such medical devices undergo a significant change in their design or intended use, we would need to obtain a new CE Certificate under the MDR for these devices.

If the FDA disagrees with us and requires us to submit a new application for then-existing modifications and/or the competent authorities of the EU member states or our notified body disagree with our assessment of the change introduced in a product, its design or its intended use, we may be required to cease promoting or to recall the modified product until we obtain approval and/or until a new conformity assessment has been conducted in relation to the product, as applicable. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if the FDA, comparable regulatory authorities in other jurisdictions, or our notified body determine, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Any recall or requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenues and potential operating restrictions imposed by the FDA, comparable foreign regulatory authorities in other jurisdictions, or our notified body. Delays in receipt or failure to receive approvals/certification, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

In addition to FDA requirements, we will spend considerable time and money complying with other federal, state, local and foreign rules, regulations and guidance and, if we are unable to fully comply with such rules, regulations and guidance, we could face substantial penalties.

We are subject to extensive regulation by the U.S. federal government and the states and other countries in which we conduct our business. U.S. federal government healthcare laws apply when we submit a claim on behalf of a U.S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government-funded healthcare program, such as Medicare or Medicaid. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, an intent-based federal criminal statute which prohibits knowingly and willfully offering, providing, soliciting or receiving remuneration of any kind to induce or reward, or in return for, referrals or the purchase, lease, order or recommendation or arranging of any items or services reimbursable by a federal healthcare program;
- the Federal Civil False Claims Act, which imposes civil penalties, including through civil whistleblower or "qui tam" actions, for knowingly submitting or causing the submission of false or fraudulent claims of payment to the federal government, knowingly making, using or causing to be made or used a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the Federal Criminal False Claims Act, which is similar to the Federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government;
- Medicare laws and regulations that prescribe requirements for coverage and reimbursement, and laws prohibiting false claims or unduly influencing selection of products for reimbursement under Medicare and Medicaid;
- healthcare fraud statutes that prohibit false statements and improper claims to any third-party payer;
- the Federal Physician Self-Referral Law, commonly known as the Stark law, which, absent an applicable exception, prohibits physicians from referring Medicare and Medicaid patients to an entity for the provision of certain designated health services ("DHS"), if the physician (or a member of the physician's immediate family) has an impermissible financial relationship with that entity and prohibits the DHS entity from billing for such improperly referred services;
- the Federal Beneficiary Anti-Inducement Statute, which prohibits the offering of any remuneration to a beneficiary of Medicare or Medicaid that is likely to influence that beneficiary's choice of provider or supplier. This can include, but is not limited to, inappropriate provision of patient services including financial assistance. Recent government investigations have focused on this particular prohibition. There are established exceptions from liability, but we cannot guarantee that all of our practices will fall squarely within those exceptions;
- the U.S. Foreign Corrupt Practices Act, which can be used to prosecute companies in the U.S. for arrangements with physicians or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country;
- the Federal Trade Commission Act, the Lanham Act and similar federal and state laws regulating truthfulness in advertising and consumer protection; and
- the Federal Physician Payments Sunshine Act, the French Sunshine Act and similar state and foreign laws, which require periodic reporting of payments and other transfers of value made to U.S. and French-licensed physicians, teaching hospitals, and in the U.S., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

Similar laws exist in the EU, individual EU member states and other countries. These laws are complemented by EU or national professional codes of practices.

HIPAA provides data privacy and security provisions for safeguarding medical information. Additionally, states in the U.S. are enacting local privacy laws (e.g., California). In the EU, the GDPR harmonizes data privacy laws and rules on the processing of personal data, including patient and employee data, across the EU. The GDPR has a number of strict data protection and security requirements for companies processing data of EU residents, including when such data is transferred outside of the EU. Additionally, we need to comply with analogous privacy laws in other jurisdictions in which we operate, such as the Israeli Privacy Protection Law, the Asia Pacific Economic Cooperation Privacy Framework, and Japan's Act on the Protection of Personal Information.

The laws and codes of practices applicable to us are subject to evolving interpretations. Moreover, certain U.S. federal and state laws regarding healthcare fraud and abuse and certain laws in other jurisdictions regarding interactions with healthcare professionals and patients are broad and we may be required to restrict certain of our practices to be in compliance with these laws. Healthcare fraud and abuse laws also are complex and even minor, inadvertent irregularities, or even the perception of impropriety, can potentially give rise to claims that a statute has been violated.

Any violation of these laws could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Similarly, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which likewise could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Fines and penalties for violations of these laws and regulations could include severe criminal and civil penalties, including, for example, significant monetary damages, exclusion from participation in the federal healthcare programs and permanent disbarment of key employees. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business, our prospects and our financial results. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

In addition, although we believe that we have the required licenses, permits and accreditation to dispense our products in the future, a regulator could find that we need to obtain additional licenses or permits. We also may be subject to mandatory reaccreditation and other requirements in order to maintain our billing privileges. Failure to satisfy those requirements could cause us to lose our privileges to bill governmental and private payers. If we are required to obtain permits or licenses that we do not already possess, we also may become subject to substantial additional regulation or incur significant expense.

To ensure compliance with Medicare, Medicaid and other regulations, federal and state governmental agencies and their agents, including MACs, may conduct audits of our operations to support our claims submitted for reimbursement of items furnished to beneficiaries and health care providers. Depending on the nature of the conduct found in such audits and whether the underlying conduct could be considered systemic, the resolution of these audits could adversely impact our revenue, financial condition and results of operations.

If we, our collaborative partners, our contract manufacturers or our component suppliers fail to comply with the FDA's QSR or equivalent regulations established in other countries, the manufacturing and distribution of our products could be interrupted, and our product sales and results of operations could suffer.

We, our collaborative partners, our contract manufacturers and our component suppliers are required to comply with the FDA's QSR and the equivalent quality system requirements imposed by the laws and regulations in other jurisdictions, which are a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We cannot assure you that our facilities or our contract manufacturers' or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturers' or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, and lead to suspension, variation or withdrawal of our regulatory approvals or a recall of our products. If any of these events occurs, we may not be able to provide our customers with our products on a timely basis, our reputation could be harmed and we could lose customers, any or all of which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Our products may in the future be subject to recalls that could harm our reputation, business and financial results.

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, governmental bodies in other jurisdictions have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Distributors and manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our manufacturers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Requirements for the reporting of product recalls to the competent authorities are imposed in other jurisdictions in which our products are or would be marketed in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or to the competent authorities of other countries. In the future, we may initiate voluntary recalls involving our products that we determine do not require notification of the FDA or to other equivalent non-U.S. authorities. If the FDA or the equivalent non-U.S. authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and the equivalent non-U.S. authorities could take enforcement action if we fail to report the recalls when they were conducted. Recalls of our products would divert managerial and financial resources and could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA Medical Device Reporting regulations and the equivalent regulations applicable in other jurisdictions in which our products are or may be marketed in the future, medical device manufacturers are required to report to the FDA and to the equivalent non-U.S. authorities information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA or to the equivalent authorities in other jurisdictions within the required time frames, or at all, the FDA or the equivalent authorities in other jurisdictions could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses.

Medical devices may be marketed only for the indications for which they are approved. Our promotional materials and training materials must comply with FDA regulations and other applicable laws and regulations governing the promotion of our products in the U.S. and other jurisdictions.

If the FDA or the competent authorities in other jurisdictions determine that our promotional materials or training constitutes promotion of an unapproved use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled or warning letter, an injunction, seizure, civil fines and criminal penalties. It is also possible that authorities in other federal, state or national enforcement in other jurisdictions might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and the commercialization of our products could be impaired.

We are affected by and subject to environmental laws and regulations that could be costly to comply with or that may result in costly liabilities.

We are subject to environmental laws and regulations, including those that impose various environmental controls on the manufacturing, transportation, storage, use and disposal of hazardous chemicals and other materials used in, and hazardous waste produced by, the manufacturing of our products. We incur and expect to continue to incur costs to comply with these environmental laws and regulations. Additional or modified environmental laws and regulations, including those relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our products or restricting disposal or transportation of batteries, may be imposed that may result in higher costs.

In addition, we cannot predict the effect that additional or modified environmental laws and regulations may have on us, our third-party suppliers of equipment and our products or our customers.

The pediatrics and medical device industries are characterized by patent and other intellectual property litigation and disputes, and any litigation, dispute or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business, harm our reputation and require us to remove certain devices from the market.

Whether a product infringes a patent or violates other intellectual property rights involves complex legal and factual issues, the determination of which is often uncertain. Any intellectual property dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of research and development and marketing efforts, injury to our reputation and loss of revenues. Any of these events could negatively affect our business, prospects, financial condition and results of operations.

Third parties may assert that our products, the methods employed in the use of our products or other activities infringe on their patents. Such claims may be made by competitors seeking to obtain a competitive advantage or by other parties, many of whom have significantly larger intellectual property portfolios than we have. Additionally, in recent years, individuals and groups have begun purchasing intellectual property assets for the purpose of making claims of infringement and attempting to extract settlements from companies like ours. With respect to our current products, the risk of infringement claims is exacerbated by the fact that there are numerous issued and pending patents relating to the treatment of cancer. Because patent applications can take many years to issue, and in many cases remain unpublished for many months after filing, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe.

There could also be existing patents that one or more components of our products or other device candidates may inadvertently infringe. As the number of competitors in the market or other device candidates grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases. To the extent we gain greater market visibility, our risk of being subject to such claims is also likely to increase. If a third party's patent was upheld as valid and enforceable and we were found to be infringing, we could be prevented from making, using, selling, offering to sell or importing our products or other device candidates, unless we were able to obtain a license under that patent or to redesign our systems to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of device candidates to avoid infringement could require us to conduct additional clinical studies and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our devices, we may be unable to make, use, sell, offer to sell or import our devices and our business could suffer. We may also be required to pay substantial damages and undertake remedial activities, which could cause our business to suffer.

We may also be subject to claims alleging that we infringe or violate other intellectual property rights, such as copyrights or trademarks, may have to defend against allegations that we misappropriated trade secrets, and may face claims based on competing claims of ownership of our intellectual property. The confidentiality and assignment of inventions agreements that our employees, consultants and other third parties sign may not in all cases be enforceable or sufficient to protect our intellectual property rights. In addition, we may face claims from third parties based on competing claims to ownership of our intellectual property.

We may employ individuals who were previously employed at other medical device companies, and as such we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of their former employers. Any such litigation, dispute or claim could be costly to defend and could subject us to substantial damages, injunctions or other remedies, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our devices.

As is the case with other medical device companies, our success is heavily dependent on our intellectual property rights, and particularly on our patent rights. Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Certain U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could further negatively impact the value of our patents, narrow the scope of available patent protection or weaken the rights of patent owners.

Future regulatory action remains uncertain.

We operate in a highly regulated and evolving environment with rigorous regulatory enforcement. Any legal or regulatory action could be time-consuming and costly. If we or the manufacturers or distributors that supply our products fail to comply with all applicable laws, standards, and regulations, action by the FDA or other regulatory agencies could result in significant restrictions, including restrictions on the marketing or use of the products we sell or the withdrawal of the products we sell from the market. Any such restrictions or withdrawals could materially affect our reputation, business and operations.

Our product candidates will remain subject to ongoing regulatory review even after they receive marketing clearances, and if we fail to comply with continuing regulations, we could lose these clearances and the sale of any of our approved commercial products could be suspended.

Even as we received regulatory clearance to market IB-Stim, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to IB-Stim will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities or discover any previously unknown problems with any approved product, manufacturer, or manufacturing process, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- pressure to initiate voluntary product recalls;
- suspension or withdrawal of regulatory clearances and/or approvals; and
- refusal to approve pending applications for marketing clearances and/or approval of new products or supplements to approved applications.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products.

The therapeutic medical device and pharmaceutical industries are characterized by extensive intellectual property litigation and, from time to time, we may become the subject of claims of infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

We depend extensively on our patents and proprietary technology and the patents, and we must protect those assets in order to preserve our business.

Although we expect to seek patent protection for any devices, *in silico* products (if any), systems, and processes we discover and/or for any specific use we discover for new or previously known compounds, devices, biologics, products, systems, or processes, any or all of these may not be subject to effective patent protection. In addition, our issued patents may be declared invalid or our competitors may find ways to avoid the claims in the patents.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and proprietary knowledge and operate without infringing on the proprietary rights of others. We are the sole assignee of numerous granted United States patents, pending United States patent applications and international patents. The patent position of pharmaceutical and biotechnology firms like us are generally highly uncertain and involves complex legal and factual questions, resulting in both an apparent inconsistency regarding the breadth of claims allowed in United States patents and general uncertainty as to their legal interpretation and enforceability. Accordingly, patent applications assigned to us may not result in patents being issued, any issued patents assigned to us may not provide us with competitive protection or may be challenged by others, and the current or future granted patents of others may have an adverse effect on our ability to do business and achieve profitability.

Moreover, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, as a result of the assertion of rights by a third-party or otherwise, we may be required to obtain licenses to patents or other proprietary rights of others in or outside of the United States. Any licenses required under any such patents or proprietary rights may not be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product market introductions during our attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. In addition, we could incur substantial costs in defending suits brought against us or in connection with patents to which we hold licenses or in bringing suit to protect our own patents against infringement.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication, and avoid infringing the proprietary rights of others. Our patent rights and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us. Because a substantial number of patents have been issued in the field of neuromodulation therapy and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subject to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

Also, because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the United States and other countries, even after reasonable investigation, we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. We believe that the patents that we own or have applied for do not infringe any third-party patents; however, we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend our intellectual property in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We may use independent clinical investigators and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates for the foreseeable future.

The FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement action against us.

Risks Related to Our Common Stock

We may not be able to maintain a listing of our common stock on NYSE American.

Our common stock is listed on NYSE American. We must meet certain financial and liquidity criteria to maintain such listing. If we violate NYSE American's listing requirements, or if we fail to meet any of NYSE American's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from NYSE American may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

We do not expect to declare or pay dividends in the foreseeable future.

We do not expect to declare or pay dividends in the foreseeable future, as we anticipate that we will invest future earnings in the development and growth of our business. Therefore, holders of our common stock will not receive any return on their investment unless they sell their securities, and holders may be unable to sell their securities on favorable terms or at all.

If securities industry analysts publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

Any trading market for our common stock may be influenced in part by any research reports that securities industry analysts publish about us. If one or more of security analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage of us, the market price and market trading volume of our common stock could be negatively affected.

Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock-up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline and would result in the dilution of your holdings.

Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock-up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our securities, or the future expirations of lock-up agreements, on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your holdings. In addition, the perception that new issuances of our securities could occur, or the perception that locked-up parties will sell their securities when the lock-ups expire, could adversely affect the market price of our common stock. In addition to any adverse effects that may arise upon the expiration of these lock-up agreements, the lock-up provisions in these agreements may be waived, at any time and without notice. If the restrictions under the lock-up agreements are waived, our common stock may become available for resale, subject to applicable law, including without notice, which could reduce the market price for our common stock.

Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able to achieve from an investment in our common stock.

In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred stock in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our common stock must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return, if any, they may be able to achieve from an investment in our common stock.

If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on NYSE American or another national securities exchange and if the price of our common stock is less than $5.00, our common stock could be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

We are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, and our stockholders could receive less information than they might expect to receive from more mature public companies.

We are required to publicly report on an ongoing basis as an "emerging growth company" (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an emerging growth company for up to five years, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time, we would cease to be an emerging growth company as of the following December 31.

Because we are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot predict if investors will find our common stock less attractive if we elect to rely on these exemptions, or if taking advantage of these exemptions would result in less active trading or more volatility in the price of our common stock.

Because the Company is a "smaller reporting company," we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company.

We are a "smaller reporting company" as defined in the Exchange Act. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company's results of operations and financial prospectus in comparison with other public companies.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies.

If investors consider our common stock less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile.

As a "smaller reporting company," we may at some time in the future choose to exempt our Company from certain corporate governance requirements that could have an adverse effect on our public shareholders.

Under NYSE American rules, a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act, is not subject to certain corporate governance requirements otherwise applicable to companies listed on NYSE American. For example, a smaller reporting company is exempt from the requirement of having a compensation committee composed solely of directors meeting certain enhanced independence standards, as long as the compensation committee has at least two members who do meet such standards. Although we have determined not to avail ourselves of this or other exemptions from NYSE American requirements that are or may be afforded to smaller reporting companies while we will seek to maintain our shares on NYSE American, in the future we may elect to rely on any or all of these exemptions. By electing to utilize any such exemptions, our Company may be subject to greater risks of poor corporate governance, poorer management decision-making processes, and reduced results of operations from problems in our corporate organization. Consequently, if we were to avail ourselves of these exemptions, our stock price might suffer, and there is no assurance that we would be able to continue to meet all continuing listing requirements of NYSE American from which we would not be exempt, including minimum stock price requirements.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

CYBERSECURITY RISK MANAGEMENT AND STRATEGY. NeurAxis has developed and implemented a cybersecurity framework intended to assess, identify and manage risks from threats to the security of our information, systems, products and network using a risk-based approach. The framework is informed in part by the National Institute of Standards and Technology (NIST) Cybersecurity Framework and International Organization for Standardization 27001 (ISO 27001) Framework, although this does not imply that we meet all technical standards, specifications, or requirements under the NIST or ISO 27001.

Our key cybersecurity processes include the following:

- **Risk-based controls for information systems and information on NeurAxis' networks:** We seek to maintain an information technology infrastructure that implements physical, administrative and technical controls that are calibrated based on risk and designed to protect the confidentiality, integrity and availability of our information systems and information stored on NeurAxis' networks, including customer information, personal information, PHI/PII, intellectual property and proprietary information. NeurAxis added physical safeguards in the form of biometric entry systems to access server rooms and 24/7 surveillance at both NeurAxis locations.
- **Cybersecurity incident policies:** We have cybersecurity incident policies, an incident response plan and a dedicated team to respond to cybersecurity incidents, including experienced counsel. When a cybersecurity incident occurs or we identify a vulnerability, the dedicated team is responsible for leading the initial assessment of priority and severity, including external experts that may also be engaged as appropriate. NeurAxis' response to incidents depends on the severity level and seeks to improve its cybersecurity incident response plan. NeurAxis, through experienced cybersecurity and HIPAA/HITECH counsel, has developed a security manual and a privacy policy. These policies and manuals are reviewed and updated annually.

- **Training:** We provide security awareness training to help our employees understand their information protection and cybersecurity responsibilities at NeurAxis. We also provide additional role-based training to some employees based on customer requirements, regulatory obligations, and industry risks.
- **Supplier risk assessments:** We have participated in several third-party risk assessment processes that include expectations regarding information and cybersecurity. NeurAxis also seeks contractual commitments from key suppliers to appropriately secure and maintain their information technology systems and protect NeurAxis information that is processed or stored on their systems, when applicable. This may or may not include business associate agreements, downstream vendor agreements and vendor auditing in some cases.
- **Third-party assessments of NeurAxis:** We have third-party cybersecurity companies engaged to assess NeurAxis' cybersecurity readiness and to assist in identifying and remediating risks from cybersecurity threats. NeurAxis has a "real time" cybersecurity partner that monitors our servers 24/7/365 for any attempted intrusions and directs the execution of the Company's disaster recovery plan.

NeurAxis routinely reviews the Office of Civil Right (OCR) audit requirements to assess any gaps within our cybersecurity, privacy and security programs. We have not identified risks from known cybersecurity threats, that have materially affected us, including our operations, business strategy, results of operations, cash flows or financial condition. We face certain ongoing risks from cybersecurity threats, including active interactions with children's hospitals while assisting with insurance prior approvals, that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, cash flows or financial condition.

As of the fiscal year ended December 31, 2025, the Company had not experienced any material cybersecurity incidents that have had a significant impact on our operations, data integrity, results of operations, or financial performance.

CYBERSECURITY GOVERNANCE. NeurAxis' Board of Directors is responsible for oversight of cybersecurity risk. The Board receives reporting about NeurAxis' practices, programs, notable threats or incidents and other developments related to cybersecurity throughout the year, including through periodic updates from NeurAxis' Chief Regulatory Officer/ Privacy Officer and VP of IT/Security Officer.

NeurAxis' Security Officer reports to NeurAxis' Chief Regulatory Officer and together, they lead the Company's overall cybersecurity function. The Security Officer has over 15 years of experience in managing and leading IT or cybersecurity teams and participates in various cyber security trainings frequently. The Security Officer collaborates with NeurAxis personnel and our outside vendors to identify and analyze cybersecurity risks to NeurAxis, considers industry trends, implement controls, as appropriate and feasible, to mitigate these risks and enables business leaders to make risk-based business decisions that impact cybersecurity considerations. The Security Officer meets with senior leadership to review and discuss NeurAxis' cybersecurity program, including emerging cyber risks, threats, and industry trends. The Security Officer also supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, including by collaborating with external security personnel and business stakeholders, and incorporating threat intelligence and other information obtained from governmental, public, or private sources to strengthen our cybersecurity technologies and processes.

Management continues to enhance the Company's cybersecurity governance through ongoing improvements to its internal control compliance program. As part of these efforts, the Company has adopted the Control Objectives for Information and Related Technologies (COBIT) 2019 framework to support the design and governance of its Information Technology General Controls (ITGCs).

During the reporting period, management advanced the identification and implementation of ITGCs within the Company's risk control matrix as part of the implementation of internal control over financial reporting ("ICFR"). While the ITGC controls have been identified and incorporated into the risk control matrix, management expects to conduct the formal assessment and testing of these controls during fiscal year 2026 in alignment with the continued rollout and enhancement of internal controls over financial reporting.

In addition, the Company established a dedicated internal control department during fiscal year 2025. This function reports directly to the Audit Committee of the Board of Directors regarding the status and progress of the Company's internal control over financial reporting program, including matters related to ITGCs, to strengthen governance and oversight.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Carmel, Indiana, where we lease office space for employees. The term of this lease commenced on January 1, 2024 and is scheduled to end on May 31, 2029. Over the term of the lease, the monthly base rent is $6,721 with an annual 2.5% escalator. We received a 50% reduction in our monthly rent for the first 10 months of the lease.

We also lease office space in Batesville, Indiana, pursuant to an agreement that commenced August 1, 2025 for an inital term of three years with automatic one year renewal options subject to an annual 4% rent escalation, unless 60 day notice of vacating is given. The Company prepaid $25,200 of rent on June 13, 2025 which will be amortized over the initial lease term and thereby reduced the monthly base rent to $1,300.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of the date of issuance, other than those described below, there were no pending or threatened legal proceedings that could reasonably be expected to have a material effect on the results of the Company's operations. There are also no proceedings in which any of the Company's directors, officers or affiliates is an adverse party to the Company or has a material interest adverse to the Company's interest.

On February 6, 2019, plaintiff Ritu Bhambhani, M.D., initiated a lawsuit against Innovative Health Solutions, Inc. and others in the United States District Court for the District of Maryland. Plaintiffs Bhambhani and Sudhir Rao subsequently amended the complaint, with the Third Amended Complaint ("Complaint") containing the most recent set of allegations. The Complaint asserted claims under the RICO Act, as well as of fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and sought compensatory damages in excess of $5 million, pre-judgment interest, punitive damages, attorney's fees, court costs and designation of the case as a class action. The Complaint stated that the Company, distributors of the Company's product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company's NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On February 11, 2022, the Company filed a motion for summary judgment based upon the plaintiffs not being proper parties to assert claims against the Company. On June 14, 2022, the Court granted the Company's motion for summary judgment and dismissed the Complaint.

On July 14, 2022, plaintiffs Ritu Bhambhani and Sudhir Rao filed a notice of appeal with the Fourth Circuit Court of Appeals. On June 3, 2024, the Fourth Circuit denied the plaintiff's appeal and entered judgment against the plaintiffs. On June 25, 2024, the Fourth Circuit entered its mandate declaring that its judgment against the plaintiffs took effect that day. The plaintiffs did not seek any further review or appeal of that judgment.

Also on July 14, 2022, plaintiffs Ritu Bhambhani, LLC; Box Hill Surgery Center, LLC; Pain and Spine Specialists of Maryland, LLC; and SimCare ASC, LLC initiated a lawsuit against the Company and others in the United States District Court for the District of Maryland. The plaintiffs in this lawsuit are business entities owned or partially owned by the plaintiffs that initiated the litigation described above. The Complaint asserted claims under the RICO Act, as well as fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and seeks compensatory damages in excess of $75,000, pre-judgment interest, punitive damages, attorney's fees, and court costs. The Complaint states that the Company, distributors of the Company's product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company's NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On September 28, 2022, the Company filed a motion to dismiss all claims. On May 25, 2023, the Court issued an Order and a Memorandum Opinion which dismissed the plaintiffs' claims related to the RICO Act. The remaining claims are still pending, and no trial date has been set for the case. The Court has vacated its Scheduling Order at the parties' request so that the parties could try to resolve the disputes in both cases through an independent third-party mediator

On April 25, 2025, the parties reached a tentative $750,000 settlement payable in 12 equal monthly installments beginning in January of 2026 as filed with the United States District Court for the District of Maryland with the settlement agreement duly executed on May 15, 2025.

In January 2024, Dr. Arturo Taca served notice to the Company that asserted an interest in its U.S. Patent No. 10,413,719 valued at $2,000,000 based on his own work in neurostimulation. The Company denied both the neurostimulation patent and compensation claims. The case remains unresolved.

While it is too early to predict the ultimate outcome of these matters, we believe the Company has meritorious defenses and intends to defend these matters vigorously.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders of Common Stock

Our common stock is listed on the NYSE American, under the symbol "NRXS".

As of March 12, 2026, there were approximately 1,585 record holders of our common stock. The number of record holders does not include beneficial owners of common stock whose shares are held in the names of banks, brokers, nominees or other fiduciaries and holders of unissued shares of common stock.

The last reported sales price for our Common Stock as reported on the NYSE American on March 12, 2026 was $6.48.

Dividends

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and other factors that the board of directors considers to be relevant.

Recent Sales of Unregistered Securities

On October 29, 2025, 3,334 restricted stock units ("RSUs") vested into an equivalent number of shares of common stock.

On January 22, 2026, the Company granted 437,431 RSUs pursuant to the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan as amended on August 15, 2024. The RSUs vest annually pro rata over a three-year period and are payable in shares of the Company's common stock. The RSUs fully vest upon (i) death or disability or (ii) change of control. Dividend equivalents accrue on RSUs and are paid upon vesting; there were no accrued dividends on unvested RSUs as of the report date.

Also on January 22, 2026, the Company issued 86,392 shares of common stock to its independent board members for their 2025 and 2026 service.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a growth stage company focused on developing neuromodulation therapies to address chronic and debilitating conditions in children. Our mission is to advance drug-free neuromodulation therapies that improve patient outcomes and reduce medication burden in complex disorders, while expanding access to effective care for populations with significant unmet needs. Our IB-Stim device is a PENFS system with FDA indications for patients 8 years and older with functional abdominal pain associated with IBS, functional dyspepsia (FD), and associated FD nausea symptoms. Our RED device is an easy-to-use, office-based, point-of-care test that identifies patients with chronic constipation due to pelvic floor dyssnergia and has FDA for adults. Other indications in our pipeline are comprised of post-concussion syndrome, cyclic vomiting syndrome, post-operative pain and fibromyalgia pain.

Since our inception, we have incurred significant operating losses. Our net loss was $7,800,555 and $8,241,501 for the years ended December 31, 2025 and 2024, respectively. Although we had stockholders' equity of $3,399,372, our auditors have expressed substantial doubt about our ability to continue as a going concern in their audit opinion. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to pursue widespread insurance coverage of our IB-Stim and RED devices and seek FDA clearance of our device for other indications. There are a number of milestones and conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including FDA clearance of IB-Stim to treat future indications.

Factors Affecting our Business and Results of Operations

Revenue

Our revenue is derived from the sale of IB-Stim to healthcare companies, primarily hospitals and clinics. Sales generally are not seasonal and only mildly correlated with economic cycles. IB-Stim sells for $1,195 per device, and each patient being treated for functional abdominal pain associated with IBS, functional dyspepsia (FD), and/or associated FD nausea symptoms will use four devices.

Our sales typically are made on a purchase order basis rather than through long-term purchase commitments. We enter into sales agreements with customers for IB-Stim based on purchase orders and standard terms, which vary slightly based on the customer's form, and conditions of sale. Standard payment terms generally are net 30 days. Our largest sales were to two customers representing approximately 28% and 35% of total sales for the years ended December 31, 2025 and 2024, respectively.

Inflation did not have a material impact on our operations for any applicable period, and we do not expect inflation to have a material impact on our operations for the foreseeable future.

Gross profit and Gross Margin

Our management uses gross profit and gross margin to evaluate the efficiency of operations and as a key component to determining the effectiveness and allocation of resources. We calculate gross profit as net sales less cost of goods sold, and gross margin as gross profit divided by net sales. Our gross margin has been and will continue to be affected by a variety of factors, primarily the average selling price of IB-Stim, production volume, order flows, change in mix of customers, third-party manufacturing costs related to components of our devices and cost-reduction strategies. We expect our gross profit to increase in the foreseeable future as our net sales grows, both through broader insurer acceptance of IB-Stim in the near term and approval of our technology for the treatment of other indications over the longer term. Our gross margin may fluctuate from quarter to quarter due to changes in average selling prices and the mix of patient healthcare coverage (e.g., discounts are provided to lower income patients without healthcare insurance), particularly as we introduce enhancements to IB-Stim and new products to address other indications, and as we adopt new manufacturing processes and technologies.

Expenses

We have four categories of expenses: cost of goods sold, selling, research and development ("R&D"), and general and administrative ("G&A").

Costs of goods sold consist of costs paid for the IB-Stim and RED devices to our contract manufacturers along with shipping and handling costs and expired inventory charges. Expired inventory expense is related to the FDA clearance period from the date our devices are manufactured, and if the device is not sold in such period, a reserve is recorded. Expired inventory charges totaled $19,973 and $0 for the years ended December 31, 2025 and 2024. We have fixed-price contracts with the manufacturers of our devices.

Our selling expenses primarily consist of advertising, marketing and promotion of the Company's products including salaries, commissions and other related personnel costs including travel expenses. The Company reclassified $1,144,176 of general and administrative expenses to selling expenses in the Consolidated Statements of Operations for the year ended December 31, 2024, to conform to current year presentation.

Research and development expenses consist primarily of clinical research studies, new product development, costs of materials and supplies used in research and development activities and salaries and other related personnel costs for employees engaged in research and development activities to have our IB-Stim and RED devices cleared by the FDA for other indications. The Company reclassified $227,507 of general and administrative expenses to research and development expenses in the Consolidated Statements of Operations for the year ended December 31, 2024, to conform to current year presentation. We expect future R&D expenses for other indications, such as post-concussion syndrome, cyclic vomiting syndrome, post-operative pain and fibromyalgia pain.

General and administrative expense primarily consists of wages and benefits, professional fees including legal and audit, insurance, investor relations, facility costs, utilities and travel.

Results of Operations

Comparison of Year Ended December 31, 2025, and Year Ended December 31, 2024

The following table presents our statements of operations for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	2024
Net sales	$ 3,569,282	$ 2,685,925
Cost of goods sold	562,916	362,002
Gross profit	3,006,366	2,323,923
Selling expenses	2,279,974	1,468,884
Research and development	493,611	443,614
General and administrative	8,062,689	7,578,242
Operating loss	(7,829,908)	(7,156,817)
Other income (expense), net:		
Financing charges	(30,240)	(230,824)
Interest expense	(73,969)	(174,328)
Change in fair value of warrant liability	(7,634)	(941)
Amortization of debt discount and issuance costs	--	(126,387)
Other income (expense), net	141,196	(552,204)
Total other income (expense), net	29,353	(1,084,684)
Net loss	$ (7,800,555)	$ (8,241,501)

Net Sales

Net sales increased $883,357, or 32.9%, from $2,685,925 for the year ended December 31, 2024, to $3,569,282 for the year ended December 31, 2025, primarily due to volume growth from (i) both patients with health insurance coverage and those participating our financial assistance programs that provide discounts to patients without health insurance coverage and (ii) device sales from the Company's launch of the RED product in 2025. Although unit growth from the discounted financial assistance programs outpaced the full health insurance reimbursement programs, the Company's overall growth was function of new customers (both hospitals and private physical practices), new insurance carrier coverage in certain locations across the United States and higher prior authorization approval rates of the Company's Category III CPT Code.

Gross Profit and Gross Margin

Gross profit increased $682,443, or 29.4%, from $2,323,923 for the year ended December 31, 2024, to $3,006,366 for the year ended December 31, 2025, due to higher sales volume. Despite the increase in sales volume, the decrease in gross margin from 86.5% for the year ended December 31, 2024, to 84.2% for the year ended December 31, 2025, was due to higher discounting in the Company's financial assistance programs provide to patients without insurance coverage, a higher unit growth rate of the discounted financial assistance programs compared to the full reimbursement health insurance programs and expired RED inventory.

Selling Expenses

Selling expenses increased $811,090, or 55.2%, from $1,468,884 for the year ended December 31, 2024, to $2,279,974 for the year ended December 31, 2025, due to higher commissions from higher sales volume, a higher temporary commission structure to facilitate growth and adoption in new states, incremental sales and marketing headcount and increased advertising and marketing costs focused on health insurance carriers due to the January 1, 2026 effective date of IB'Stim's new Category I CPT Code

Research and Development

Research and development expenses increased $59,997, or 13.8%, from $433,614 for the year ended December 31, 2024, to $493,611 for the year ended December 31, 2025, due to costs to higher year-over-year spending on a medical research project, improved IB-Stim design features and costs to develop the RED device.

General and Administrative

General and administrative expenses increased $484,447, or 6.4%, from $7,578,242 for the year ended December 31, 2024, to $8,062,689 for the year ended December 31, 2025, primarily due to a $630,568 one-time, non-recurring charge to settle a lawsuit, headcount and related costs incurred to improve and enhance the Company's internal control environment and the introduction of annual short-term and long-term incentive plans in 2024 that were not outstanding for the full fiscal year, partially offset by the absence of certain one-time non-recurring severance, hiring, consulting and advisory costs incurred in 2024 and lower legal, accounting and insurance costs as new hires in 2024 have internally absorbed certain services.

Operating Loss

Our operating loss increased $673,091, or 9.4%, from $7,156,817 for the year ended December 31, 2024, to $7,829,908 for the year ended December 31, 2025, primarily due to higher selling and general and administrative expenses partially offset by higher gross profit from sales volume.

Other Income (Expense)

Other income increased $1,114,037, or 102.7%, from $1,084,684 of expense for the year ended December 31, 2024, to $29,353 of income for the year ended December 31, 2025, due to the absence of one-time, non-recurring 2024 settlements relating to a 2023 convertible note dispute and certain pre-IPO Series A Preferred Stock shareholder claims and the conversion of convertible notes into Series B Preferred Stock in 2024 which eliminated any related debt discount and interest charges.

Net Loss

Our net loss decreased $440,946, or 5.4%, from $8,241,501 for the year ended December 31, 2024, to $7,800,555 for the year ended December 31, 2025, primarily due to higher sales volume and the absence of one-time, non-recurring 2024 settlements relating to a 2023 convertible note dispute and certain pre-IPO Series A Preferred Stock shareholder claims, partially offset by higher selling expenses and the one-time non-recurring settlement of a lawsuit in 2025.

Liquidity and Capital Resources

We had cash on hand of $4,965,072 and $3,696,870 as of December 31, 2025 and 2024, respectively. We maintained a working capital surplus of $2,941,091 and $1,832,858 as of December 31, 2025 and 2024, respectively. The increase in working capital was primarily due to the sale and issuance of 3,108,170 shares of common stock pursuant to the shelf registration statement and warrant exercises for gross proceeds of $8,826,615 offset by cash used in operations of $6,432,843 for the year ended December 31, 2025 which improved the Company's liquidity position.

We have incurred losses since inception and have funded our operations primarily with a combination of sales, debt, the exercises of warrants and the sale of capital stock. As of December 31, 2025, we had stockholders' equity of $3,399,372, short-term outstanding borrowings of $148,293 and long-term debt of $9,999.

Our future capital requirements will depend upon many factors, including progress with developing, manufacturing, and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes and overall economic conditions in our target markets. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products from customers currently identified in our sales pipeline and to new customers as well. The primary activity that will drive all customers and revenues is the adoption of insurance coverage by commercial insurance carriers nationally, so this is a top priority of the Company. These activities, including our planned research and development efforts, will require significant uses of working capital through the rest of 2026 and beyond. Based on our current operating plans, we believe that our existing cash at the time of this filing will only be sufficient to meet our anticipated operating needs before the end of 2026.

Additionally, we will have to meet all the financial disclosure and reporting requirements associated with being a publicly reporting company. Our management will have to spend additional time on policies and procedures to make sure it is compliant with various regulatory requirements, especially that of Section 404 of the Sarbanes-Oxley Act. This additional corporate governance time required of management could limit the amount of time our management has to implement our business plan and may delay our anticipated growth plans.

The following table summarizes our cash flows from operating, investing, and financing activities for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (6,432,843)	$ (6,098,264)
Net cash used in investing activities	(131,150)	(27,776)
Net cash provided by financing activities	7,832,195	9,744,350
Net increase in cash and cash equivalents	1,268,202	3,618,310
Cash and cash equivalents at beginning of period	3,696,870	78,560
Cash and cash equivalents at end of period	$ 4,965,072	$ 3,696,870

Operating Activities – Net cash used in operating activities increased $334,579, or 5.5% from $6,098,264 for the year ended December 31, 2024, to $6,432,843 for the year ended December 31, 2025, primarily due to the payment of the 2024 short-term incentive program in 2025 (no program existed previously) and higher inventory purchases as the Company prepared for the January 1, 2026 effective date of the Category I CPT code for the IB-Stim device, partially offset by better receivable collections.

Investing Activities – Net cash used in investing activities increased $103,374, or 372.2%, from $27,776 for the year ended December 31, 2024, to $131,150 for the year ended December 31, 2025, primarily due to the $100,000 installment payment to Masimo pursuant to the July 1, 2025 NSS-2 Bridge license termination agreement that allowed the Company to recapture the rights to a trademark and two patent applications.

Financing Activities – Net cash provided by financing activities decreased $1,912,155, or 19.6%, from $9,744,350 for the year ended December 31, 2024, to $7,832,195 for the year ended December 31, 2025, primarily due to (i) gross financing proceeds of $10,214,846 for the year ended December 31, 2024 from the issuance of Series B preferred stock and convertible notes in addition to the exercise of warrants compared to gross financing proceeds of $8,826,615 for the year ended December 31, 2025 through the issuance of common stock and the exercise of warrants and (ii) higher financing fees, offering costs and legal fees paid in 2025 versus 2024.

Critical Accounting Estimates

Management considers its allowance for credit losses, reserve for sales returns and reserve for excess and expired inventory to be the most critical accounting estimates and assumptions in understanding our financial statements because they involve significant judgments and uncertainties. Actual results could differ from management's estimates. See Note 2 for further information on our most significant accounting policies.

Allowance for Credit Losses

The Company sells its IB-Stim and RED devices primarily to hospitals and private physician practices with payment generally due within 30 days. The Company does not offer discounts if the customer pays some or all of an invoiced amount prior to the due date. We maintain an allowance for credit losses to reflect our estimate of expected losses on accounts receivable from the sale of our medical devices. The estimate of expected credit losses is a considered a critical accounting estimate because it requires significant judgment and the use of assumptions about future customer payment behavior and economic conditions.

In estimating the allowance for credit losses, management regularly reviews its past due account receivable balances and evaluates many factors including, but not limited to, creditworthiness, past transaction and payment history, historical loss experience, current economic industry trends and payment terms. The Company performs that review by utilizing an aging schedule to assess the collectability of accounts. Actual credit losses may differ from estimated amounts. Differences between estimated and actual credit losses are recognized in earnings in the period in which such changes are identified. A change in the past due account balance by 10 percentage points as of December 31, 2025, would increase or decrease the allowance for credit losses by $558.

Allowance for Sales Returns

We recognize revenue net of estimated product returns upon customer receipt under FOB destination terms. Customers may return devices if the goods are found to be defective, nonconforming or otherwise do not meet the technical specifications. Historically, the Company has also allowed returns at the request of physicians, on a case-by-case basis, as long as the devices are returned in their original, unopened packaging. As a result, we record an allowance for sales returns which is considered a critical accounting estimate because it requires significant judgment and is sensitive to changes in assumptions.

In establishing the allowance for sales returns, management evaluates historical return rates by product and adjusts those rates to reflect current trends and conditions. Estimates are reassessed each reporting period based on actual return activity and updated information. Actual product returns may differ from estimated amounts. Differences between estimated and actual returns are recognized as adjustments to revenue in the period in which they become known. A change in the return rate of one percentage point as of December 31, 2025, would have increased or decreased the allowance by $5,593.

Allowance for Excess and Expired Inventory

Inventories are valued at the lower of cost or net realizable value. An allowance for excess and expired inventory is recorded to reflect inventory quantities that are not expected to be sold or that are expected to be sold below cost. The determination of this allowance is considered a critical accounting estimate because it requires significant judgment regarding future product demand and the timing of orders.

In estimating the allowance for excess and expired inventory, management considered a number of factors including, but not limited to, historical sales trends, product shelf life and expiration dates, regulatory and clinical requirements, backlog and anticipated demand and future orders. Actual inventory usage and obsolescence may differ from management's estimates. Differences between estimated and actual inventory usage are recognized as adjustments to earnings in the period in which they become known. A change in the forecasted demand of 20 percentage points as of December 31, 2025, would have increased or decreased the allowance by $758.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Index to Financial Statements and Financial Statement Schedules from page F-1 of this annual report on Form 10-K, which are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as that term is defined in Rule 13a-15(e), promulgated by the SEC pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our Company's reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer to allow timely decisions regarding required disclosure. Our management, with the participation of our principal executive officer and principal financial officer, evaluated our Company's disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2025, our disclosure controls and procedures were, is design and operation, not effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our principal executive officer and principal financial officer and oversight of the Board of Directors, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework set forth in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our management, including our principal executive officer and principal financial officer, recognizes that disclosure controls and procedures and internal controls over financial reporting, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

Based on our evaluation, management concluded that our internal control over financial reporting was not effective as of December 31, 2025.

Material Weaknesses

A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The following material weaknesses in our internal control over financial reporting were identified:

- Ineffective approval processes governing (i) timely Board of Directors authorization and (ii) segregation of duties and roles and responsibilities configurations within the Company's financial reporting system; and
- Inadequate contract management process to capture all executed agreements prior to the commencement of services in order to ensure accuracy within the proper accounting period.
- Misapplication of U.S. GAAP; and
- Ineffective disclosure controls and procedures a result of (i) lack of segregation of duties, (ii) lack of internal control structure review and (iii) misapplication of U.S. GAAP.

In order to remediate the identified material weaknesses, management, with the oversight of the Audit Committee of the Board of Directors, undertook measures to enhance the Company's internal control environment, including the (i) hiring of a principal financial officer and other accounting personnel to ensure the appropriate application of U.S. GAAP including the annual completion of a minimum number of continuing professional education hours, (ii) hiring of a dedicated internal control manager that reports directly to the Audit Committee and whose sole responsibility is to develop, document, implement and maintain our internal control framework and program including walk throughs, narratives, flow charts, risk control matrices and independent testing of our financial and IT controls, (iii) documentation and communication of business policies such as a delegation of authority over contracts and transactions as well as invoice and journal entry approvals, (iv) completion of a formal monthly close process including account reconciliations with supporting documentation and (v) engagement of a third-party firm that implemented controls to segregate duties and approvals with the proper assignment of roles and responsibilities within the Company's financial system.

ITEM 9B. OTHER INFORMATION

Our directors and officers may enter into trading plans or other arrangements with financial institutions to purchase or sell shares of our common stock, which plans or arrangements are intended to comply with the affirmative defense provisions of Rule 10b5-1 of the Exchange Act or which may represent a non-Rule 10b5-1 trading arrangement, as defined under Item 408(a) of Regulation S-K.

During the three months ended December 31, 2025, none of our directors or officers adopted, terminated or modified a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table and biographical summaries set forth information, including principal occupation and business experience, about our directors and executive officers as of March 13, 2025:

Name	Age	Position
Brian Carrico	44	President, Chief Executive Officer and Director
Timothy Henrichs (1)	53	Chief Financial Officer
Dr. Adrian Miranda	57	Chief Medical Officer, Senior Vice President of Science and Technology
Dr. Thomas Carrico	69	Chief Regulatory Officer, Compliance Officer and Privacy Officer
Dr. Christopher Robin Brown	72	Director
Bradley Mitch Watkins	51	Director and Chairman of the Board
Beth Keyser	57	Director
Kristin Ferge	52	Director
Gilad Aharon	52	Director

(1) On January 30, 2024, our former Chief Financial Officer John Seale resigned from his position, effective as of the close of business on January 30th. On the same day, Timothy R. Henrichs resigned as a member of the board of directors, effective February 2, 2024. On January 26, 2024, the board of directors appointed Mr. Henrichs to serve as the CFO, effective on February 5, 2024.

Brian Carrico, President, Chief Executive Officer and Director

Brian Carrico has served as President, Chief Executive Officer, and a Director of the Company since January 1, 2018. He joined the Company in 2012 and has held multiple senior leadership roles of increasing responsibility, including Vice President of Sales and President.

As an early employee and long-tenured executive, Mr. Carrico has played a central role in guiding the Company from an early-stage concept through research and development, FDA clearance, and full commercial scale. Under his leadership, the Company has advanced its proprietary technology from initial clinical validation to broad adoption, securing multiple pediatric and adult indications, achieving wide-scale insurance policy coverage across commercial and government payers, and obtaining a Category I CPT code for the Company's first-to-market flagship technology.

Mr. Carrico has been instrumental in setting the Company's long-term strategic vision, building and leading the commercial organization, raising growth capital, expanding clinical and payer evidence, and establishing durable reimbursement pathways to support sustainable revenue growth. His leadership has focused on disciplined execution, stakeholder alignment across clinicians, payers, and investors, and the development of a scalable platform to support future indications and product expansion.

Prior to joining the Company, Mr. Carrico held sales and clinical-facing roles at Bard Medical and St. Jude Medical, where he gained extensive experience in operating room and cath lab environments. He holds a Bachelor of Science in Business Marketing from Indiana State University.

Timothy Henrichs, Chief Financial Officer

Timothy Henrichs has served as the Company's Chief Financial Officer since February 5, 2024 and was a director of the Company from August 9, 2023 to February 2, 2024. Mr. Henrichs' global leadership experience spans over 20 years and across several industries, including healthcare, home improvement, retail, software and education. Previously, Mr. Henrichs served as the Chief Financial Officer of Renovo Home Partners since 2022. He also served as the Executive Vice President and Chief Financial Officer of Follett Corporation from 2008 to 2022 and Global Controller of General Electric Company's Healthcare Clinical Systems division responsible for the manufacture and distribution of medical devices to the ultrasound, patient monitoring and anesthesiology markets from 2005 to 2008 in addition to leadership positions at Federal Signal Corporation and Ernst & Young LLP. Mr. Henrichs earned his bachelor's degree in accounting from the University of Notre Dame and is a Certified Public Accountant.

Dr. Adrian Miranda, Chief Medical Officer, Senior Vice President of Science and Technology

Dr. Adrian Miranda has served as the Company's Chief Medical Officer since 2018 and provides clinical, scientific, and strategic leadership. He brings more than 20 years of clinical, academic, and research experience to the role. Dr. Miranda is a board-certified pediatric gastroenterologist and Professor of Pediatrics at the Medical College of Wisconsin.

Dr. Miranda received his undergraduate degree in Biology from San Diego State University and his medical degree from the Medical College of Wisconsin. He completed his pediatric residency and subspecialty fellowship training in pediatric gastroenterology at Children's Hospital of Wisconsin.

As a physician-scientist, Dr. Miranda has spent over two decades investigating the pathophysiology of visceral and somatic pain, with a particular focus on disorders of gut-brain interaction. His research has emphasized the role of adverse early life events, neuroplasticity, and central nervous system modulation in the development and treatment of chronic pain conditions. He has authored and co-authored numerous peer-reviewed publications and book chapters and is a frequent lecturer at national and international medical and scientific conferences.

Dr. ***Thomas Carrico, Chief Regulatory Officer, Compliance Officer and Privacy Officer***

Dr. Thomas Carrico has served as our Chief Regulatory Officer since November 2017. He joined the Company in February 2012 as Director of Regulatory Affairs. Prior to and during his early years with Neuraxis, he was President & Clinic Director at Spine and Neuromuscular Associates in Lawrenceburg, Indiana from January 2002 to December 2018. He has over 40 years of experience in the healthcare field and has been involved in the study and application of techniques and treatments that directly affect the autonomic nervous system, especially regarding homeostasis and balance of the parasympathetic and the sympathetic nervous system. Dr. Carrico has a history of working with attorneys while serving on state and national boards, which has positioned him to integrate into regulatory responsibilities at the Company. Dr. Carrico received his undergraduate education from Indiana University and his Doctorate from Palmer College of Chiropractic.

Dr. Christopher Robin Brown, Director

Dr. Chirstopher Robin Brown is a co-founder of the Company. He developed clinical protocol, initial practice guidelines, designed and implemented the practitioner certification program and personally financed the first two years of the Company. After developing the technique of transillumination to isolate auricular neurovascular bundles, he authored and designed the initial studies establishing neurovascular and tissue energy transfer theories upon which the devices' use are based. Dr. Brown is listed as the sole or principal inventor on all Neuraxis patents and is currently active in further device development working closely with compliance, product design and engineering.

Upon graduation from the Indiana University School of Dentistry in 1982, while serving as clinic chief in the United States Army Reserve (USAR) dental corps at Fort Benjamin Harrison in Indianapolis, Indiana, Dr. Brown started a private practice (current) concentrating in head, neck, and facial pain developing the first hospital based facial pain clinic in Indiana. He received his master's degree in Biomechanical Trauma in 1996 from Lynn University, one of only 12 dentists in the United States to hold the combination of DDS and MPS degrees. Dr. Brown has authored several textbook chapters, published peer reviewed articles on the physics of soft tissue trauma, pain, financial management, was regional editor for a national facial pain management Journal, and has lectured extensively nationally and internationally. He served on the Board of Directors of the American Academy of Pain Management for 15 years, helping grow the organization from 800 members to over 5,000. Throughout his tenure, he developed educational tracks, served as Industry liaison, one term as treasurer and one term as President. He served on the national board of The Alliance of TMD practitioners, serving one term as president.

Throughout his career, Dr. Brown has been active in the purchasing and management of several destressed clinics and re-structuring them into profitable enterprises. He has performed extensive volunteer work overseas providing surgical care in the Dominican Republic, local dental clinics serving the underprivileged, and recently provided dental screenings for the deployment of soldiers in the USAR and National Guard.

Bradley Mitch Watkins, Director and Chairman of the Board

Bradley Mitch Watkins has overseen four companies through their early commercialization periods within the medical device sector over the last 20 years. He has directly reported to the CEO or board of directors and operated as the lead for all field operations. Over his 20 years in a multitude of medical device markets, Mr. Watkins has overseen $410 million in company acquisitions in an array of leadership roles. He has thrived in early commercialization, recruitment, and strategic company direction. These duties have groomed Mr. Watkins with a wide array of responsibilities beyond sales, including marketing, clinical study design, manufacturing, R&D, FDA submissions, and fiscal oversight. Mr. Watkins has been the National Sales Manager of Terumo Interventional Systems since 2015, where he has led multiple new technology sales teams within the peripheral IV and Electrophysiology markets. Mr. Watkins received his bachelor's degree in behavioral science from the University of Maryland.

Beth Keyser, Director

Beth Keyser is a 30-year healthcare industry veteran with a passion for leading organizations that are on a mission to make people healthier. Ms. Keyser was named president of the Anthem Blue Cross and Blue Shield West Region for the Commercial Health Benefits division in 2025, which includes Colorado, Indiana, Kentucky, Missouri, Nevada, Ohio and Wisconsin and is also responsible for Sales Enablement and Centralized Sales Support within the Commercial Health Benefits division.

Previously, Ms. Keyser served as president of Anthem Blue Cross and Blue Shield of Indiana from 2020 to 2025. The Anthem health plan in Indiana is the largest in the state with nearly 5,000 Indiana-based associates, serving more than four million members. Before joining Anthem, Ms. Keyser focused on improving doctor-patient relationships as the president of Create® health plans in New York City. Prior to her time at *Create*®, Beth held several leadership roles at Healthways where she was accountable for domestic and international revenue growth, customer experience, call center operations and establishing partnerships with health plans, employers, physician organizations and hospitals. Early in her career she helped stand up Gordian Health Solutions, a Nashville start-up, that was eventually sold to Blue Cross Blue Shield of Tennessee.

Beth currently serves on the Board of Directors of Women in Health Care Leadership at University of Alabama at Birmingham, which provides mentoring and training programs to develop tomorrow's leaders. She also serves on the board of directors of the Indiana Sports Corp, Neuraxis and the WellPoint Holding Corporation. Beth is also a proud member of the Red Cross Tiffany Circle. Ms. Keyser is a graduate of the University of Southern Mississippi and earned a master's degree from the University of Alabama at Birmingham.

Kristin Ferge, Director

Kristin Ferge 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 currently services as a Director of Citizens Bank and is a certified public accountant.

Gilad Aharon, Ph.D.

Dr. Aharon is a co-founder of and has served as a Portfolio Manager at Rosalind Advisors, Inc., since 2006. Dr. Aharon holds a Ph.D. in Biophysics and Molecular Biology from the University of Toronto. Prior to co-founding Rosalind Advisors, Dr. Aharon worked as an equity analyst at Infinium Securities Inc.

Family Relationships

Brian Carrico, our Chief Executive Officer and Director, is the son of Dr. Carrico, our Chief Regulatory Officer. There are no other family relationships between or among any of our executive officers or other directors.

Role of the Board

It is the paramount duty of the board to oversee our management in the competent and ethical operation of the Company on a day-to-day basis and to assure that the long-term interests of the stockholders are being served. To satisfy this duty, the directors take a proactive, focused approach to their positions, and set standards to ensure that we are committed to business success through maintenance of ambitious standards of responsibility and ethics.

Director Terms; Qualifications

Our directors are elected for a term of one year and until their successors qualified, nominated, and appointed or elected.

When considering whether directors and nominees have the experience, qualifications, attributes and skills to enable the board of directors to satisfy its oversight responsibilities effectively in light of the Company's business and structure, the board of directors focuses primarily on the industry and transactional experience, and other background, in addition to any unique skills or attributes associated with a director.

Director or Officer Involvement in Certain Legal Proceedings

There are no material proceedings to which any director or officer, or any associate of any such director or officer, is a party that is adverse to our Company or any of our subsidiaries or has a material interest adverse to our Company or any of our subsidiaries. No director or executive officer has been a director or executive officer of any business which has filed a bankruptcy petition or had a bankruptcy petition filed against it during the past ten years. No director or executive officer has been convicted of a criminal offense or is the subject of a pending criminal proceeding during the past ten years. No director or executive officer has been the subject of any order, judgment or decree of any court permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities during the past ten years. No director or officer has been found by a court to have violated a federal or state securities or commodities law during the past ten years.

Directors and Officers Liability Insurance

The Company maintains directors' and officers' liability insurance insuring its directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance may also insure the Company against losses, which it may incur in indemnifying its officers and directors. In addition, officers and directors also have indemnification rights under applicable laws, and the Company's Certificate of Incorporation and Bylaws.

Director Independence

The listing rules of NYSE American require that independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of NYSE American require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of NYSE American, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with it that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, the board of directors has determined that four are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of NYSE American. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances our board of directors deemed relevant in determining their independence.

Board Committees

As of December 31, 2025, the following three standing committees have been established: Audit Committee; Compensation Committee; and Nominating and Corporate Governance Committee. Each of our independent directors, Bradley Mitch Watkins, Beth Keyser, Kristin Ferge and Dr. Gil Aharon, serve on certain committees. Our board has adopted written charters for each of these committees. Copies of the charters are available on our website. Our board may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

The Audit Committee, among other things, is responsible for:

- appointing; approving the compensation of; overseeing the work of; and assessing the independence, qualifications, and performance of the independent auditor;
- reviewing the internal audit function, including its independence, plans, and budget;
- approving, in advance, audit and any permissible non-audit services performed by our independent auditor;
- reviewing our internal controls with the independent auditor, the internal auditor, and management;
- reviewing the adequacy of our accounting and financial controls as reported by the independent auditor, the internal auditor, and management;
- overseeing our financial compliance system; and
- overseeing our major risk exposures regarding the Company's accounting and financial reporting policies, the activities of our internal audit function, and information technology.

The board of directors has affirmatively determined that each member of the Audit Committee meets the additional independence criteria applicable to audit committee members under SEC rules and listing standards of NYSE American All members of the Audit Committee are able to read and understand fundamental financial statements, are familiar with finance and accounting practices and principles and are financially literate. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee. The board of directors has affirmatively determined that each member of the Audit Committee is financially literate, and that Kristin Ferge meets the qualifications of an Audit Committee financial expert.

The Audit Committee consists of Kristin Ferge, Bradley Mitch Watkins, and Beth Keyser and Ms. Ferge serves as chair of the Audit Committee. The functioning of the Audit Committee complies with the applicable requirements of the rules and listing standards of NYSE American and the SEC.

Compensation Committee

The Compensation Committee is responsible for:

- reviewing and making recommendations to the Board with respect to the compensation of our officers and directors, including the CEO;
- overseeing and administering the Company's executive compensation plans, including equity-based awards;
- negotiating and overseeing employment agreements with officers and directors; and
- overseeing how the Company's compensation policies and practices may affect the Company's risk management practices and/or risk-taking incentives.

The Compensation Committee consists of Dr. Gil Aharon, Bradley Mitch Watkins, Beth Keyser, and Kristin Ferge, and Dr. Aharon serves as chair of the Compensation Committee. The board of directors has affirmatively determined that each member of the Compensation Committee meets the independence criteria applicable to compensation committee members under SEC rules and listing standards of NYSE American. The Company believes that the composition of the Compensation Committee meets the requirements for independence under, and the functioning of such Compensation Committee comply with, any applicable requirements of the rules and regulations of listing standards of NYSE American and the SEC.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee, among other things, is responsible for:

- reviewing and assessing the development of the executive officers and considering and making recommendations to the Board regarding promotion and succession issues;
- evaluating and reporting to the Board on the performance and effectiveness of the directors, committees and the board of directors as a whole;
- working with the Board to determine the appropriate and desirable mix of characteristics, skills, expertise and experience, including diversity considerations, for the full Board and each committee;
- annually presenting to the Board a list of individuals recommended to be nominated for election to the board;
- reviewing, evaluating, and recommending changes to the Company's committee charters;
- recommending to the Board individuals to be elected to fill vacancies and newly created directorships;
- overseeing the Company's compliance program, including the Code of Conduct; and
- overseeing and evaluating how the Company's corporate governance and legal and regulatory compliance policies and practices, including leadership, structure, and succession planning, that may affect the Company's major risk exposures.

The Nominating and Corporate Governance Committee consists of Bradley Mitch Watkins, Beth Keyser, and Kristin Ferge and Ms. Keyser serves as chair of the Nominating and Corporate Governance Committee. The Company's board of directors has determined that each member of the Nominating and Corporate Governance Committee is independent within the meaning of the independent director requirements for independence under the NYSE American listing standards and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

None of the Company's executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of the Company's board of directors or its compensation committee. None of the members of the Company's compensation committee is, or has ever been, an officer or employee of the Company.

Code of Business Conduct and Ethics

The Company's board of directors has adopted a code of business conduct and ethics ("Code of Conduct") applicable to its employees, directors and officers, in accordance with applicable U.S. federal securities laws and the corporate governance rules of NYSE American. The Code of Conduct is effective and is publicly available on the Company's website. Any substantive amendments or waivers of the Code of Conduct may be made only by the Company's board of directors and will be promptly disclosed as required by applicable U.S. federal securities laws and the corporate governance rules of NYSE American.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning all compensation earned by our Chief Executive Officer and three other persons who served as executive officers as, at, or during the years ended December 31, 2025 and 2024, and who earned compensation exceeding $100,000 during 2025 and 2024 (the "Named Executive Officers"), for services as executive officers for the last two years.

Name and Principal Position	Year	Salary ($) (1)	Bonus ($) (2)	Stock Awards ($) (3)	Benefits ($) (4)	Total ($)
Brian Carrico	2025	345,102	180,960	388,841	21,536	936,439
Chief Executive Officer	2024	352,973	206,730	—	18,673	578,376
Timothy Henrichs	2025	327,336	140,551	327,922	21,536	817,345
Chief Financial Officer	2024	274,077	112,239	227,000	15,561	628,877
Dr. Thomas Carrico	2025	300,000	77,533	166,308	23,042	566,883
Chief Regulatory Officer	2024	288,307	63,772	—	16,835	368,914
Dr. Adrian Miranda	2025	300,000	77,533	171,900	21,536	570,969
Chief Medical Officer	2024	300,000	63,772	—	18,673	382,445

(1) Represents W-2 Box 1 bi-weekly payments to our executive officers pursuant to their respective employment agreements. Mr. Henrichs began employment on February 5, 2024.

(2) Represents bonus earned by our executive officers from the annual incentive plan upon achievement of certain targets. Mr. Carrico's 2024 bonus includes $62,222 related to the successful issuance of the 2024 Convertible Notes. Bonuses are paid in the following fiscal year.

(3) Represents grant date fair value of restricted stock awards. Mr. Henrichs was granted 100,000 common stock awards in 2024 as a hiring grant. All restricted stock awards in 2025 and 2024 are subject to a three-year cliff vesting schedule.

(4) Represents medical, dental, vision and supplemental insurance benefits.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding equity awards held by the Named Executive Officers as of December 31, 2025.

	Option Awards				Restricted Stock Units		
Name	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Units of Stock That Have Not Vested (#) (2)	Market Value of Units of Stock That Have Not Vested ($)	Vesting Date
	320,000	-	$ 6.94	9/13/2029			
Brian Carrico					100,640	$ 456,906	9/30/2027
					70,019	$ 317,886	1/3/2028
	-	-	na	na			
Timothy Henrichs					174,037	$ 790,128	9/30/2027
					67,980	$ 308,629	1/3/2028
	306,236	-	$ 6.94	9/13/2029			
Dr. Thomas Carrico					37,435	$ 169,955	9/30/2027
					35,000	$ 158,900	1/3/2028
	337,204	-	$ 6.94	9/13/2029			
Dr. Adrian Miranda					40,000	$ 181,600	9/30/2027
					35,000	$ 158,900	1/3/2028

(1) All option awards were granted under the Innovative Health Solutions, Inc. 2017 Stock Compensation Plan, as Amended, and vested fully upon grant.

(2) All restricted stock awards were granted under the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan, as Amended, and are subject to a three-year cliff vest.

Innovative Health Solutions, Inc. 2017 Stock Compensation Plan, As Amended

On October 12, 2017, the Company adopted the Innovative Health Solutions, Inc. 2017 Stock Compensation Plan, as amended on September 13, 2019, September 9, 2021, and November 1, 2022 (collectively, the "2017 Plan"). The purpose of the 2017 Plan is to grant incentive stock options, nonqualified stock options, or restricted stock awards to our officers, employees, directors, advisors, and consultants. The maximum numbers of shares of common stock that may be issued pursuant to awards granted were 1,319,394. Cancelled and forfeited stock options and stock awards may again become available for grant under the 2017 Plan. As of December 31, 2025 and 2024, options to purchase all 1,319,394 shares of common stock have been granted under the 2017 Plan and remain outstanding, and no shares remain available for issuance under the 2017 Plan. The following summary briefly describes the principal features of the 2017 Plan and is qualified in its entirety by reference to the full text of the 2017 Plan, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Purpose of the 2017 Plan: The purposes of the 2017 Plan are to encourage ownership of shares by eligible employees and key non-employees in order to attract and retain such eligible employees in the employ of the Company or an affiliated entity, or to attract such key non-employees to provide services to the Company or an affiliated entity, and to provide additional incentive for such persons to promote the long-term success of the Company or an affiliated entity.

Administration of the Plan: The 2017 Plan is administered by the board of directors, or the committee to which the board of directors delegates the power to act. Among other things, the administrator has the authority to select persons who will receive awards, determine the types of awards and the number of shares to be covered by awards, and to establish the terms, conditions, restrictions and other provisions of awards. The administrator has authority to establish, amend and rescind rules and regulations relating to the 2017 Plan.

Eligible Recipients: Persons eligible to receive awards under the 2017 Plan are those officers, employees, directors, advisors, and consultants of the Company or an affiliated entity who are selected by the administrator.

Shares Available under the 2017 Plan: The maximum number of shares of our common stock that may be delivered to participants under the 2017 Plan is 1,319,394 shares, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. No new grants will be made under the 2017 Plan, and shares subject to an award under the 2017 Plan for which the award is canceled, forfeited or expires will become available for grants under the 2022 Plan described below. Shares subject to an award that is settled in cash will not again be made available for grants under the 2017 Plan.

Stock Options

General. Subject to the provisions of the 2017 Plan, the administrator has the authority to determine all grants of stock options, although there are currently no shares of common stock remaining reserved for grants under the 2017 Plan.

Option Price. The exercise price for stock options is determined at the time of grant. The exercise price may not be less than the fair market value on the date of grant. Additionally, incentive stock option grants to any person owning more than 10% of our voting stock must have an exercise price of not less than 110% of the fair market value on the grant date.

Exercise of Options. An option may be exercised only in accordance with the terms and conditions for the option agreement as established by the administrator at the time of the grant. The option must be exercised by notice to us, accompanied by payment of the exercise price. Payments may be made in cash or, at the option of the administrator, by actual or constructive delivery of shares of common stock to the holder of the option based upon the fair market value of the shares on the date of exercise.

Expiration or Termination. Options, if not previously exercised, will expire on the expiration date established by the administrator at the time of grant. In the case of incentive stock options, such term cannot exceed ten years provided that in the case of holders of more than 10% of our voting stock, such term cannot exceed five years. Options will terminate before their expiration date only if the holder's service with our Company or an affiliate terminates before the expiration date and the holder is terminated for cause. The option may remain exercisable until the expiration date of the option after terminations of employment for any reason other than for cause, including terminations as a result of death, disability or retirement.

Incentive and Non-Qualified Options. An incentive stock option is an option that is intended to qualify under certain provisions of the Internal Revenue Code, for more favorable tax treatment than applies to non-qualified stock options. Any option that does not qualify as an incentive stock option will be a non-qualified stock option. Under the Code, certain restrictions apply to incentive stock options. For example, the exercise price for incentive stock options may not be less than the fair market value of the shares on the grant date and the term of the option may not exceed ten years. In addition, an incentive stock option may not be transferred, other than by will or the laws of descent and distribution and is exercisable during the holder's lifetime only by the holder. In addition, no incentive stock options may be granted to a holder that is first exercisable in a single year if that option, together with all incentive stock options previously granted to the holder that also first become exercisable in that year, relate to shares having an aggregate market value in excess of $100,000, measured at the grant date.

Restricted Stock Awards: Restricted stock awards could have also been granted under the 2017 Plan, although there are currently no shares of common stock remaining reserved for grants under the 2017 Plan. A restricted stock award is a grant of shares of common stock or of a right to receive shares in the future.

*Other Material Provisions***:** Awards are evidenced by a written agreement, in such form as may be approved by the administrator. In the event of various changes to the capitalization of our Company, such as stock splits, stock dividends and similar re-capitalizations, an appropriate adjustment will be made by the administrator to the number of shares covered by outstanding awards or to the exercise price of such awards. The administrator is also permitted to include in the written agreement provisions that provide for certain changes in the award in the event of a change of control of our Company, including acceleration of vesting. Except as otherwise determined by the administrator at the date of grant, awards will not be transferable, other than by will or the laws of descent and distribution. Prior to any award distribution, we are permitted to deduct or withhold amounts sufficient to satisfy any employee withholding tax requirements. Our board of directors also has the authority, at any time, to discontinue the granting of awards. The Plan may be amended by the board of directors and such amendment shall become effective upon adoption by the board of directors; provided, however, that any amendment shall be subject to the approval of the stockholders of the Company at or before the next annual meeting of the stockholders of the Company if such stockholder approval is required by applicable laws. No amendment that would adversely affect any outstanding award made under the Plan can be made without the consent of the holder of such award.

No new grants can be made under the 2017 Plan. The terms and conditions of awards granted under the 2017 Plan prior to the effective date of the 2022 Plan will not be affected by the adoption or approval of the 2022 Plan, and the 2017 Plan will remain effective with respect to such awards.

Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan, As Amended on August 15, 2024

On November 1, 2022, the Company adopted the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan (as amended January 18, 2023, the "2022 Plan"). The purpose of the 2022 Plan is to attract, retain and provide incentives to key management employees and non-employee directors of, and non-employee consultants to, the Company and its affiliates, and to align the interests of such employees, non-employee directors and non-employee consultants with those of the Company's stockholders. The maximum number of shares of common stock that may be issued pursuant to awards granted are 300,000. Cancelled and forfeited stock options and stock awards may again become available for grant under the 2022 Plan. On August 15, 2024, the Company held an annual meeting of stockholders whereby an amendment was approved such that the maximum number of shares of common stock (including shares of common stock underlying options designated as incentive stock options) that may be issued under the Plan shall not exceed six hundred thousand (600,000) shares of Common Stock, plus an annual increase on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2031 equal to the lesser of (i) five percent (5%) of the shares of common stock outstanding on the final day of the immediately preceding calendar year, and (ii) such smaller number of shares of common stock as determined by the Board or the Compensation Committee.

As of the date of this Form 10-K, 896,028 awards have been granted under the 2022 Plan, and 62,791 shares of common stock remain available for issuance under the 2022 Plan. The following summary briefly describes the principal features of the 2022 Plan and is qualified in its entirety by reference to the full text of the 2022 Plan.

Purpose of the 2022 Plan: The purposes of the 2022 Plan is to benefit the stockholders of the Company, by assisting the Company to attract, retain and provide incentives to key management employees and non-employee directors of, and non-employee consultants to, the Company and its affiliates, and to align the interests of such employees, non-employee directors and non-employee consultants with those of the Company's stockholders.

Administration of the 2022 Plan: The 2022 Plan shall be administered by the board of directors or the committee designated by the board of directors. Among other things, the administrator has the authority to select persons who will receive awards, determine the time or times when an award shall be made, what type of award shall be granted, the term of an award, the date or dates on which an award vests (including acceleration of vesting), the form of any payment to be made pursuant to an award, the terms and conditions of an award (including the forfeiture of the award (and/or any financial gain) if the holder of the award violates any applicable restrictive covenant thereof), the restrictions under a restricted stock award and the number of common stock which may be issued under an award, all as applicable. In addition, subject to the express provisions of the 2022 Plan, the administrator is authorized to construe the 2022 Plan and the respective award agreements executed thereunder, to prescribe such rules and regulations relating to the 2022 Plan as it may deem advisable to carry out the intent of the 2022 Plan, to determine the terms, restrictions and provisions of each award, and to make all other determinations necessary or advisable for administering the 2022 Plan.

Eligible Recipients: Persons eligible to receive awards under the 2022 Plan will be those officers, employees, directors, advisors, and consultants of the Company or an affiliated entity who are selected by the administrator.

Shares Available under the Plan: The maximum number of shares of our common stock that may be delivered to participants under the 2022 Plan is 958,820 shares, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. Shares subject to an award under the 2022 Plan for which the award lapses, expires, is canceled, terminated, unexercised or ceases to be exercisable again become available for grants under the 2022 Plan.

Stock Options

General. Subject to the provisions of the 2022 Plan, the administrator has the authority to determine all grants of stock options.

Option Price. The exercise price for stock options is determined at the time of grant. The exercise price may not be less than the fair market value on the date of grant. Additionally, incentive stock option grants to any person owning more than 10% of our voting stock must have an exercise price of not less than 110% of the fair market value on the grant date.

Exercise of Options. An option may be exercised only in accordance with the terms and conditions for the option agreement as established by the administrator at the time of the grant. The option must be exercised by notice to us, accompanied by payment of the exercise price. Payments may be made in cash or, at the option of the administrator, by actual or constructive delivery of shares of common stock to the holder of the option based upon the fair market value of the shares on the date of exercise.

Expiration or Termination. Options, if not previously exercised, will expire on the expiration date established by the administrator at the time of grant. In the case of incentive stock options, such term cannot exceed ten years provided that in the case of holders of more than 10% of our voting stock, such term cannot exceed five years. Options will terminate before their expiration date if the holder's service with our Company or a subsidiary terminates before the expiration date. The option may remain exercisable for specified periods after certain terminations of employment, including terminations as a result of death, disability or retirement, with the precise period during which the option may be exercised to be established by the administrator and reflected in the grant evidencing the award.

Incentive and Non-Qualified Options. As described elsewhere in this summary, an incentive stock option is an option that is intended to qualify under certain provisions of the Code, for more favorable tax treatment than applies to non-qualified stock options. Any option that does not qualify as an incentive stock option will be a non-qualified stock option. Under the Code, certain restrictions apply to incentive stock options. For example, generally, the exercise price for incentive stock options may not be less than the fair market value of the shares on the grant date and the term of the option may not exceed ten years. In addition, an incentive stock option may not be transferred, other than by will or the laws of descent and distribution, and is exercisable during the holder's lifetime only by the holder. In addition, to the extent that the aggregate fair market value of common stock with respect to which incentive stock options are exercisable for the first time by an individual during any calendar year under all plans of the Company and any parent corporation or subsidiary corporation thereof which provide for the grant of incentive stock options exceeds $100,000, the portion of such incentive stock options that exceeds such threshold shall be treated as non-qualified stock options. Incentive stock options shall be granted to employees only.

Restricted Stock Awards: Restricted stock awards can be granted under the 2022 Plan. A restricted stock award is a grant of shares of common stock or of a right to receive shares in the future. These awards will be subject to such conditions, restrictions and contingencies as the administrator shall determine at the date of grant. Those may include requirements for continuous service and/or the achievement of specified performance goals.

Unrestricted Stock Awards: Unrestricted stock awards can also be granted under the 2022 Plan. An unrestricted stock award is a grant of shares of common stock which is not subject to restrictions, in consideration for past services rendered thereby to the Company or an affiliate or for other valid consideration.

Restricted Stock Unit Awards: Restricted stock unit awards ("RSUs") can be granted under the 2022 Plan upon the satisfaction of predetermined individual service related vesting requirements. The holder of a restricted stock unit shall be entitled to receive a cash payment equal to the fair market value of shares of common stock, for each unit awarded to the holder.

Performance Stock Unit Awards: Performance stock unit awards can be granted under the 2022 Plan. A holder of performance stock units shall be entitled to receive a cash payment equal to the dollar value or number of shares of common stock assigned to such units if the holder and/or the Company satisfy the predetermined performance goals and objectives.

Distribution Equivalent Rights: Distribution equivalent right awards can be granted under the 2022 Plan. A distribution equivalent right award entitles the holder to receive bookkeeping credits, cash payments and/or common stock distributions equal in amount to the distributions that would have been made to the holder had the holder held a specified number of common stock during the period the holder held the distribution equivalent right.

*Stock Appreciation Right*s: Stock appreciation rights can also be granted under the 2022 Plan, which is a right, granted alone or in connection with a related Option, to receive a payment on the date of exercise. The base value of the stock appreciation right shall be set forth by the administrator and shall not be less than the fair market value of the common stock at the date of grant for the stock appreciation right which is not a tandem stock appreciation right. No stock appreciation right shall be exercisable after the expiration of ten (10) years from the date of its grant. Upon the exercise of some or all of the portion of a stock appreciation right, the holder shall receive a payment from the Company, in cash or in the form of common stock having an equivalent fair market value or in a combination of both. If the administrator grants a stock appreciation right which is intended to be a tandem stock appreciation right, the tandem stock appreciation right shall be granted at the same time as the related option.

Other Material Provisions: Awards are evidenced by a written agreement, in such form as may be approved by the administrator. In the event of various changes to the capitalization of our Company, such as stock splits, stock dividends and similar re-capitalizations, an appropriate adjustment will be made by the administrator to the number of shares covered by outstanding awards or to the exercise price of such awards. The administrator is also permitted to include in the written agreement provisions that provide for certain changes in the award in the event of a change of control of our Company, including acceleration of vesting. Except as otherwise determined by the administrator at the date of grant, awards will not be transferable, other than by will or the laws of descent and distribution. Prior to any award distribution, we are permitted to deduct or withhold amounts sufficient to satisfy any employee withholding tax requirements. Our board of directors also has the authority, at any time, to discontinue the granting of awards. The 2022 Plan may be amended by the board of directors and such amendment shall become effective upon adoption by the board of directors; provided, however, that any amendment shall be subject to the approval of the stockholders of the Company at or before the next annual meeting of the stockholders of the Company if such stockholder approval is required by applicable laws. No amendment that would adversely affect any outstanding award made under the 2022 Plan can be made without the consent of the holder of such award. The 2022 Plan shall continue in effect, unless sooner terminated, until the tenth (10th) anniversary of the date on which it is adopted by the board of directors.

Employment Agreements

Brian Carrico, our Chief Executive Officer, entered into an employment agreement with the Company, dated August 9, 2022 and amended on May 4, 2023, which has a five-year initial term and provides for a base salary of $330,000, which shall be increased each year by not less than 3% per annum. Mr. Carrico also will receive a one-time incentive payment in the amount of $435,577, which amount consists of accrued and unpaid salary and a bonus to incentivize Mr. Carrico to remain with the Company for future service. Neither the accrued and unpaid salary nor bonus was the subject of any contract or agreement between Mr. Carrico and the Company prior to the execution of the employment agreement. The agreement contemplated that the incentive payment would be paid by December 15, 2022, but due to administrative impracticability, payment was made with a portion of the proceeds from the IPO in August 2023. In addition, Mr. Carrico is entitled to payment of a deferred bonus in an amount equal to (i) the aggregate of the strike price or exercise price of all 320,000 unexercised options to purchase stock or shares of the Company held by Mr. Carrico (the "Aggregate Strike Price") plus (ii) a tax gross-up payment on the Aggregate Strike Price reasonably calculated by the Company at the highest marginal rates so that after payment of all ordinary income taxes on such Aggregate Strike Price, there remains an amount sufficient to pay such ordinary income taxes. The special deferred bonus will be paid in substantially equal 20% installments (the "Annual Deferred Bonus Payment") on January 2 on each of 2024, 2025, 2026, 2027, and 2028 (the "Scheduled Payment Dates"), with a condition that on or before each Scheduled Payment Date, Mr. Carrico shall exercise at least 64,000 of the stock option. None of stock options has been exercised, therefore, no special deferred bonus has been paid as of the date of this prospectus. Mr. Carrico may exercise any portion of the stock options after a Scheduled Payment Date; provided, however, an exercise after the applicable Scheduled Payment Date shall result in forfeiture of the related Annual Deferred Bonus Payment.

If the employment agreement is terminated by the Company without cause (as defined in the employment agreement), Mr. Carrico will receive any accrued compensation (as defined in the employment agreement) and is entitled to severance payments as follows:

- If termination occurs during the initial term, the severance payment shall be the amount equal to the greater of (a) three times Mr. Carrico's base salary as of the termination date; and (b) three times the total amount of Mr. Carrico's bonus payments the Company paid Mr. Carrico over the one year prior to the termination date, to be paid in substantially equal monthly installments over the course of the three years.

- If termination occurs after the initial term, the severance payment shall be the amount equal to the greater of (a) one and one half (1.5) times Mr. Carrico's base salary as of the termination date; and (b) one and one half (1.5) times the total amount of Mr. Carrico's bonus payments the Company paid Mr. Carrico over the one (1) year prior to the termination date, to be paid in substantially equal monthly installments over the course of 18 months following the termination date.

- In addition, as part of the severance payment, we agreed to pay Mr. Carrico monthly COBRA premiums for continuation of health coverage for 18 months post termination.

If the employment agreement is terminated by the Company for cause, Mr. Carrico will forfeit any unpaid Annual Deferred Bonus Payment, but will receive any unpaid base salary that has been earned at the time of such termination, reimbursement of any expenses properly incurred prior to the Mr. Carrico's termination date; and accrued and unused paid time off ("PTO"), if any, in accordance with the Company's PTO policy in effect on Mr. Carrico's termination date.

Mr. Carrico may terminate the employment agreement without good reason upon more than thirty (30) days' prior written notice or for good reason without prior written consent, and will receive accrued compensation (as defined in the employment agreement) and the unpaid balance of the deferred bonus.

In the event that Mr. Carrico is terminated without cause, non-forfeited portions of the deferred bonus will be paid in equal installments over the remaining scheduled payment dates, if vested options as scheduled are exercised before the scheduled payment dates. A deferred bonus tranche will be forfeited if its corresponding options have expired.

On a change in control (as defined in the employment agreement), full vesting of the Annual Deferred Bonus Payment will occur and be paid in a single lump sum within 30 days after the change in control. The offering shall not be considered a change in control.

Pursuant to the employment agreement, Mr. Carrico also agreed to (i) not disclose to any unauthorized person or use for his own account any confidential information without the prior written consent of the Company or the board of directors, (ii) will not, directly or indirectly encourage, solicit, induce (or attempt to encourage, solicit or induce) any employee or agent of the Company that was employed (or otherwise engaged) at the time of his separation during his employment and for 24 months after his separation from that employment for any reason; (iii) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with Company; (iv) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with the Company during his employment and, (v) will not, directly or indirectly and in a competitive capacity own, manage, finance, operate, control or participate in ownership, management, or operation of, act as an agent, consultant, or be employed with, any business engaged in the design, manufacture, marketing, sale or servicing of any service or product with which Mr. Carrico was involved during his last year of employment with the Company; or which the Company is developing, producing, marketing, selling or servicing (or plans to develop, produce, market, sale or service) and about which Mr. Carrico gained any confidential information in the course of his employment with the Company for a period of 24 months after his separation from the Company.

Timothy Henrichs, our Chief Financial Officer entered into an employment agreement with the Company, dated January 1, 2025 which has a five-year initial term and provides for a base salary of $330,000, which shall be increased each year by not less than 3% per annum. Mr. Henrichs also will receive a one-time hiring grant of 100,000 shares of common stock.

If the employment agreement is terminated by the Company without cause (as defined in the employment agreement), Mr. Henrichs will receive any accrued compensation (as defined in the employment agreement) and is entitled to severance payments as follows:

- If termination occurs during the initial term, the severance payment shall be the amount equal to the greater of (a) one times Mr. Henrichs' base salary as of the termination date; and (b) one times the total amount of Mr. Henrichs' bonus payments the Company paid Mr. Henrichs over the one year prior to the termination date, to be paid in substantially equal monthly installments over the course of one year.

- If termination occurs after the initial term, the severance payment shall be the amount equal to the greater of (a) one and times Mr. Henrichs' base salary as of the termination date; and (b) one times the total amount of Mr. Henrichs' bonus payments the Company paid Mr. Henrichs over the one (1) year prior to the termination date, to be paid in substantially equal monthly installments over the course of 12 months following the termination date.

- In addition, as part of the severance payment, we agreed to pay Mr. Henrichs monthly COBRA premiums for continuation of health coverage for 18 months post termination.

If the employment agreement is terminated by the Company for cause, Mr. Henrichs will forfeit any unpaid Annual Deferred Bonus Payment, but will receive any unpaid base salary that has been earned at the time of such termination, reimbursement of any expenses properly incurred prior to the Mr. Henrichs' termination date; and accrued and unused paid time off ("PTO"), if any, in accordance with the Company's PTO policy in effect on Mr. Henrichs' termination date.

Mr. Henrichs may terminate the employment agreement without good reason upon more than thirty (30) days' prior written notice or for good reason without prior written consent, and will receive accrued compensation (as defined in the employment agreement) and the unpaid balance of the deferred bonus.

Pursuant to the employment agreement, Mr. Henrichs also agreed to (i) not disclose to any unauthorized person or use for his own account any confidential information without the prior written consent of the Company or the board of directors, (ii) will not, directly or indirectly encourage, solicit, induce (or attempt to encourage, solicit or induce) any employee or agent of the Company that was employed (or otherwise engaged) at the time of his separation during his employment and for 24 months after his separation from that employment for any reason; (iii) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with Company; (iv) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with the Company during his employment and, (v) will not, directly or indirectly and in a competitive capacity own, manage, finance, operate, control or participate in ownership, management, or operation of, act as an agent, consultant, or be employed with, any business engaged in the design, manufacture, marketing, sale or servicing of any service or product with which Mr. Henrichs was involved during his last year of employment with the Company; or which the Company is developing, producing, marketing, selling or servicing (or plans to develop, produce, market, sale or service) and about which Mr. Henrichs gained any confidential information in the course of his employment with the Company for a period of 24 months after his separation from the Company.

Dr. Adrian Miranda, our Chief Medical Officer and Senior Vice President of Science and Technology, entered into an employment agreement with the Company, dated August 17, 2022, which has a two-year initial term and provides for a base salary of $300,000 with annual compensation increase. In addition, Dr. Miranda shall be entitled to payment of a special deferred bonus in an amount equal to (i) the aggregate of the strike price or exercise price of all 337,204 unexercised options to purchase stock or shares of the Company held by Dr. Miranda (the "Aggregate Strike Price") plus (ii) a tax gross-up payment on the Aggregate Strike Price reasonably calculated by the Company at the highest marginal rates so that after payment of all ordinary income taxes on such Aggregate Strike Price, there remains an amount sufficient to pay such ordinary income taxes. The deferred bonus will be paid in substantially equal 20% installments (the "Annual Deferred Bonus Payment") on January 2 on each of 2024, 2025, 2026, 2027, and 2028, with a condition that on or before each scheduled payment date, Dr. Miranda shall exercise at least 67,441 of the stock options.

If the employment agreement is terminated by the Company without cause (as defined in the employment agreement) occurs during the term of the agreement, Dr. Miranda will receive any accrued compensation (as defined in the employment agreement) and is entitled to certain amount of severance payments as follows:

- If termination occurs during the initial term, the Company shall provide Dr. Miranda with severance compensation in the form of salary continuation at his Base Salary as of the termination date and ending the later of (i) 6 months or (ii) on the expiration date of the initial term.
- If termination occurs after the initial term, the severance payment shall be the amount equal to one half (1/2) of Dr. Miranda's Base Salary as of the termination date.
- In addition, if termination occurs during the initial term, as part of the severance payment, we agreed to pay Dr. Miranda reimbursement of his monthly COBRA premiums for continuation of health coverage for 18 months post termination.

If the employment agreement is terminated by the Company for cause, Dr. Miranda will forfeit any unpaid Annual Deferred Bonus Payment, but will receive any unpaid base salary that has been earned at the time of such termination, reimbursement of any expenses properly incurred prior to the Dr. Miranda's termination date; and (iii) accrued and unused PTO, if any, in accordance with the Company's PTO policy in effect on Dr. Miranda's termination date.

Dr. Miranda may terminate the employment agreement without good reason upon more than thirty (30) days' prior written notice or for good reason without prior written consent, and will receive accrued compensation (as defined in the employment agreement) and the unpaid balance of the special deferred bonus.

In the event that Dr. Miranda is terminated without cause, non-forfeited portions of the deferred bonus will be paid in equal installments over the remaining scheduled payment dates, if vested options as scheduled are exercised before the scheduled payment dates. A deferred bonus tranche will be forfeited if its corresponding options have expired.

On a change in control (as defined in the employment agreement), full vesting of the Annual Deferred Bonus Payment will occur and be paid in a single lump sum within 30 days after the change in control. The offering shall not be considered a change in control.

Pursuant to the employment agreement, Dr. Miranda also agreed to (i) not disclose to any unauthorized person or use for his own account any confidential information without the prior written consent of the Company or the board of directors, (ii) will not, directly or indirectly encourage, solicit, induce (or attempt to encourage, solicit or induce) any employee or agent of the Company that was employed (or otherwise engaged) at the time of his separation during his employment and for 24 months after his separation from that employment for any reason; (iii) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with Company; (iv) not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with the Company during his employment and (v) will not, directly or indirectly and in a competitive capacity own, manage, finance, operate, control or participate in ownership, management, or operation of, act as an agent, consultant, or be employed with, any business engaged in the design, manufacture, marketing, sale or servicing of any service or product with which Dr. Miranda was involved during his last year of employment with the Company; or which the Company is developing, producing, marketing, selling or servicing (or plans to develop, produce, market, sale or service) and about which Dr. Miranda gained any confidential information in the course of his employment with the Company for a period of 24 months after his separation from the Company.

Dr. Thomas Carrico, Chief Regulatory Officer, entered into an employment agreement with the Company, dated August 9, 2022 and amended on May 4, 2023, which has a two-year initial term and provides for a base salary of $275,000 with annual compensation increase. Dr. Carrico will also receive a one-time incentive payment in the amount of $135,655, which amount includes accrued and unpaid salary and a bonus to incentivize Dr. Carrico to remain with the Company for future service. Neither the accrued and unpaid salary nor bonus was the subject of any contract or agreement between Dr. Carrico and the Company prior to the execution of the employment agreement. The agreement contemplated that the incentive payment would be paid by December 15, 2022, but due to administrative impracticability, payment was made with a portion of the proceeds from the IPO in August 2023. In addition, Dr. Carrico shall be entitled to payment of a deferred bonus in an amount equal to (i) the aggregate of the strike price or exercise price of all 306,236 unexercised options to purchase stock or shares of the Company held by Dr. Carrico (the "Aggregate Strike Price") plus (ii) a tax gross-up payment on the Aggregate Strike Price reasonably calculated by the Company at the highest marginal rates so that after payment of all ordinary income taxes on such Aggregate Strike Price, there remains an amount sufficient to pay such ordinary income taxes. The special deferred bonus will be paid in substantially equal 20% installments (the "Annual Deferred Bonus Payment") on January 2 on each of 2024, 2025, 2026, 2027, and 2028 (the "Scheduled Payment Dates"), with a condition that on or before each Scheduled Payment Date, Dr. Carrico shall exercise at least 61,274 of the stock option. None of stock options has been exercised, therefore, no special deferred bonus has been paid as of the date of this prospectus. Dr. Carrico may exercise any portion of the stock options after a Scheduled Payment Date; provided, however, an exercise after the applicable Scheduled Payment Date shall result in forfeiture of the related Annual Deferred Bonus Payment.

If the employment agreement is terminated by the Company without cause (as defined in the employment agreement), Dr. Carrico will receive any accrued compensation (as defined in the employment agreement) and is entitled to certain amount of severance payments as follows:

- If termination occurs during the initial term, the Company shall provide Dr. Carrico with severance compensation in the form of salary continuation at his Base Salary as of the termination date and ending the later of (i) 6 months or (ii) on the expiration date of the initial term.
- If termination occurs after the initial term, the severance payment shall be the amount equal to one half (1/2) of Dr. Carrico's Base Salary as of the termination date.
- In addition, if termination occurs during the initial term, as part of the severance payment, we agreed to pay Dr. Carrico reimbursement of his Medicare, Medicare Supplement and prescription drug coverage insurance premiums for continuation of health coverage for 18 months post termination.

If the employment agreement is terminated by the Company for cause, Dr. Carrico will forfeit any unpaid Annual Deferred Bonus Payment, but will receive any unpaid base salary that has been earned at the time of such termination, reimbursement of any expenses properly incurred prior to the Dr. Carrico's termination date; and (iii) accrued and unused PTO, if any, in accordance with the Company's PTO policy in effect on Dr. Carrico's termination date.

Dr. Carrico may terminate the employment agreement without good reason upon more than thirty (30) days' prior written notice or for good reason without prior written consent, and will receive accrued compensation (as defined in the employment agreement) and the unpaid balance of the special deferred bonus.

In the event that Dr. Carrico is terminated without cause after this offering, non-forfeited portions of the deferred bonus will be paid in equal installments over the remaining scheduled payment dates, if vested options as scheduled are exercised before the scheduled payment dates. A deferred bonus tranche will be forfeited if its corresponding options have expired.

On a change in control (as defined in the employment agreement), full vesting of the Annual Deferred Bonus Payment will occur and be paid in a single lump sum within 30 days after the change in control. The offering shall not be considered a change in control.

Pursuant to the employment agreement, Dr. Carrico also agreed to (i) not disclose to any unauthorized person or use for his own account any confidential information without the prior written consent of the Company or the board of directors, (ii) will not, directly or indirectly encourage, solicit, induce (or attempt to encourage, solicit or induce) any employee or agent of the Company that was employed (or otherwise engaged) at the time of his separation during his employment and for 24 months after his separation from that employment for any reason; (iii) will not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with Company; (iv) not, directly or indirectly, have any ownership interest in, work for, advise, manage, act as an agent or consultant for, or have any business connection or business or employment relationship with any entity or person which competes with the Company during his employment and (v) will not, directly or indirectly and in a competitive capacity own, manage, finance, operate, control or participate in ownership, management, or operation of, act as an agent, consultant, or be employed with, any business engaged in the design, manufacture, marketing, sale or servicing of any service or product with which Dr. Carrico was involved during his last year of employment with the Company; or which the Company is developing, producing, marketing, selling or servicing (or plans to develop, produce, market, sale or service) and about which Dr. Carrico gained any confidential information in the course of his employment with the Company for a period of 24 months after his separation from the Company.

Non-Employee Director Compensation

The following table presents the compensation awarded to or earned by or paid to all individuals who served as non-employee directors during the years ended December 31, 2025 and 2024. We do not provide additional compensation to directors who are our employees for also serving as a director.

Name	Year	Fees Earned ($)	Stock Awards Earned ($)	Total ($)
Bradley M. Watkins	2025	60,537	50,000	110,537
	2024	60,000	50,000	110,000
Beth Keyser	2025	60,000	50,000	110,000
	2024	60,000	50,000	110,000
Kristin Ferge (1)	2025	65,004	50,000	115,004
	2024	49,151	40,959	90,110
Gilad Aharon (2)	2025	60,883	50,000	110,883
	2024	—	—	—
Timothy Henrichs (3)	2025	—	—	—
	2024	5,260	4,384	9,644

(1) Kristin Ferge was appointed to the board of directors on March 7, 2024.
(2) Gilad Aharon was appointed to the board of directors on January 1, 2025.
(3) On January 30, 2024, Timothy R. Henrichs resigned as a member of the board of directors, effective February 2, 2024 and became the Company's Chief Financial Officer.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information known to us with respect to the beneficial ownership of our common stock as of March 12, 2026 based on 11,187,639 shares of common stock outstanding. In addition, holders of Series B Preferred Stock are entitled to an additional 2,378,015 votes (solely for purposes of voting rights, the conversion price is $3.80 per share). Therefore, the total votes of the Company's currently outstanding securities is 13,565,654 votes, subject to a maximum voting percentage cap of between 4.99% and 19.99% of the votes outstanding set at the discretion of each holder of Series B Preferred Stock.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities as well as any common stock that the person has the right to acquire within 60 days of March 12, 2026 through the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

	Beneficially Ownership Common Stock		
	Shares	Percentage	Percentage of Voting Power
Name of beneficial owner 5% shareholders:			
Brian P. Hannasch (1)	1,139,374	10.2%	8.4%
Bigger Capital Fund LP (2)	863,538	7.7%	6.3%
Rosalind Master Fund LP (3) (8)	1,184,208	9.6%	8.0%
Named executive officers and directors:			
Brian Carrico (4)	340,118	3.0%	2.5%
Timothy Henrichs	-	*	*
Adrian Miranda (5)	337,204	2.9%	2.4%
Thomas Carrico (6)	311,236	2.7%	2.2%
Christopher Robin Brown	1,044,617	9.3%	7.7%
Bradley Mitch Watkins	46,335	*	*
Beth Keyser	46,335	*	*
Kristin Ferge	35,938	*	*
Gilad Aharon(7)	412,778	3.7%	3.0%
All executive officers and directors as a group (nine (9) persons)	**2,574,561**	**21.6%**	**17.8%**

* Less than 1%.

(1) Shares of common stock beneficially owned consist of (i) 1,126,522 shares of common stock and (ii) warrants to purchase 12,852 shares of common stock.
(2) The business address for Bigger Capital Fund LP is 11700 West Charleston Boulevard 170-659, Las Vegas, NV 89135. Shares of common stock beneficially owned consist of (i) 797,400 shares of common stock and (ii) warrants to purchase 66,138 shares of common stock.
(3) The business address for Rosalind Master Fund LP is c/o Rosalind Advisors, Inc., 15 Wellesley Street West, Suite 326, Toronto, ON, Canada M4Y 0G7. Shares of beneficially owned common stock consist of 1,890,756 shares of common stock issuable upon conversion of 1,890,756 shares of Series B Preferred Stock, subject to an ownership cap of 9.99%, which equals 1,184,208 shares. 1,890,756 shares of Series B Preferred Stock entitle Rosalind Master Fund LP to 1,184,208 votes, subject to a maximum percentage of 9.99%.
(4) Shares of common stock beneficially owned consist of (i) 20,118 shares of common stock and (ii) 320,000 stock options.
(5) Shares of common stock beneficially owned consist of 337,204 stock options.
(6) Shares of common stock beneficially owned consist of (i) 5,000 shares of common stock and (ii) 306,236 stock options.
(7) Shares of common stock beneficially owned consist of (i) 307,736 shares of common stock and (ii) 105,042 shares of common stock issuable upon conversion of 105,042 shares of Series B Preferred Stock. 105,042 shares of Series B Preferred Stock entitle Gil Aharon to 65,787 votes.
(8) Mr. Aharon has indirect ownership over Rosalind Master Fund LP.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions since January 1, 2024, to which we have been a party in which the amount involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent (1%) of the average of our total assets at year-end for the prior two fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Item 11. Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

The Company has two demand notes receivable from its two founding shareholders related to the sale of common stock on January 1, 2016. The initial balances of both notes were $506,400, with interest calculated monthly based on applicable federal rates. No payments have been received on the notes. As of December 31, 2025, the balances of both notes were $506,400. The entire $1,012,800 balance has been fully reserved as of December 31, 2025.

The Company was granted an exclusive, worldwide non-transferable, royalty-free license for the auricular portion of certain patents owned by a limited liability company in which the Company's President and Chief Executive Officer and Chief Regulatory, Compliance and Privacy Officer both maintain an ownership interest. The license allows for the development, marketing and sales of electro-therapy treatments by stimulation of cranial nerves, cranial nerve branches, auricular nerves, auricular nerve branches, auricular nerve bundles and auricular anatomical structures in human patients. The exclusive license agreement expires on October 18, 2037, may be terminated by either party upon 60 days prior written notice and requires the Company to pay costs associated with the maintenance, prosecution and continuation of patent filings. The Company's Board of Directors pre-approved the reimbursement of up to $10,000 for the year ended December 31, 2025. License costs incurred were $4,412 and $4,973 for the years ended December 31, 2025 and 2024, respectively. No amounts were owed to the limited liability company as of December 31, 2025 and 2024, respectively.

From time to time, a member of the Company's Board of Directors purchases NeuroStim devices at cost to conduct research and development activities. The Company's Board of Directors pre-approved the sale of these NeuroStim devices up to $16,000 for the year ended December 31, 2025. The Company sold NeuroStim devices totaling $9,380 and $3,522 for the years ended December 31, 2025 and 2024, respectively, under this program.

The Company's former Chief Financial Officer was contracted for certain accounting and tax services on a continuous basis through a through a third-party public accounting firm. He was the firm's managing partner and majority shareholder. The services totaled $44,365 and $207,103 for the years ended December 31, 2025 and 2024, respectively. The Company owed the third-party accounting firm for open invoices of $2,578 and $4,173 that are included in accounts payable in the Balance Sheets as of December 31, 2025 and 2024, respectively. On June 28, 2024, the Company also issued 20,000 common shares with a fair value $55,600 to the former Chief Financial Officer for services rendered during the IPO process.

We have adopted a formal policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our Audit Committee, or other independent members of our Board of Directors if it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal shareholder, or any of their immediate family members or affiliates, in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Fees Billed for Audit and Non-Audit Services

The following table presents for each of the last two fiscal years the aggregate fees billed in connection with the audits of our financial statements and other professional services rendered by our independent registered public accounting firm Rosenberg Rich Baker Berman, P.A.

	2025	2024
Audit Fees (1)	$ 176,700	$ 181,195

(1) *Audit Fees*. These are fees for professional services for the audit of our annual financial statements, and for the review of the financial statements included in our filings on Form 10-K and Form 10-Q, and for services that are normally provided in connection with statutory and regulatory filings or engagements.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financial statements and Report of Independent Registered Public Accounting Firm are listed in the "Index to Financial Statements and Schedules" on page F-1 and included from F-2 onwards.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission (the "Commission") are either not required under the related instructions, are not applicable (and therefore have been omitted), or the required disclosures are contained in the financial statements included herein.

3. Exhibits (including those incorporated by reference).

(b) Exhibits

Exhibit Number	Exhibit Description
3.1	Certificate of Incorporation (incorporated by reference to exhibit 3.1 to Registration Statement on Form S-1, filed on January 10, 2023)
3.2	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to exhibit 3.2 to Registration Statement on Form S-1, filed on January 26, 2023)
3.3	Certificate of Amendment to the Certificate of Incorporation of Neuraxis, Inc., dated August 22, 2024 (incorporated by reference to exhibit 3.1 to Quarterly Report on Form10-Q, filed on November 12, 2024)
3.4	Certificate of Designation of Series B Preferred Stock, dated August 22, 2024 (incorporated by reference to exhibit 3.2 to Quarterly Report on Form10-Q, filed on November 12, 2024)
3.6	Amendment No. 1 to Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock (incorporated by reference to exhibit 3.1 to current report on Form 8-K, furnished to the SEC on November 21, 2024)
3.7	Bylaws (incorporated by reference to exhibit 3.3 to Registration Statement on Form S-1, filed on January 10, 2023)
4.1	Description of the Company's Securities (incorporated by reference to exhibit 4.1 to annual report on Form 10-K, filed with the SEC on March 20, 2025)
4.2	Second Amendment to Shareholders' Agreement, dated January 8, 2023 (incorporated by reference to exhibit 4.21 to Registration Statement on Form S-1, filed on January 10, 2023)
10.1†	Employment Agreement between Neuraxis, Inc. and Brian Carrico, dated as of August 9, 2022 (incorporated by reference to exhibit 10.12 to Registration Statement on Form S-1, filed on January 10, 2023)
10.2†	First Amendment to Executive Employment Agreement between Neuraxis, Inc. and Brian Carrico, dated as of May 4, 2023 (incorporated by reference to exhibit 10.13 to Registration Statement on Form S-1, filed on June 1, 2023)
10.3†	Employment Agreement between Neuraxis, Inc. and Adrian Miranda, dated as of August 17, 2022 (incorporated by reference to exhibit 10.13 to Registration Statement on Form S-1, filed on January 10, 2023)
10.4†	Employment Agreement between Neuraxis, Inc. and Thomas Carrico, dated as of August 9, 2022 (incorporated by reference to exhibit 10.14 to Registration Statement on Form S-1, filed on January 10, 2023)

10.5†	First Amendment to Executive Employment Agreement between Neuraxis, Inc. and Thomas Carrico, dated as of May 4, 2023 (incorporated by reference to exhibit 10.16 to Registration Statement on Form S-1, filed on June 1, 2023)
10.6†	Employment Agreement between Neuraxis, Inc. and Dan Clarence, dated as of August 9, 2022 (incorporated by reference to exhibit 10.15 to Registration Statement on Form S-1, filed on January 10, 2023)
10.7†	First Amendment to Executive Employment Agreement between Neuraxis, Inc. and Dan Clarence, dated as of May 4, 2023 (incorporated by reference to exhibit 10.18 to Registration Statement on Form S-1, filed on June 1, 2023)
10.8†	Employment Agreement between Neuraxis, Inc. and Christopher Robin Brown, dated as of August 9, 2022 (incorporated by reference to exhibit 10.16 to Registration Statement on Form S-1, filed on January 10, 2023)
10.9†	First Amendment to Executive Employment Agreement between Neuraxis, Inc. and Christopher Robin Brown, dated as of May 4, 2023 (incorporated by reference to exhibit 10.20 to Registration Statement on Form S-1, filed on June 1, 2023)
10.10†	Employment Agreement between Neuraxis, Inc. and Gary Peterson, dated as of August 9, 2022 (incorporated by reference to exhibit 10.17 to Registration Statement on Form S-1, filed on January 10, 2023)
10.11†	First Amendment to Executive Employment Agreement between Neuraxis, Inc. and Gary Peterson, dated as of May 4, 2023 (incorporated by reference to exhibit 10.22 to Registration Statement on Form S-1, filed on June 1, 2023)
10.12†	Innovative Health Solutions, Inc. 2017 Stock Compensation Plan, as amended (incorporated by reference to exhibit 10.20 to Registration Statement on Form S-1, filed on January 10, 2023)
10.13†	Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan (incorporated by reference to exhibit 10.21 to Registration Statement on Form S-1, filed on January 10, 2023)
10.14†	First Amendment to Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan (incorporated by reference to exhibit 10.26 to Registration Statement on Form S-1, filed on January 26, 2023)
10.15	Securities purchase agreement, dated November 9, 2023, between the Company and Flagstaff International, LLC (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on November 14, 2023)
10.16	Registration rights agreement, dated November 9, 2023, between the Company and Flagstaff International, LLC (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on November 14, 2023)
10.21	Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on February 15, 2024)
10.22	Form of Convertible Promissory Note (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on February 15, 2024)
10.23	Form of Registration Rights Agreement (incorporated by reference to exhibit 10.3 to current report on Form 8-K, furnished to the SEC on February 15, 2024)
10.24	First Amendment to Securities Purchase Agreement, dated February 12, 2024, between the Company and Flagstaff International (incorporated by reference to exhibit 10.4 to current report on Form 8-K, furnished to the SEC on February 15, 2024)
10.25	Third Amendment to Securities Purchase Agreement, dated March 22, 2024, between the Company and Flagstaff International, LLC (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on March 28, 2024)
10.26	Form of Convertible Promissory Note issued to Flagstaff International, LLC (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on March 28, 2024)
10.27	Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on May 28, 2024)
10.28	Form of Convertible Promissory Note (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on May 28, 2024)
10.29	Form of Registration Rights Agreement (incorporated by reference to exhibit 10.3 to current report on Form 8-K, furnished to the SEC on May 28, 2024)

10.30†	Form of Unrestricted Stock Award Agreement by and between NeurAxis, Inc. and Grantees dated on July 1, 2024 (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on July 5, 2024)
10.31	Fourth Amendment to Securities Purchase Agreement, dated October 12, 2024, between the Company and Flagstaff International, LLC (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on October 18, 2024)
10.32	Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on October 18, 2024)
10.33	Form of Registration Rights Agreement (incorporated by reference to exhibit 10.3 to current report on Form 8-K, furnished to the SEC on October 18, 2024)
10.34	Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on November 15, 2024)
10.35	Form of Registration Rights Agreement (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on November 15, 2024)
10.36	Settlement Agreement and Mutual Release, dated May 15, 2025 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K, furnished to the SEC on May 21, 2025)
10.37	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to current report on Form 8-K, furnished to the SEC on May 22, 2025)
10.38	Termination Agreement, dated July 1, 2025, by and between Neuraxis, Inc. and Masimo Corporation (incorporated by reference to Exhibit 10.1 to current report on Form 8-K, furnished to the SEC on July 3.2025)
10.39	Neuraxis, Inc. 2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to current report on Form 8-K, furnished to the SEC on July 3, 2025)
10.40	At The Market Offering Agreement, dated August 29, 2025, by and between Neuraxis, Inc, and Craig-Hallum Capital Group LLC (incorporated by reference to Exhibit 10.1 to current report on Form 8-K furnished to the SEC on September 2, 2025)
19.1	Insider Trading Policy (incorporated by reference to exhibit 19.1 to annual report on Form 10-K, filed with the SEC on March 20, 2025)
21.1	List of Subsidiaries of Neuraxis, Inc. (incorporated by reference to exhibit 21.1 to Registration Statement on Form S-1, filed on January 10, 2023)
23.1*	Consent of Rosenberg Rich Baker Berman, P.A.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act Of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act Of 2002
32.1**	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002
97.1	NeurAxis, Inc. Compensation Recovery Policy (incorporated by reference to exhibit 97.1 to Annual Report on Form 10-K, filed on April 16, 2024)
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Executive compensation plan or arrangement.
* Filed herewith.
** Furnished herewith.

ITEM 16. FORM 10-K SUMMARY

Not Applicable.

FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Neuraxis, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NeurAxis, Inc. (the Company) as of December 31, 2025 and 2024, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred losses and negative cash flows since inception and will need substantial capital to support its operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Rosenberg Rich Baker Berman, P.A.

We have served as the Company's auditor since 2022.

Somerset, New Jersey
March 19, 2026

Neuraxis, Inc.
Balance Sheets

	December 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	**$ 4,965,072**	$ 3,696,870
Accounts receivable, net of credit losses of $7,326 and $5,000 as of December 31, 2025 and 2024, respectively	**195,703**	244,618
Inventories, net of reserves of $34,524 and $4,454 as of December 31, 2025 and 2024, respectively	**257,132**	44,328
Prepaids and other current assets	**315,283**	280,367
Total current assets	**5,733,190**	4,266,183
Property and Equipment, at Cost:	**382,465**	464,402
Less - accumulated depreciation	**(306,901)**	(374,420)
Property and equipment, net	**75,564**	89,982
Other Assets:		
Operating lease right of use asset, net	**261,565**	284,656
Intangible assets, net	**274,778**	96,588
Other non-current assets	**58,939**	20,163
Total Assets	**$ 6,404,036**	$ 4,757,572

Notes to financial statements are an integral part of these statements.

Neuraxis, Inc.
Balance Sheets

	December 31, 2025	December 31, 2024
Liabilities		
Current Liabilities:		
Accounts payable	**$ 139,365**	$ 596,946
Accrued expenses	**2,393,229**	1,577,780
Notes payable	**148,293**	154,152
Current portion of operating lease payable	**65,752**	62,754
Customer deposits	**28,660**	32,527
Warrant liabilities	**16,800**	9,166
Total current liabilities	**2,792,099**	2,433,325
Non-Current Liabilities:		
Operating lease payable, net of current portion	**202,566**	256,499
Other non-current liabilities	9,999	-
Total non-current liabilities	**212,565**	256,499
Total liabilities	**3,004,664**	2,689,824
Commitments and contingencies (see note 17)		
Stockholders' Equity		
Convertible Series B Preferred stock, $0.001 par value; 5,000,000 shares authorized; 3,796,907 and 4,280,939 shares issued and outstanding as of December 31, 2025 and 2024, respectively	**3,797**	4,281
Common stock, $0.001 par value; 100,000,000 shares authorized; 10,652,812 and 6,990,227 issued and outstanding as of December 31, 2025 and 2024, respectively	**10,653**	6,990
Additional paid in capital	**67,985,089**	58,856,089
Accumulated deficit	**(64,600,167)**	(56,799,612)
Total stockholders' equity	**3,399,372**	2,067,748
Total Liabilities and Stockholders' Equity	**$ 6,404,036**	$ 4,757,572

Notes to financial statements are an integral part of these statements.

Neuraxis, Inc.
Statements of Operations

	For the Years Ended December 31,	
	2025	**2024**
Net sales	**$ 3,569,282**	$ 2,685,925
Cost of goods sold	**562,916**	362,002
Gross profit	**3,006,366**	2,323,923
Selling expenses	**2,279,974**	1,468,884
Research and development	**493,611**	433,614
General and administrative	**8,062,689**	7,578,242
Operating loss	**(7,829,908)**	(7,156,817)
Other income (expense):		
Financing charges	**(30,240)**	(230,824)
Interest expense	**(73,969)**	(174,328)
Change in fair value of warrant liability	**(7,634)**	(941)
Amortization of debt discount and issuance cost	**—**	(126,387)
Extinguishment of debt liabilities	**—**	—
Other income	**141,196**	33,620
Other expense	**—**	(585,824)
Total other income (expense), net	**29,353**	(1,084,684)
Net loss	**$ (7,800,555)**	$ (8,241,501)
Preferred stock dividends	(814,597)	(211,268)
Net loss available to common stockholders	$ (8,615,152)	$ (8,452,769)
Per-share data		
Basic and diluted loss per share	**$ (0.95)**	$ (1.22)
Weighted average shares outstanding		
Basic and diluted	**9,083,399**	6,918,887

Notes to financial statements are an integral part of these statements.

Neuraxis, Inc.
Statements of Stockholders' Equity (Deficit)

	Convertible Series B Preferred Stock		Common Stock		Additional Paid In	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balances at December 31, 2023	-	$ -	6,508,897	$ 6,509	$ 47,148,361	$ (48,558,111)	$ (1,403,241)
Warrants exercised	-	-	11,000	11	26,169	-	26,180
Additional paid in capital from warrants issued under advisory agreement	-	-	-	-	157,745	-	157,745
Additional paid in capital from warrants issued as debt discount	-	-	-	-	97,465	-	97,465
Common stock issued from agreements	-	-	470,330	470	1,407,541	-	1,408,011
Debt discount on mandatory conversion of convertible promissory notes to Series B Preferred Stock	-	-	-	-	(165,577)	-	(165,577)
Conversion of convertible promissory notes to Series B Preferred Stock	2,073,524	2,074	-	-	4,932,929	-	4,935,003
Issuance of Series B Preferred Stock	2,207,415	2,207	-	-	5,251,456	-	5,253,663
Net loss	-	-	-	-	-	(8,241,501)	(8,241,501)
Balances at December 31, 2024	4,280,939	4,281	6,990,227	6,990	58,856,089	(56,799,612)	2,067,748
Warrants exercised	-	-	946,525	947	1,097,245	-	1,098,192
Common stock issued from agreements	-	-	52,989	53	146,353	-	146,406
Conversion of Series B Preferred Stock to Common Stock	(484,032)	(484)	484,032	484	-	-	-
Issuance of common stock pursuant to shelf registration statement	-	-	2,161,645	2,162	7,726,261	-	7,728,423
Offering costs	-	-	-	-	(688,804)	-	(688,804)
Additional paid in capital from restricted stock units	-	-	-	-	251,110	-	251,110
Common stock issued under the 2022 Omnibus Securities and Incentive Plan	-	-	17,394	17	(17)	-	-
Stock-based compensation	-	-	-	-	596,852	-	596,852
Net loss	-	-	-	-	-	(7,800,555)	(7,800,555)
Balances at December 31, 2025	3,796,907	$ 3,797	10,652,812	$ 10,653	$ 67,985,089	$ (64,600,167)	$ 3,399,372

Notes to financial statements are an integral part of these statements.

Neuraxis, Inc.
Statements of Cash Flows

	For the Years Ended December 31,	
	2025	**2024**
Cash Flows from Operating Activities		
Net loss	**$ (7,800,555)**	$ (8,241,501)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization of debt discount and issuance cost	**—**	126,387
Depreciation and amortization	**59,501**	37,831
Provisions for losses on accounts receivable	**2,326**	7,395
Provision for losses on inventory	**30,070**	4,454
Loss on disposal of property and equipment	**7,878**	—
Non-cash lease expense	**23,092**	32,075
Stock based compensation	**596,852**	227,000
Issuance of common stock for non-cash consideration	**—**	1,177,187
Fair value of warrants issued for non-cash consideration	**—**	157,745
Finance charges	**30,240**	230,824
Change in fair value of warrant liabilities	**7,634**	941
Changes in operating assets and liabilities:		
Accounts receivable	**46,589**	(178,845)
Inventory	**(242,874)**	(32,500)
Prepaids and other current assets	**240,975**	56,157
Accounts payable	**(457,583)**	(607,273)
Accrued expenses	**1,082,727**	949,693
Customer deposits	**(3,867)**	(42,420)
Operating lease liability	**(50,935)**	(3,414)
Other non-current liabilities	**(4,913)**	—
Net cash used by operating activities	**(6,432,843)**	(6,098,264)
Cash Flows from Investing Activities		
Additions to property and equipment	**(31,150)**	(27,776)
Additions to intangible assets	**(100,000)**	—
Net cash used by investing activities	**(131,150)**	(27,776)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	**7,728,423**	—
Proceeds from issuance of Series B preferred stock	**—**	5,253,663
Deferred offering costs paid	**(712,669)**	—
Proceeds from exercised warrants	**1,098,192**	26,180
Principal payments on notes payable	**(281,751)**	(275,994)
Proceeds from convertible notes	**—**	4,935,003
Financing fees paid	**—**	(194,502)
Net cash provided by financing activities	**7,832,195**	9,744,350
Net Increase in Cash and Cash Equivalents	**1,268,202**	3,618,310
Cash and Cash Equivalents at Beginning of Period	**3,696,870**	78,560
Cash and Cash Equivalents at End of Period	**$ 4,965,072**	$ 3,696,870
Supplemental Disclosure of Operating Activities		
Cash paid for interest	**$ 11,854**	$ 33,830
Cash paid for federal income taxes	**—**	—
Cash refunded for state income taxes	**13,140**	10,164
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Recognition of right of use asset	**$ 37,970**	$ 284,339
Derecognition of right of use asset	**29,014**	—
Conversion of convertible promissory notes to Series B preferred stock	**—**	4,935,000
Fair value of warrants from debt discount in convertible notes classified as additional paid in capital	**—**	97,465
Write-off of debt discount on convertible notes classified as additional paid in capital	**—**	165,577
Issuance of note payable to financing company for insurance premiums and software subscription	**292,253**	282,086
Common stock issued upon cashless exercise of warrants	**186**	—
Common stock issued upon cashless conversion of Series B Preferred Stock	**484**	—
Common stock issued for services accrued as of December 31, 2024	**112,493**	—
Common stock issued upon settlement of certain claims	**3,673**	—
Intangible asset purchase	**100,000**	—

Notes to financial statements are an integral part of these statements.

Neuraxis, Inc.
Notes to Financial Statements

1. Basis of Presentation, Organization and Other Matters

Neuraxis, Inc. ("we," "us," the "Company," or "Neuraxis") was established in 2011 and incorporated in the state of Indiana in 2012 under the name of Innovative Health Solutions, Inc. The name was changed to NeurAxis, Inc. in 2022 when the Company filed a Certificate of Conversion to become a Delaware corporation.

The Company is headquartered in Carmel, Indiana, and specializes in the development, production, and sale of medical neuromodulation devices. The Company has developed four FDA cleared products: (i) IB-Stim (DEN180057, 2019), (ii) Rectal Expulsion Device ("RED") (K242304, 2024), (iii) NSS-2 Bridge (DEN170018, 2017) and (iv) the original 510(K) clearance (K140530, 2014).

- IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) device that is indicated in patients 8 years and older with functional abdominal pain associated with irritable bowel syndrome, functional dyspepsia (FD) and associated FD nausea symptoms.

- RED is indicated to evaluate the neuromuscular function of a patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity patients who experience desire or urge to defecate at lower volumes of distention. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

- The NSS-2 Bridge is a percutaneous nerve field stimulator (PNFS) device indicated for use in the reduction of the symptoms of opioid withdrawal and was licensed to Masimo Corporation ("Masimo"). Masimo marketed and sold this product as its Masimo Bridge. On July 1, 2025, The Company terminated the NSS-2 Bridge license with Masimo in exchange for $200,000 of consideration payable of which $100,000 was paid on December 31, 2025 and $100,000 is due June 30, 2026. The termination agreement allowed the Company to recapture the rights to the trademark (U.S. Registration No. 7,394,465) and two patent applications (Application No. 18/821/255 and Application No. 29/960.608) that were originally licensed to Masimo on April 9, 2020.

- The original 510(K) device was the EAD, an electroacupuncture device, now called NeuroStim. The EAD is no longer being manufactured, sold or distributed but reserved only for research purposes.

2. Summary of Significant Accounting Policies

The summary of significant accounting policies of Neuraxis, Inc. is presented to assist in understanding the Company's financial statements. The financial statements and notes are representations of the Company's management, who are responsible for their integrity and objectivity. These accounting policies conform to U.S. generally accepted accounting principles and have been consistently applied in the preparation of the financial statements.

Use of Estimates and Critical Accounting Estimates and Assumptions

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

These significant accounting estimates or assumptions bear the risk of change due to the fact that there are uncertainties attached to these estimates or assumptions, and certain estimates or assumptions are difficult to measure or value.

Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience, and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. The Company uses estimates in accounting for, among other items, revenue recognition, allowance for credit losses, stock-based compensation, income tax provisions, excess and obsolete inventory reserve, and impairment of property and equipment, and intellectual property. Actual results could differ from those estimates.

Reclassification of Prior Year Amounts

Certain prior year amounts have been reclassified to conform to current period presentation. The Company reclassified $1,144,176 of general and administrative expenses to selling expenses in the Statements of Operations for the year ended December 31, 2024. The Company also reclassified $227,507 of general and administrative expenses to research and development expenses in the Statements of Operations for the year ended December 31, 2024. These reclassifications had no impact on previously reported net loss, total assets, total liabilities or total equity.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. The Company did not hold any cash equivalents as of December 31, 2025 and 2024.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable are stated at the amount management expects to collect from outstanding balances, net of an allowance for credit losses. Management evaluates many factors when determining the collectability of specific customer accounts, including, but not limited to, creditworthiness, past transaction and payment history, current economic industry trends and changes in payment terms. Management used assumptions and judgment based on the best available facts and circumstances to estimate and record an allowance. The Company monitors accounts receivable and estimates the allowance for lifetime expected credit losses. Estimates of expected credit losses are based on historical collection experience, an aging schedule, and other factors, including those related to current and forecasted market conditions and events. The allowance for credit losses was $7,326 and $5,000 as of December 31, 2025 and 2024, respectively. The Company recorded credit losses for the years ended December 31, 2025 and 2024 of $2,326 and $7,395, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the weighted average method. The inventory is comprised of finished medical devices on hand. Certain components within the devices have an expiration date that are removed from current inventory and expensed at the date of expiration. The Company has reserved for expired inventory as charges to cost of goods sold of $19,973 and $0 for the years ended December 31, 2025 and 2024, respectively, and research devices as charges to research and development of $10,097 and $4,454 for the for the years ended December 31, 2025 and 2024, respectively. Inventory reserves totalled $34,524 and $4,454 as of December 31, 2025 and 2024, respectively.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets.

Depreciation is calculated using the following estimated useful lives:

Classification	Years
Machinery and Equipment	7-10
Furniture and Fixtures	3-10
Computer Hardware	5
Leasehold Improvements	10-20

Depreciation expense was $37,691 and $26,346 during the years ended December 31, 2025 and 2024, respectively.

Intangible Assets

Intangible assets consist of software, patents, a trademark and a license. Intangible assets are stated at their historical cost and amortized on a straight-line basis over their expected useful lives. Capitalized patent costs, net of accumulated amortization, includes legal costs incurred for patent applications. In accordance with ASC 350, once a patent is granted, the capitalized patent costs are amortized over the remaining life of the patent using the straight-line method. If the patent is not granted, we write off any capitalized patent costs at that time.

The Company purchased a trademark related to the Company’s name for $50,000. The trademark does not have a determinate life and therefore the cost is not being amortized.

We review intangible assets for impairment annually or when events or circumstances indicate that their carrying amount may not be recoverable. During the years ended December 31, 2025, and 2024, the Company recorded no intangible asset impairment charges.

Amortization expense was $21,810 and $11,485 during the years ended December 31, 2025 and 2024, respectively.

Cloud Computing Costs

The Company utilizes cloud computing arrangements that are hosted by third-party vendors to support its operations. The Company accounts for these arrangements as service contracts. Implementation costs incurred in connection with cloud computing arrangements are evaluated in accordance with the guidance for internal-use software. Cost incurred during the application development state, including configuration, coding, testing and integration activities, are capitalized. Costs incurred during the preliminary project and post-implementation stages, as well as costs related to data conversion and ongoing support, are expensed as incurred. Payroll and payroll-related costs for employees directly associated with the project are also expensed as incurred.

Cloud computing implementation costs are included in Intangible Assets on the Company's consolidated balance sheets and amortized on a straight-line basis over the term of the relating hosting arrangement, including periods covered by renewal options that are reasonably assured to be exercised. The Company evaluates cloud computing implementation costs for impairment annually or when events or circumstances indicated that their carrying amount may not be recoverable.

Cloud computing implementation costs, net of accumulated amortization, were $19,909 and $28,454 as of December 31, 2025 and 2024, respectively. Amortization expense related to cloud computing implementation costs totaled $8,545 and $8,545 for the years ended December 31, 2025 and 2024, respectively.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable, we compare the carrying amount of the asset group to future undiscounted net cash flows, excluding interest costs, expected to be generated by the asset group and their ultimate disposition. If the sum of the undiscounted cash flows is less than the carrying value, the impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell.

Selling Expenses

Selling expenses consist primarily of advertising, marketing and promotion of the Company's products including salaries and related personnel costs and travel expenses. Advertising costs are expensed as incurred and amounted to $546,628 and $232,125 for the years ended December 31, 2025 and 2024, respectively.

Research and Development

Research and development expenses consist primarily of clinical research studies, new product development, costs of materials and supplies used in research and development activities and salaries and related personnel costs for employees engaged in research and development activities of IB-Stim and RED as we seek FDA clearance for other indications. Research and development costs are expensed as incurred.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts, and the tax bases of existing assets and liabilities for the loss and credit carry forwards using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether a tax position will be sustained upon examination. If it is more likely than not that a position will be sustained, the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Management's evaluation of the Company's deferred tax assets and liabilities did not have a material effect on the Company's financial statements. Furthermore, no interest or penalties have been accrued as of December 31, 2025 and 2024 or charged to expense for the years then ended.

Warrant Liabilities

Management evaluates all of the Company's financial instruments, including issued warrants to purchase its common stock, to determine if such instruments are liabilities pursuant to ASC 480 and ASC 815-15. The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period.

The Company utilizes a Black-Scholes option-pricing model to compute the fair value of the derivative and to mark-to-market the fair value of the derivative at each balance sheet date. The inputs utilized in the application of the Black-Scholes option-pricing model included an exercise price, the stock price as of the valuation date, an expected remaining term of each warrant as of the valuation date, estimated volatility, a dividend yield, and a risk-free rate. The Company records the change in the fair value of the warrant as other income or expense in the statements of operations.

Fair Value Measurements

The Company accounts for financial instruments in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*, which establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described as follows:

Level 1 – Quoted prices (unadjusted) for identical unrestricted assets or liabilities in active markets that the reporting entity has the ability to access as of the measurement date.

Level 2 – Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or financial instruments for which all significant inputs are observable or can be corroborated by observable market date, either directly or indirectly.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. These unobservable inputs reflect that reporting entity's own assumptions about what market participants would use in pricing the asset or liability. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value require significant management judgment or estimation.

The Company's Level 1 assets and liabilities include cash, accounts receivable, accounts payable, prepaids, and other current assets. Management believes the estimated fair value of these accounts on December 31, 2025 approximate their carrying value as reflected in the balance sheets due to the short-term nature of these instruments or the use of market interest rates for debt instruments.

The Company's Level 3 assets and liabilities include warrant liabilities and the floating lookback option provision in the Neuraxis, Inc. Employee Stock Purchase Plan. Inputs to determine fair value are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models. The valuation techniques involve management's estimates and judgment based on unobservable inputs. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Unobservable inputs used in the models are significant to the fair values of the assets and liabilities.

The following table provides a summary of the relevant assets and liabilities that are measured at fair value on a recurring basis:

	Total	Level 1	Level 2	Level 3	Valuation Methodology	Unobservable Inputs
Fair value of warrant liabilities as of December 31, 2025	$ 16,800	$ —	$ —	$ 16,800	Black-Scholes model	Project simulated cash flows
Fair value of warrant liabilities as of December 31, 2024	$ 9,166	$ —	$ —	$ 9,166	Black-Scholes model	Project simulated cash flows

There were no transfers between any of the levels during the years ended December 31, 2025 and 2024. In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's had no assets and liabilities that were measured on a nonrecurring basis as of December 31, 2025 and 2024.

Basic and Diluted Net Income (Loss) per Share

Basic earnings or loss per share ("EPS") is computed by dividing net income (loss), net of preferred stock dividends, by the weighted average number of common shares outstanding during the period. Diluted EPS is determined using the weighted average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents that were outstanding for the periods presented. In periods when losses are reported, which is the case for the years ended December 31, 2025 and 2024, the weighted average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive. Preferred stock dividends (neither declared nor paid) were $814,597 and $211,268 as of December 31, 2025 and 2024, respectively.

The Company had the following potentially dilutive common stock equivalents at December 31, 2025 and 2024:

	2025	2024
Options	1,319,394	1,319,394
Pre-Funded Warrants for Common Stock	—	289,779
Warrants	1,379,524	2,352,751
Series B Preferred Stock	3,796,907	4,280,939
Totals	6,495,825	8,242,863

The following table shows the calculation of the basic and diluted net loss per share and the effect of cumulative preferred stock dividends:

	For the Years Ended December 31,	
	2025	2024
Numerator		
Net loss	$ (7,800,555)	(8,241,501)
Cumulative preferred stock dividends	(814,597)	(211,268)
Net loss available to common stockholders	(8,615,152)	(8,452,769)
Denominator		
Weighted-average shares of common stock outstanding - basic and diluted	9,083,399	6,918,887
Basic and diluted net loss per share	$ (0.95)	$ (1.22)

Stock-Based Compensation

The Company accounts for all stock-based awards at fair value. The Company recognizes its stock-based compensation expense using the straight-line method. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture.

The Company accounts for the granting of stock options and restricted stock units to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee stock options and restricted stock units is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder is recorded in additional paid-in capital, while the par value of the shares received is reclassified from additional paid-in-capital to common stock. Upon vesting of restricted stock units, the par value of the shares issued are reclassified from additional paid-in-capital to common stock.

Stock-based awards to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date.

The Company uses the Black-Scholes option-pricing model to calculate the fair value of stock options. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when its customer obtains control of promised goods, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all the consideration it is entitled to in exchange for the goods it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods promised within each contract and determines those that are performance obligations and assesses whether each promised good is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

The Company offers a Patient Assistance Program for pediatric patients without insurance coverage for IB-Stim. This program offers potential self-pay discounts for IB-Stim, based upon household income and size.

Also, the Company offers providers an opt-in program to address adequate insurance claim payments on IB-Stim devices. This program may extend a rebate or invoice credit where the insurance payment and patient responsibility (i.e., deductible, co-payment, and/or co-insurance amounts required by the Payer) are less than the acquisition cost of IB-Stim. The Company recognizes revenue at such a time that collection of the amount due is probable.

The following table disaggregates the Company's revenue based on the customer's location by state for the years ended December 31:

	2025	2024
California	$ 898,223	$ 778,209
Ohio	578,769	431,328
Massachusetts	265,201	154,407
Illinois	222,389	246,217
Wisconsin	215,431	157,786
Florida	143,947	149,985
All other states	1,245,322	767,993
	$ 3,569,282	$ 2,685,925

Certain economic factors affect the nature, amount, timing, and uncertainty of the Company's revenue and cash flows. All of the Company's products are sold to healthcare customers including hospitals and clinics. Sales to healthcare customers are subject to seasonality and have a mild correlation with economic cycles. All of the Company's sales are to customers located within the United States. Sales contracts consist of purchase orders that are short-term (i.e., less than or equal to one year).

The Company typically satisfies its performance obligations for goods at a point in time as they are received at the customer's destination (rather than over time). Goods are shipped by common carrier to customers under FOB destination terms. As such, ownership of goods in transit is transferred to the customer upon receipt as the Company bears the associated risks (e.g., loss, damage or delay). Management typically relies on shipping information from common carriers to evaluate when the customer has obtained control of the goods. Shipping and handling costs are recorded as Cost of Goods Sold in the Statements of Operations.

The Company's contracts with customers typically do not involve variable consideration. The information that the Company uses to determine the transaction price for a contract is similar to the information that the Company's management uses in establishing the prices of goods to be sold.

Orders may not be cancelled after shipment. Customers may return devices if the goods are found to be defective, nonconforming, or otherwise do not meet the stated technical specifications. At the option of the customer, the Company shall either:

- Refund the price paid for any defective or nonconforming products.
- Supply and deliver to the customer replacement conforming products.
- Reimburse the customer for the cost of repairing any defective or nonconforming products.

At the time revenue is recognized, the Company estimates expected returns and excludes those amounts from revenue. The Company also reflects the effects of expected returns on the Company's financial position and periodically adjusts those accounts to reflect its actual return experience. Estimated returns totalled $13,824 and $5,000 as of December 31, 2025 and 2024, respectively.

Payment for goods sold by the Company is typically due after an invoice is sent to the customer, within 30 days. The Company does not offer discounts if the customer pays some or all of an invoiced amount prior to the due date. None of the Company's contracts have a significant financing component.

Customer deposits are contract liabilities under ASC 606. As of December 31, 2025, and 2024, the Company had customer deposits of $28,660 and $32,527, respectively.

Medical devices that the Company contracts to sell and transfer to customers are manufactured by two separate and distinct third-party manufacturers located within the states of Indiana and Michigan. In no case does the Company act as an agent (i.e., the Company does not provide a service of arranging for another party to transfer goods to the customer).

Leases

In accordance with ASC 842, at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense, or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date. The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all the contract consideration to the lease component only.

Concentrations of Credit Risk

The Company's business activity consists of the sale of medical neuromodulation devices to doctors, clinics, and hospitals across the country. Receivables consist of unsecured amounts due from customers. The table below sets forth the Company's customers that accounted for greater than 10% of its net accounts receivable for the years ended December 31, 2025 and 2024, respectively.

	2025	Percentage of Net Accounts Receivable	2024	Percentage of Net Accounts Receivable
Customer A	$ 43,020	22%	$ -	0%
Customer B	-	0%	119,616	49%
	$ 43,020	22%	$ 119,616	49%

The table below sets forth the Company's customers that accounted for greater than 10% of its net sales for the years ended December 31, 2025 and 2024, respectively.

	2025	Percentage of Net Sales	2024	Percentage of Net Sales
Customer A	$ **512,288**	14%	$ 396,950	15%
Customer B	**493,444**	14%	521,810	20%
	$ **1,005,732**	28%	$ 918,760	35%

From time to time, the Company's bank balances may exceed the FDIC limit of $250,000. As of December 31, 2025 and 2024, the Company had $4,465,073 and $3,263,618 of its cash balance uninsured, respectively.

Going Concern

We have incurred losses and negative cash flows since inception and have funded our operations primarily with a combination of sales, debt, and the sale of capital stock. As of December 31, 2025, we had stockholders' equity of $3,399,372, short-term outstanding borrowings of $148,293, cash of $4,965,072 and a working capital surplus of $2,941,091.

Our future capital requirements will depend upon many factors, including progress with developing, manufacturing, and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes and overall economic conditions in our target markets. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products from customers currently identified in our sales pipeline and to new customers as well. The primary activity that will drive all customers and revenues is the adoption of insurance coverage by commercial insurance carriers nationally which is a top priority of the Company. These activities, including our planned research and development efforts, will require significant uses of working capital through the rest of 2026 and beyond. Based on our current operating plans, we believe that our existing cash at the time of this filing will only be sufficient to meet our anticipated operating needs before the end of 2025.

Management evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date the financial statements are issued.

While the Company believes in the viability of its strategy to further implement its business plan and generate sufficient revenues and in its ability to raise additional funds by way of a public or private offering of its debt or equity securities, there can be no assurance that it will be able to do so on reasonable terms, or at all. The ability of the Company to continue as a going concern is dependent upon its ability to further implement its business plan and generate sufficient revenues and its ability to raise additional funds by way of a public or private offering. Neither future cash generated from operating activities, nor management's contingency plans to mitigate the risk and extend cash resources through the evaluation period, are considered probable. As a result, substantial doubt is deemed to exist about the Company's ability to continue as a going concern. As we continue to incur losses, our transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until doing so, we intend to fund future operations through additional dilutive or nondilutive financing. There can be no assurances, however, that additional funding will be available on terms acceptable to us, if at all.

The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires disclosure of (i) significant segment expenses, (ii) other segment items and (iii) the title and position of the Chief Operating Decision Maker ("CODM") on an annual and interim basis. Additionally, ASU 2023-07 requires that a public entity that has a single reportable segment provide all the disclosures required by Topic 280. Public business entities are required to adopt the standard for fiscal years beginning after December 15, 2023 and interim periods withing fiscal year beginning after December 15, 2024. Disclosures are required for all prior periods presented in the financial statements. The Company adopted the disclosure provisions of ASU 2023-07 as of December 31, 2024 as operations are managed through one reportable segment.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires the enhancement of income tax disclosures to provide better insight into how an entity's operations and related tax risks, planning and opportunities affect its tax rate and prospects for future cash flows. The enhanced disclosures require (i) specific categories in a tabular rate reconciliation including both amounts and percentages and (ii) additional information for reconciling items and income tax paid that meet a quantitative threshold. Public business entities are required to adopt the standard for annual periods beginning after December 15, 2024. The Company adopted the disclosure provisions of ASU 2023-09 as of December 31, 2025, on a prospective basis. The adoption of this guidance did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvement to the Accounting for Internal-Use Software*, which replaces project stage milestones with required capitalization when management has authorized and committed to funding the software project and it is probably that the project will be completed and the software will be used to perform the function intended. Depreciation expense and accumulated depreciation for internal-use software are also required to be disclosed for all periods presented. All entities are required to adopt the standard for fiscal years beginning after December 15, 2027 and interim periods within those annual reporting periods. Early adoption is permitted as of the beginning of an annual reporting period. The adoption is not expected to have a material impact on the Company's financial statements.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments—Credit Losses (Topic 326)*, which allows registrants to elect a practical expedient when estimating expected credit losses on accounts receivable. Under the practical expedient, an entity may assume that the current conditions as of the balance sheet date persist for the remaining life of the asset, thereby removing the requirement to generate forward-looking forecasts. All entities are required to adopt the standard prospectively for fiscal years beginning after December 15, 2025, and interim periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods. The adoption is not expected to have a material impact on the Company's financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic (220-40): Disaggregation of Income Statement Expenses*, which requires disclosures that disaggregate, in a tabular presentation, each relevant expense caption on the face of the income statement that includes inventory purchases, employee compensation, depreciation and intangible amortization expense. Additional disclosures are also required to provide a qualitative description of the amounts in an expense caption that are not separately disaggregated quantitatively and the total amount of selling expenses including a definition. Public business entities are required to adopt the standard for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. Disclosures are required for all prior periods presented in the financial statements. Although the standard requires enhanced disclosures, the adoption is not expected to have a material impact on the Company's financial statements.

3. Related Party Transactions

The Company has two demand notes receivable from shareholders related to the sale of common stock on January 1, 2016. Both notes' initial balances were $506,400, with interest calculated monthly based on applicable federal rates. No payments have been received on the notes. Since repayment is not assured, the Company has fully reserved for the entire balance of principal and interest. The current allowance is $1,241,559 as of December 31, 2025. The current loan balances are as follows:

December 31, 2025	Loan Receivable	Interest Receivable	Interest Income
Shareholder 1	$ 506,400	$ 114,447	$ 20,096
Shareholder 2	506,400	114,312	20,096
Principal Balance	1,012,800	228,759	40,192
Allowance for Collection Risk	(1,012,800)	(228,759)	(40,192)
Net Balance	$ —	$ —	$ —

December 31, 2024	Loan Receivable	Interest Receivable	Interest Income
Shareholder 1	$ 506,400	$ 94,351	$ 23,413
Shareholder 2	506,400	94,216	23,413
Principal Balance	1,012,800	188,567	46,826
Allowance for Collection Risk	(1,012,800)	(188,567)	(46,826)
Net Balance	$ —	$ —	$ —

The Company has loans payable to shareholders related to funding needs for operations. The current loan details for all related party loans are as follows:

December 31, 2025	Due Date	Interest Rate	Loan Balance	Interest & Service Fee Accrued	Interest Paid
Other Convertibles	Various	5.0%	—	66,648	—
Total			$ —	$ 66,648	$ —

December 31, 2024	Due Date	Interest Rate	Loan Balance	Interest & Service Fee Accrued	Interest Paid
Other Convertibles	Various	5.0%	—	66,648	—
Total			$ —	$ 66,648	$ —

The Company was granted an exclusive, worldwide non-transferable, royalty-free license for the auricular portion of certain patents owned by a limited liability company in which the Company's President and Chief Executive Officer and Chief Regulatory, Compliance and Privacy Officer both maintain an ownership interest. The license allows for the development, marketing and sales of electro-therapy treatments by stimulation of cranial nerves, cranial nerve branches, auricular nerves, auricular nerve branches, auricular nerve bundles and auricular anatomical structures in human patients. The exclusive license agreement expires on October 18, 2037, may be terminated by either party upon 60 days prior written notice and requires the Company to pay costs associated with the maintenance, prosecution and continuation of patent filings. The Company's Board of Directors pre-approved the reimbursement of up to $10,000 for the year ended December 31, 2025. License costs incurred were $4,412 and $4,973 for the years ended December 31, 2025 and 2024, respectively. No amounts were owed to the limited liability company as of December 31, 2025 and 2024, respectively.

From time to time, a member of the Company's Board of Directors purchases NeuroStim devices at cost to conduct research and development activities. The Company's Board of Directors pre-approved the sale of these NeuroStim devices up to $16,000 for the year ended December 31, 2025. The Company sold NeuroStim devices totaling $9,380 and $3,522 for the years ended December 31, 2025 and 2024, respectively, under this program.

The Company's former Chief Financial Officer through February 5, 2024 was contracted for certain accounting and tax services on a continuous basis through a through a third-party public accounting firm. He was the firm's managing partner and majority shareholder. The services totaled $44,365 and $207,103 for the years ended December 31, 2025 and 2024, respectively. The Company owed the third-party accounting firm for open invoices of $2,578 and $4,173 that are included in accounts payable in the Balance Sheets as of December 31, 2025 and 2024, respectively. On June 28, 2024, the Company also issued 20,000 common shares with a fair value $55,600 to the former Chief Financial Officer for services rendered during the IPO process.

4. Prepaids and Other Current Assets

Prepaid and other current assets consisted of the following:

	December 31, 2025	December 31, 2024
Prepaid insurance	$ 141,299	$ 186,028
Prepaid software subscriptions	103,390	39,834
Other	70,594	54,505
Total prepaids and other current assets	$ 315,283	$ 280,367

5. Property and Equipment

Property and equipment, net consists of the following:

	December 31, 2025	December 31, 2024
Machinery and equipment	$ 300,181	$ 282,181
Furniture and fixtures	37,403	111,036
Computer hardware	44,881	50,121
Leasehold improvements	-	21,064
Total property and equipment	382,465	464,402
Less: accumulated depreciation	(306,901)	(374,420)
Property and equipment, net	$ 75,564	$ 89,982

Depreciation expense was $37,691 and $26,346 for the years ended December 31, 2025 and 2024, respectively. The Company expects to record future depreciation expense totalling $32,136, $21,708, $10,123, $3,380, $2,028 and $6,189 for the years ending December 31, 2026, 2027, 2028, 2029, 2030 and thereafter, respectively.

6. Intangible Assets

Intangible assets, net consists of the following:

	December 31, 2025	December 31, 2024
Cloud computing implementation costs	$ 49,815	$ 49,815
Patents	232,464	32,463
Trademark	50,000	50,000
Licenses	-	1,000
Total intangible assets	332,279	133,278
Less: accumulated amortization	(57,501)	(36,690)
Intangible assets, net	$ 274,778	$ 96,588

On July 1, 2025, the Company terminated the NSS-2 Bridge license with Masimo in exchange for $200,000 of consideration payable of which $100,000 was paid on December 31, 2025, and $100,000 is due June 30, 2026. The termination agreement allowed the Company to recapture the rights to the trademark (U.S. Registration No. 7,394,465) and two patent applications (Application No. 18/821,225 and Application No. 29/960,608) that were licensed to Masimo on April 9, 2020 for use in the reduction of the symptoms of opioid withdrawal. The intellectual property will be amortized over its remaining patent life of approximately nine years.

The Company entered into an option agreement on April 12, 2023 to bring an optionor's invention to commercialization via a royalty-bearing licensing agreement. The agreement required an initial payment of $1,000 and was fully amortized in the year ended December 31, 2024.

Amortization expense was $21,810 and $11,485 for the years ended December 31, 2025 and 2024, respectively. The Company expects to record future amortization expense totalling $33,135, $33,135, $27,410, $24,591, $24,591 and $81,916 for the years ending December 31, 2026, 2027, 2028, 2029, 2030 and thereafter, respectively. The Company's trademark does not have a determinate life and therefore the cost is not being amortized.

7. Other Non-Current Assets

Other non-current assets consisted of the following

	December 31, 2025	December 31, 2024
Deferred offering costs	$ 23,864	$ —
Prepaid software subscriptions	14,912	—
Security deposit	20,163	20,163
Total other non-current assets	$ 58,939	$ 20,163

8. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Compensation and benefits	$ 1,359,993	$ 1,261,317
Settled litigation	692,683	—
NSS Bridge lease termination fee	100,000	—
Legal fees	65,714	43,891
Interest	66,648	66,648
Advisory fees	-	176,750
Other	108,191	29,174
Total accrued expenses	$ 2,393,229	$ 1,577,780

9. Notes Payable

Promissory Notes

On August 9, 2025, the Company entered into a $170,000 promissory note to finance the premiums of a business insurance policy, bearing interest at an annual rate of 7.45% and maturing on June 9, 2026, to replace the $210,000 promissory note entered into on August 9, 2024, with an annual interest rate of 7.40% that matured on June 9, 2025 in conjunction with the annual renewal period. On November 1, 2024, the Company entered into another promissory note with a principal balance of $64,328 to finance premiums of other business insurance policies, bearing interest at a rate of 7.65% per annum that matured on September 1, 2025.

On May 26, 2025, the Company also entered into a promissory note with a principal balance of $122,253 to finance subscription fees on certain software arrangements maturing on March 1, 2027.

The Company's outstanding principal on it promissory notes was $158,292, of which $9,999 is included in other non-current liabilities, and $154,152 as of December 31, 2025 and 2024, respectively.

2024 Convertible Notes

On November 8, 2023, the Company entered into a Securities Purchase Agreement ("SPA") with a shareholder for the issuance 1,260,504 shares of Series B Convertible Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock"), for an aggregate purchase price of $3,000,000 paid in 15 monthly installments of $200,000 each, commencing on the later of January 10, 2024 or a date after stockholder approval of an amendment to the Company's Certificate of Incorporation to authorize the creation of the Series B Preferred Stock. The Series B Preferred Stock was convertible at any time into shares of common stock of the Company without any further consideration. Following the issuance of the Series B Preferred Stock, it would rank senior to the common stock with respect to payments upon the liquidation, dissolution and winding up of the Company. Due to a delay in the stockholder approval, the Company amended the SPA on February 12, 2024 to issue a promissory note, due and payable on the earlier of 15 months or 12 months if the Series B Preferred Stock has not been authorized, convertible into Series B Convertible Preferred Stock with identical funding amounts and terms (the "$3,000,000 Convertible Promissory Note"). The shareholder funded $800,000 of the $3,000,000 commitment in 2024.

The Company then proceeded to enter into a series of incremental convertible promissory notes with other investors totaling $1,135,000 with terms identical to the $3,000,000 Convertible Promissory Note (collectively referred to as the "Original 2024 Convertible Promissory Notes") for an aggregate principal amount of $1,935,000.

The 2024 Original Convertible Promissory Notes earned interest at 8.5% per annum payable quarterly in either cash or common stock at the election of the Company. At any time following the date of shareholder approval to authorize the creation of Series B Preferred Stock prior to the maturity date, the investor may elect to convert all or part of the principal into the Company's Series B Preferred Stock at a conversion price per share equal to $2.38. Without limiting the forgoing, all principal amounts outstanding on the maturity date will automatically convert into the Company's Series B Preferred Stock. The Series B Preferred Stock is entitled to cumulative dividends at 8.5% per annum (whether or not declared) payable quarterly in either cash or common stock at the $2.38 conversion price at the election of the Company. Upon conversion to Series B Preferred Stock, the investor may elect, at its option at any time, to convert all or part of the Series B Preferred Stock plus accrued but unpaid dividends into an equivalent amount of common stock at the $2.38 conversion price.

Subsequently, the Company entered into three convertible promissory notes with related institutional accredited investors with terms similar to the Original 2024 Convertible Promissory Notes (collectively referred to as the "Amended 2024 Convertible Promissory Notes") for an additional principal amount of $3,000,000. Certain provisions to the SPA and Certificate of Designation previously issued on February 12, 2024 changed, including (i) the number of shares of preferred stock to be designated as Series B Preferred Stock was increased to 4,000,000 shares, (ii) the stated value of the Series B Preferred Stock was changed to $2.38 per share, (iii) the right to receive dividends will expire automatically on June 30, 2025, (iv) the liquidation rights will automatically expire on June 30, 2025, and (v) the number of shares of the common stock that a holder of Series B preferred stock is entitled to receive shall not exceed the maximum percentage chosen by the holder, which is initially set at between 4.99% and 19.99% until shareholder approval is obtained, of the number of outstanding shares of the common stock at the time of the conversion of the Series B Preferred Stock shares. On November 11, 2024, the Company's shareholders authorized an increase in the number of designated Series B preferred stock to 5,000,000 shares and extended the 8.5% per cumulative dividend period to December 31, 2026.

The maturity date was on the earlier of (i) June 21, 2025, (ii) upon written demand occurring on or after March 21, 2025 in the event that the Series B Preferred Stock has not been duly authorized on or before such date, or (iii) immediately upon the occurrence of an event of default. Automatic conversion into shares of Series B preferred stock (at a conversion price of $2.38 per share) would occur following the date of shareholder approval. In the event the Company failed to obtain shareholder approval before August 15, 2024, rights existed to convert the outstanding amount into shares of the common stock, at a price per share of $2.38.

As of August 15, 2024, the Company received $4,935,000 of the principal amount of the Amended 2024 Convertible Notes with the remainder due in monthly installments through March of 2025 resulting in an effective interest rate of 12.5%. On August 15, 2024, the Company's shareholders authorized 5,000,000 shares of preferred stock of which 4,000,000 shares were designated as $0.001 par value Series B preferred stock. Pursuant to the terms of the Amended 2024 Convertible Promissory Notes, the outstanding principal balance of $4,935,000 was mandatorily converted into 2,073,524 Series B Preferred Shares at a conversion price of $2.38. Upon the mandatory conversion, the unamortized debt discount of $165,577 was reclassified to Additional Paid-In-Capital in the Statements of Stockholders' Equity (Deficit).

Interest expense totalled $73,969 and $174,328 for the years ended December 31, 2025 and 2024, respectively. The Company's accrued interest totaled $66,648 as of December 31, 2025 and 2024.

10. Leases

Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the implicit interest rate is generally not readily determinable, the Company uses an incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate reflects the estimated rate of interest that the Company would pay to borrow on a collateralized basis over a similar economic environment. Lease expense for the operating lease is recognized on a straight-line basis over the lease term.

Leases may include renewal options, and the renewal option is included in the lease term if the Company concludes that it is reasonably certain that the option will be exercised. Certain leases may contain rent escalation clauses, either fixed or adjusted periodically for inflation of market rates, that are factored into the calculation of lease payments to the extent they are fixed and determinable at lease inception. The Company also has variable lease payments that do not depend on a rate or index, primarily for items such as common area maintenance and real estate taxes, which are recorded as expenses when incurred.

The Company's leases are comprised of operating leases for office space. At the inception of the lease, the Company determines whether the lease contract conveys the right to control the use of identified property for a period of time in exchange for consideration. Leases are classified as operating or finance leases at the commencement date of the lease. Operating leases are recorded as operating lease right-of-use assets, other current liabilities, and operating lease liabilities in the Balance Sheets. The Company did not have any finance leases at December 31, 2025 and 2024.

The Company has two leases consisting of office space in Batesville and Carmel, Indiana. The lease in Batesville, Indiana commenced on August 1, 2025, and has an initial term of three years, with automatic one year renewals subject to an annual 4% rent escalation, unless 60 day notice of vacating is given. On May 19, 2025, the Company terminated its prior lease in Versailles, Indiana, with a monthly lease payment of $1,800, effective July 31, 2025, without penalty due to relocation of the office space to Batesville, Indiana, with the same landlord. The current monthly lease payment is $2,000 with no escalations during the initial lease term. During the year ended December 31, 2025, the Company derecognized the right of use asset and operating lease liabilities of $29,014 and $29,286, respectively, related to the terminated lease in Versailles, Indiana. Correspondingly, the Company recognized a right of use asset and operating lease liabilities of $63,170 and $37,970, respectively, during the year ended December 31, 2025, related to the new lease in Batesville, Indiana. On June 13, 2025, the Company prepaid $25,200 towards the Batesville, Indiana monthly lease payments which will be amortized over the initial lease term. The lease in Carmel, Indiana commenced January 1, 2024, with an initial term of five years and five months. The monthly lease payment started at $6,721 with an annual increase of 2.5%. The Company was only obligated to pay an amount equal to 50% of the monthly base rent for the first 10 months of the term.

For the years ended December 31, 2025 and 2024, the Company recognized $99,899 and $96,177 of operating lease expense, including short-term lease expense and variable lease costs.

The following table presents information related to the Company's operating leases:

	December 31, 2025	December 31, 2024
Operating lease right-of-use assets	$ 261,565	$ 284,656
Current portion of operating lease payable	65,752	62,754
Operating lease liabilities	202,566	256,499
Total	$ 268,318	$ 319,253
Weighted-average remaining lease term (in years)	3.31	2.75
Weighted-average discount rate	15.0%	15.0%

As of December 31, 2025, the maturities of the Company's operating lease liabilities were as follows:

2026	$ 100,347
2027	102,456
2028	98,127
2029	38,025
Total lease payments	338,955
Less: imputed interest	(70,637)
Total present value of lease payments	$ 268,318

11. Common Stock and Warrants

The Company authorized 100,000,000 shares of common stock, of which 10,652,812 and 6,990,227 shares were issued and outstanding as of December 31, 2025 and 2024, respectively.

On October 27, 2025, pursuant to the August 2025 At The Market Offering Agreement, the Company issued 623,184 shares of common stock to investors for gross proceeds of $2,728,424 with such shares registered pursuant to the Company's effective Registration Statement on Form S-3 (File No. 333-283798), previously filed with the Securities and Exchange Commission ("SEC") on December 13, 2024, and declared effective on February 11, 2025, and the related prospectus supplements filed with the SEC on August 29, 2025, and on October 23, 2025.

On May 22, 2025, the Company issued 1,538,461 shares of common stock for gross proceeds totalling $4,999,999 pursuant to a securities purchase agreement with certain institutional investors at a purchase price of $3.25 per share of common stock. The common shares were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-283798) which was declared effective by the Securities and Exchange Commission on February 11, 2025, a base prospectus dated February 11, 2025 and a prospectus supplement dated May 20, 2025.

The Company incurred placement agent fees and other offering expenses totaling $688,804 during the year ended December 31, 2025. No offering expenses were incurred during the year ended December 31, 2024.

Additionally during the year ended December 31, 2025, the Company issued (i) 186,166 common shares upon the cashless exercise of 502,647 warrants, (ii) 484,032 common shares upon conversion of an equivalent amount of Series B Preferred Stock, (iii) 760,359 common shares upon the exercise of warrants, (iv) 13,518 common shares to settle a shareholder dispute, (v) 17,394 common shares upon the acceleration of restricted stock units and (vi) 39,471 common shares for board service.

During the year ended December 31, 2024, the Company issued (i) 245,955 common shares to settle 2022 Convertible Note and Series A Preferred Stock holder disputes, (ii) 11,000 common shares upon the exercise of warrants, (iii) 115,145 common shares as payment to vendors for services, (iv) 59,055 common shares in lieu of interest on the 2024 Convertible Notes, (v) 25,832 shares pursuant to the severance provisions of an employment agreement and (vi) 24,343 common shares for board service.

The following is a summary of warrant activity for common stock during the years ended December 31, 2025 and 2024:

	Number of Warrants for Common Stock	Weighted-Avg. Exercise Price	Weighted-Avg. Remaining Contractual Life
Outstanding as of December 31, 2023	1,822,358	$ 4.69	3.05
Granted	861,424	2.38	3.49
Cancelled	(30,252)	2.38	4.79
Exercised	(11,000)	2.38	3.61
Outstanding as of December 31, 2024	2,642,530	2.41	2.93
Granted	—	—	—
Cancelled	—	—	—
Exercised	(1,263,006)	1.82	2.12
Outstanding as of December 31, 2025	1,379,524	$ 2.44	2.26

During the year ended December 31, 2025, investors (i) converted 502,647 warrants into 186,166 common shares in a cashless exercise, (ii) exercised 73,337 warrants into an equivalent number of common shares at an exercise price of $2.08 in exchange for $152,541 in cash proceeds, (iii) exercised 397,243 warrants into an equivalent number of common shares at an exercise price of $2.38 in exchange for $945,438 in cash proceeds and (iii) exercised 289,779 warrants into an equivalent number of common shares at an exercise price of $0.0001 in exchange for $29 in cash proceeds.

During the year ended December 31, 2024, the Company issued (i) 38,697 five-year warrants to purchase common stock equal to six percent (6%) of the aggregate number of Original 2024 Convertible Promissory Note common stock equivalents pursuant to an underwriting agreement at an exercise price of $2.38 per share, (ii) 68,067 five-year warrants to purchase common stock pursuant to an advisory agreement at an exercise price of $2.38 per share. The Common Stock Purchase Warrant Agreements attached to the 2023 Convertible Promissory Notes contained anti-dilution provisions on both the exercise price and the number of warrants. These anti-dilution features were triggered when the Company issued the Original 2024 Convertible Promissory Notes that contained a conversion price of $2.38 per share as compared to the $5.25 per share exercise price in the 2023 Convertible Promissory Note Common Stock Purchase Warrant Agreements. As a result, the Company issued 754,660 additional warrants in 2024 to the holders of the 2023 Convertible Promissory Note Common Stock Purchase Warrant Agreements. Additionally, investors converted 11,000 warrants into an equivalent number of common shares at an exercise price of $2.38 in exchange for $26,180 in cash proceeds. The Company also canceled 30,252 warrants for no consideration in conjunction with an amendment to an advisory agreement.

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2025:

	Number of Warrants Outstanding		Exercise Price	Expiration Date
Investor Warrant	12,852	$	8.76	September 18, 2028
2022 Convertible Notes	227,098	$	2.38	Various in 2027
2023 Convertible Notes	971,916	$	2.38	Various in 2028
Underwriter Warrants	91,146	$	2.38	August 8, 2028
Advisory Agreement Warrants	76,512	$	2.38	Various in 2029
	1,379,524			

12. Preferred Stock

On August 15, 2024, the Company's shareholders (i) authorized 5,000,000 shares of preferred stock of which 4,000,000 shares were designated as $0.001 par value Series B Preferred Stock inclusive of cumulative dividends, (ii) retired 1,000,000 shares of Series A Preferred Stock and (iii) retired 120,000 shares of Series Seed Preferred Stock. Series B Preferred Stock shareholders vote with Common Stock shareholders on an as-converted basis and not as a separate class. Cumulative dividends accrue at 8.5% per annum and were due and payable in either cash for common shares at the Company's discretion on a quarterly basis through June 30, 2025. Series B Preferred Stock converts to common stock on a 1:1 basis, subject to adjustments for stock dividends, splits, combinations and similar events as well as unpaid dividends thereon, solely at the election of the holder at any time.

Pursuant to the terms of the Amended 2024 Convertible Notes, the principal balance of $4,935,000 on August 15, 2024 was mandatorily converted into 2,073,524 Series B Preferred Shares at a conversion price of $2.38. Subsequently, the Company then proceeded to issue 64,913 shares of Series B Preferred Stock to various investors for $154,500.

On November 11, 2024, the Company's shareholders authorized (i) an increase in the number of designated Series B Preferred Stock to 5,000,000 shares and (ii) an extension of the 8.5% per annum cumulative dividend period to December 31, 2026. Subsequently, the Company issued 2,100,840 shares of Series B Preferred Stock to a dedicated life sciences fund for $5,000,000 and 41,662 shares of Series B Preferred Stock to various investors for $99,164.

During the year ended December 31, 2025, the Company issued 484,032 shares of common stock to certain investors upon conversion of an equivalent amount of Series B Preferred Stock.

Upon any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the Series B Preferred Stock shareholders maintain priority preference over all other classes of capital stock. A merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) and a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company will be treated as a liquidation event, thereby triggering payment of the liquidation preferences.

There were 3,796,907 and 4,280,939 shares of Series B Preferred Stock issued and outstanding as of December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, there were no preferred stock dividends declared or paid. Series B Preferred Stock undeclared cumulative dividends totaled $1,025,865, or $0.27 per share, and $211,268, or $0.05 per share, as of December 31, 2025 and 2024, respectively.

13. Stock-Based Compensation

Restricted Stock Units

Pursuant to the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan, the Company initiated grants of restricted stock units ("RSUs") on January 3, 2025, March 4, 2025 and May 15, 2025, to certain employees as follows:

	Number of RSUs	Weighted Average Fair Value
Outstanding as of December 31, 2024	—	$ —
Granted	852,214	2.32
Vested	(20,868)	2.31
Outstanding as of December 31, 2025	831,346	$ 2.32
Vested as of December 31, 2025	20,868	$ 2.31

The RSUs are subject to a three-year cliff-vesting period and are payable in shares of the Company's common stock. The RSUs fully vest upon (i) death or disability or (ii) change of control. Dividend equivalents accrue on RSUs and are paid upon vesting; there were no accrued dividends on unvested RSUs as of December 31, 2025. On August 19, 2025, 17,534 RSUs were accelerated and issued as 14,060 shares of common stock, net of taxes. On October 29, 2025, 3,334 RSU vested into an equivalent number of common shares. No RSUs were granted during the year ended December 31, 2024.

Total stock-based compensation expense is classified in the Company's Statements of Operations as general and administrative expense and amounted to $596,852, of which $5,678 relates to the Employee Stock Purchase Plan, and $227,000 for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, total unrecognized stock-compensation expense relating to unvested stock units granted under the Company's share-based compensation plans amounted to $1,130,970.

Stock Options

The following table presents a summary of the Company's outstanding stock options as of December 31, 2025 and 2024:

	Number of Options	Weighted Avg. Remaining Contractual Life (in years)	Weighted Avg. Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	1,319,394	4.69	$ 6.94	$ —
Outstanding as of December 31, 2025	1,319,394	3.69	$ 6.94	$ —
Vested and Exercisable as of December 31, 2025	1,319,394	3.69	$ 6.94	$ —

There was no stock-based compensation expense related to stock options recorded during the years ended December 31, 2025 and 2024.

Employee Stock Purchase Plan

On July 1, 2025, the Compensation Committee of the Board of Directors ("Board") of the Company adopted the NeurAxis, Inc. 2025 Employee Stock Purchase Plan (the "ESPP"), effective as of the same date and subject to Shareholder approval by July 1, 2026. The purpose of the ESPP is to provide eligible employees an opportunity to acquire common stock of the Company at a 15% discount using payroll deductions. The maximum number of shares of the Company's common stock that may be issued under the ESPP is 100,000, subject to an annual increase on January 1st of each year from 2026 through 2035 by the lesser of (i) 1% of the Company's outstanding capital stock as of the prior December 31st or (ii) 100,000 shares. The Board may reduce or eliminate this annual increase before February 1st of any given year. Total stock-based compensation expense includes $5,678 relating to the Employee Stock Purchase Plan for the year ended December 31, 2025.

14. Warrant Liabilities

The Company has evaluated financial instruments arising from warrants that are issued and outstanding as of December 31, 2025 and 2024. The Company utilizes a Black-Scholes option-pricing model to compute the fair value of the liability and to mark to market the fair value of the warrant at each balance sheet date. The inputs utilized in the application of the Black-Scholes option-pricing model included (i) an exercise price of $8.76 per share, (ii) an expected remaining term of each warrant based on the remaining contractual maturity of the each warrant, (iii) estimated volatility ranging from 65.3% to 94.7% based on historical stock prices of comparable companies with a look back period commensurate with the period to maturity, (iv) a risk-free interest rate ranging from 3.56% to 4.38% based on the interest rates of U.S. Treasury Notes consistent with the expected remaining contract term and (v) a 0% expected dividend yield as the Company has not paid dividends to date and does not anticipate declaring dividends in the near future.

The following are the changes in the warrant liabilities during the years ended December 31, 2025 and 2024:

	Level 1	Level 2	Level 3
Warrant liabilities as of December 31, 2023	$ —	$ —	$ 8,225
Changes in fair value of warrant liabilities	—	—	941
Warrant liabilities as of December 31, 2024	—	—	9,166
Changes in fair value of warrant liabilities	—	—	7,634
Warrant liabilities as of December 31, 2025	$ —	$ —	$ 16,800

15. Segment Information

The Company evaluates the following factors to identify its reportable segments: (i) nature of products and services, (ii) type of customer for the products and services, (iii) sales, production and distribution methods of the products and services and (iv) the nature of the regulatory environment, if applicable. Based on an evaluation of these factors, management concluded that the Company's operations are managed through one reportable segment, IB-Stim, that derives its revenues in the United States from a PENFS device that is used to treat patients 8-21 years of age with functional abdominal pain associated with irritable bowel syndrome and in patients 8 years and older with functional abdominal pain associated with functional dyspepsia and related nausea symptoms. The accounting policies of the IB-Stim segment are the same as those described in the Summary of Significant Accounting Policies (see Footnote 2). The Chief Operating Decision Maker ("CODM") regularly evaluates the performance of the IB-Stim segment for the purpose of allocating resources based on net sales and operating loss, both of which are reported in the Statements of Operations. The CODM uses net sales to evaluate IB-Stim's adoption and utilization by insurance carriers and physicians. As Neuraxis is an emerging growth company, operating loss is used to monitor the Company's cost structure in order to achieve future segment profitability. Both net sales and operating loss are measured against an annual budget on a periodic basis to assess achievement toward annual compensation incentive targets. The Company's CODM is its President and Chief Executive Officer.

The following reconciles the reportable segment net sales and operating loss to the Company's reported net loss:

	For the Years Ended December 31,	
	2025	**2024**
Net Sales	$ 3,569,282	$ 2,685,925
Cost of Goods Sold	562,916	362,002
Gross Profit	3,006,366	2,323,923
Selling Expenses (a)	2,279,974	1,468,884
Research and Development (a)	493,611	433,614
Wages and Benefits (a)	4,550,833	4,380,434
Professional Services (a)	1,296,368	1,945,331
Legal Settlement	630,568	--
Depreciation	37,691	26,346
Amortization	21,810	11,485
Other Operating Expenses (a) (b)	1,525,419	1,214,646
Segment Operating Loss	(7,829,908)	(7,156,817)
Other Income (Expense):		
Financing charges	(30,240)	(230,824)
Interest expense	(73,969)	(174,328)
Change in fair value of warrant liability	(7,634)	(941)
Change in fair value of derivative liability	—	—
Amortization of debt discount and issuance cost	—	(126,387)
Extinguishment of debt liabilities	—	—
Other income	141,196	33,620
Other expense	—	(585,824)
Total other income (expense), net	29,353	(1,084,684)
Net Loss	$ (7,800,555)	$ (8,241,501)

(a) The significant expense categories and amounts align with the segment-level information provided on a regular basis to the CODM.
(b) Other operating expenses include advertising, rent and utilities, insurance, depreciation and amortization, travel, software subscription fees, board fees and bad debt expense.

Total segment assets for IB-Stim amounted to $6,404,036 and $4,757,572 as of December 31, 2025 and 2024, respectively. Total segment capital expenditures for IB-Stim amounted to $131,150 and $27,776 for the years ended December 31, 2025 and 2024, respectively. Total segment depreciation and amortization amounted to $59,501 and $37,831 for the years ended December 31, 2025 and 2024, respectively.

Significant segment non-cash charges settled in common stock include (i) consulting and advisory fees totaling $146,423 and $754,685 for the years ended December 31, 2025 and 2024, respectively, and (ii) hiring grants totaling $7,268 and $227,000 for the years ended December 31, 2025 and 2024, respectively.

16. Settled Litigation

On February 6, 2019, plaintiff Ritu Bhambhani, M.D., initiated a lawsuit against Innovative Health Solutions, Inc. and others in the United States District Court for the District of Maryland. Plaintiffs Bhambhani and Sudhir Rao subsequently amended the complaint, with the Third Amended Complaint ("Complaint") containing the most recent set of allegations. The Complaint asserted claims under the RICO Act, as well as of fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and sought compensatory damages in excess of $5,000,000, pre-judgment interest, punitive damages, attorney's fees, court costs and designation of the case as a class action. The Complaint stated that the Company, distributors of the Company's product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company's NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On February 11, 2022, the Company filed a motion for summary judgment based upon the plaintiffs not being proper parties to assert claims against the Company. On June 14, 2022, the Court granted the Company's motion for summary judgment and dismissed the Complaint.

On July 14, 2022, plaintiffs Ritu Bhambhani and Sudhir Rao filed a notice of appeal with the Fourth Circuit Court of Appeals. On June 3, 2024, the Fourth Circuit denied the plaintiff's appeal and entered judgment against the plaintiffs. On June 25, 2024, the Fourth Circuit entered its mandate declaring that its judgment against the plaintiffs took effect that day. The plaintiffs did not seek any further review or appeal of that judgment.

Also on July 14, 2022, plaintiffs Ritu Bhambhani, LLC; Box Hill Surgery Center, LLC; Pain and Spine Specialists of Maryland, LLC; and SimCare ASC, LLC initiated a lawsuit against the Company and others in the United States District Court for the District of Maryland. The plaintiffs in this lawsuit are business entities owned or partially owned by the plaintiffs that initiated the litigation described above. The Complaint asserted claims under the RICO Act, as well as fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and seeks compensatory damages in excess of $75,000, pre-judgment interest, punitive damages, attorney's fees, and court costs. The Complaint states that the Company, distributors of the Company's product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company's NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On September 28, 2022, the Company filed a motion to dismiss all claims. On May 25, 2023, the Court issued an Order and a Memorandum Opinion which dismissed the plaintiffs' claims related to the RICO Act. The remaining claims were still pending, and no trial date was set for the case. The Court vacated its Scheduling Order at the parties' request so that the parties could try to resolve the disputes in both cases through an independent third-party mediator.

On April 25, 2025, the parties reached a tentative $750,000 settlement payable in 12 equal monthly installments beginning in January of 2026 as filed with the United States District Court for the District of Maryland with the settlement agreement duly executed on May 15, 2025. The Company recorded a charge of $630,568 for the year ended December 31, 2025, in the Statements of Operations classified as general and administrative expense, while imputed interest expense was recorded as incurred and totaled $62,115. As of December 31, 2025, the Company accrued $692,683 as accrued expenses in the Balance Sheet.

17. Commitments and Contingencies

Manufacturing Services Agreements

The Company is party to two separate manufacturing services agreements for the manufacture and supply of the Company's IB-Stim and RED devices based on the Company's product specifications that expire in March and August, 2027, respectively, and automatically renew annually unless either party provides a written termination notice to the other party within 180 days prior to the end of the then-current term. The Company's IB-Stim and RED devices are manufactured in Indiana and Michigan, respectively. The Company provides the necessary equipment to the manufacturers and retains ownership. The manufacturers bear the risk of loss of and damage to the equipment and consigned materials. Performance under the agreement is initiated by orders issued by the Company and accepted by the manufacturers. The Company also entered into quality agreements with the manufacturers to perform quality assurance services on product provided by the Company.

Advisory Agreement

On March 18, 2024, the Company terminated its private placement services agreement and entered into an advisory agreement with a financial advisor for debt, equity and public securities market services for one year. The advisory agreement included a monthly fee of $30,000 and 7,563 common stock warrants to be issued monthly at an exercise price of $2.38 with a term of five years. On December 31, 2024, the Company and the financial advisor terminated the advisory agreement subject to the cancelation of 30,252 common stock warrants issued after July 2024 and the payment for services rendered totaling $180,000 during the year ended December 31, 2025.

Settlement Agreements

The Company issued 13,518 and 245,955 shares of common stock to various pre-IPO 2022 Convertible Note, warrant and Series A Preferred Stock holders to settle certain claims for the years ended December 31, 2025 and 2024, respectively. The Company recorded the fair value of the settlements totaling $30,240 as Finance Charges for the year ended December 31, 2025 and $230,824 of Finance Charges and $580,250 of Other Expense for the year ended December 31, 2024 in the Statements of Operations.

Executive Employment Agreements

The Company, as authorized by the board of directors, entered into employment agreements with nine key employees to provide incentives to improve shareholder value and to contribute to the growth and financial success of the Company. The agreements had an employment start date of October 1, 2022, with initial terms from two to five years and optional one-year renewals.

There are nine key employees and two non-employees that have stock options of the Company totaling 1,319,394 shares. These key employees have a provision in their agreements whereas the Company will pay a special bonus equal to the aggregate of the strike price or exercise price of all their stock options plus a tax gross-up payment. The special bonus shall be paid in twenty percent (20%) installments starting January 2, 2024, and the same date each of the next four years. As a condition of the payment, the key employee must exercise at least 20% of their stated number of stock options. There are additional provisions to cover termination and change of control events. None of the key employees exercised any of options as of January 2, 2026.

In April 2023, the Company amended the employee agreements to, among other things, clarify that the special one-time incentive payment and the deferred bonus are contingent upon the effective date of the planned initial public offering. The amendment also sets forth a process for executives to exercise the stock options in accordance with the terms of the stock option agreement in effect as of the date of the employment agreement and to clarify that there is no modification to the stock option agreements.

The Company recorded the fair value of the stock options totaling $8,596,661 on the grant date. In addition, a $6,225,169 incremental tax gross up payment is contingent upon the employees exercising their deferred bonus provision which will be recorded when probable.

On April 10, 2024, the Company terminated the employment of the Company's Chief Operating Officer. Pursuant to the employment agreement, the Company made (i) salary continuation payments for six months during the year ended December 31, 2024, (ii) issued 25,832 shares of common stock at a fair value of $78,788 and (iii) made a $41,980 one-time payment in lieu of the exercise of 13,764 stock options that expired on January 2, 2024. The Company was also obligated to provide health care coverage through October 2025.

Threatened Litigation

From time to time, the Company may be involved in litigation relating to claims arising out of operations in the normal course of business. As of the date of issuance, other than those described below, there were no pending or threatened legal proceedings that could reasonably be expected to have a material effect on the results of the Company's operations. There are also no proceedings in which any of the Company's directors, officers or affiliates is an adverse party to the Company or has a material interest adverse to the Company's interest. Legal fees are expensed as incurred.

In January 2024, Dr. Arturo Taca served notice to the Company that asserted an interest in its U.S. Patent No. 10,413,719 valued at $2,000,000 based on his own work in neurostimulation. The Company denied both the neurostimulation patent and compensation claims. The case remains unresolved. While it is too early to predict the ultimate outcome of these matters, we believe the Company has meritorious defenses and intends to defend these matters vigorously.

18. Employee Benefits

The Company sponsors a 401(k)-retirement plan for its employees. Employees are eligible to participate in the elective deferral portion of the plan after twelve months and 1,000 hours of service. The Company can also make a 3% discretionary profit-sharing contribution on an annual basis to employees with earnings under a certain threshold. Profit sharing expense totaled $19,634 and $20,868 for years ended December 31, 2025 and 2024, respectively.

The Company participates in a self-funded employer program in conjunction with a group health plan for the benefit of eligible employees. This plan is a level funded plan, and the services and products include:

- A self-funded employer health benefit plan.
- Stop loss insurance purchased from a stop loss insurance company.
- Third party administrator to provide administrative services with regard to the plan.

The Company maintains a stop loss contract that reimburses the Company for claims paid under the plan if they exceed a predetermined level. The Company makes contributions for health care costs and associated expenses that are expected during the plan year. The amount of contributions is determined annually based on the Company's maximum liability for expected claims, administrative expenses, and premiums for the stop loss policy. The Company incurred premiums of $308,975 and $257,642 for the years ended December 31, 2025 and 2024, respectively.

The Company is responsible for the monthly premiums, as established, and nothing further. The stop loss policy covers the claims if they exceed the claims funds. After a certain time, and if there is a surplus in the claims fund, the Company may be entitled to receive a 48.5% refund from the fund. This amount is recognized by the Company when received.

19. Income Taxes

The income tax provision consists of:

	For the Years Ended December 31,	
	2025	**2024**
Total current provision	$ -	$ -
Deferred:		
Federal	(1,541,974)	(1,561,596)
State	(461,972)	(634,364)
Total deferred benefit	(2,003,946)	(2,195,960)
Valuation allowance	2,003,946	2,195,960
Total income tax provision	$ —	$ —

A reconciliation of the U.S. federal statutory income tax rate to the effective income tax rate is as follows:

	For the Years Ended December 31,			
	2025		**2024**	
	Amount	**Rate**	**Amount**	**Rate**
Federal statutory income tax rate	$ 1,638,117	$ 21.0%	1,730,715	21.0%
State rate, net of valuation allowance and federal benefit	215	—	(14,883)	(0.2)
Change in federal valuation allowance	(1,637,466)	(21.0)	(1,797,167)	(21.8)
Other	(866)	—	81,335	1.0
Effective income tax rate	$ —	—%	$ —	—%

(a) State taxes in Indiana and California comprise the majority of this category.

The Company did not recognize an income tax provision for the years ended December 31, 2025 and 2024 due to net operating losses reported in both years.

The Company did not pay any federal income taxes for the years ended December 31, 2025 and 2024. The Company received income tax refunds from the state of Indiana totaling $13,140 and $10,164 for the years ended December 31, 2025 and 2024, respectively.

On July 4, 2025, the United States enacted the *One Big Beautiful Bill Act* ("OBBBA"), Public Law No. 119-21, which includes significant changes to U.S. federal tax law. Key provisions of the OBBBA include, among other items, the extension of certain Tax Cuts and Jobs Act of 2017 ("TCJA") provisions, permanent reinstatement of 100% bonus depreciation for qualifying property and modifications to various deductions and credits within the Internal Revenue Code.

Under U.S. GAAP, the effects of changes in tax law are recognized in the period that includes the enactment date. Accordingly, the Company evaluated the provisions of the OBBBA during the year ended December 31, 2025. Based on the Company's preliminary analysis, the enactment of the OBBBA did not result in a material change to the Company's effective tax rate for the year ended December 31, 2025.

The Company continues to evaluate the full impact of the OBBBA, including interpretive guidance that may be issued by the U.S. Department of the Treasury and the Internal Revenue Service. As additional guidance becomes available, the Company may refine its estimates related to the accounting for income taxes under ASC 740.

Deferred income taxes are provided for temporary differences between the financial and tax bases of the Company's assets and liabilities. The temporary differences that give rise to net deferred tax assets and liabilities were as follows:

	December 31,	
	2025	**2024**
Deferred tax assets:		
Net operating losses	$ 11,004,401	$ 9,222,603
Stock based compensation	1,628,094	1,447,339
Accrued compensation	298,201	266,816
Notes receivable reserve	260,362	296,297
Operating lease payable	68,977	143,484
Accounts payable	23,784	84,105
Other	361,132	149,168
Total gross deferred tax assets	13,644,951	11,609,812
Valuation allowance	(13,375,770)	(11,371,824)
Total deferred tax assets	$ 269,181	$ 237,988
Deferred tax liabilities:		
Prepaid expenses	$ 81,050	$ 74,991
Operating lease right of use asset	67,241	72,560
Accounts receivable	50,310	64,443
Other	70,580	25,994
Total deferred tax liabilities	269,181	237,988
Deferred tax assets, net	$ —	$ —

Management assessed the realizability of its deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets due to a history of operating losses. As a result, the Company maintained a full valuation allowance and does not reflect any deferred taxes in its Balance Sheets as of December 31, 2025 and 2024.

On December 31, 2025, the Company's federal and state net operating loss (NOL) carryforwards totaled $43,160,139 and $41,230,553 respectively. These NOL carryforwards may be offset against future taxable income. There is no limitation on the number of years to utilize the federal NOLs. The federal deduction will be limited to 80% of modified taxable income. The state NOLs are allowed up to 100% of taxable income and generally can be carried forward no longer than 20 years after the year of the taxable loss.

Federal and state tax laws impose limitations on the utilization of NOLs and credit carryforwards in the event of an ownership change for tax purposes, as defined in Section 382 of the Internal Revenue Code. Accordingly, the Company's ability to utilize these carryforwards may be limited as a result of an ownership change. Such an ownership change could result in a limitation in the use of the NOLs in future years and possibly a reduction of the net operating losses available.

If not used, the state NOL carryforwards will expire as follows:

2037	$	72,216
2038		1,039,986
2039		2,033,750
2040		4,457,495
2041		2,406,225
Thereafter		31,102,107
No expiration		118,774
Total state NOL carryforwards	$	41,230,553

The Company believes it has made adequate provision for all income tax uncertainties. The assessment is subject to change based on the completion of audits or statute of limitation expirations.

The federal and state income tax returns have a three-year statute of limitations once filed with the appropriate jurisdiction. The Company's income tax returns are subject to examination by the federal and state taxing authorities in the United States for the years ended December 31, 2022 through 2025.

20. Subsequent Events

On January 22, 2026, the Company granted 437,431 RSUs pursuant to the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan as amended on August 15, 2024. The RSUs vest annually pro rata over a three-year period and are payable in shares of the Company's common stock. The RSUs fully vest upon (i) death or disability or (ii) change of control. Dividend equivalents accrue on RSUs and are paid upon vesting; there were no accrued dividends on unvested RSUs as of the report date.

Also on January 22, 2026, the Company issued 86,392 shares of common stock to its independent board members for their 2025 and 2026 service.

In January through March of 2026, pursuant to the August 2025 At The Market Offering Agreement with Craig-Hallum Capital Group LLC, the Company issued 405,969 shares of common stock to investors for gross proceeds of $2,312,443 with such shares registered pursuant to the Company's effective Registration Statement on Form S-3 (File No. 333-283798), previously filed with the Securities and Exchange Commission ("SEC") on December 13, 2024, and declared effective on February 11, 2025, and the related prospectus supplements filed with the SEC on August 29, 2025, and on October 23, 2025.

In February of 2026, the Company issued 136,126 shares of common stock upon exercise of an equivalent amount of common stock warrants for gross proceeds of $323,980.

The Company has evaluated subsequent events through the filing of this Annual Report on Form 10-K and determined that there have been no other events that have occurred that would require adjustments to our disclosures in the financial statements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEURAXIS, INC.

Dated: March 19, 2026

By: */s/ Brian Carrico*
Brian Carrico
Chief Executive Officer

Dated: March 19, 2026

By: */s/ Timothy R. Henrichs*
Timothy R. Henrichs
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Brian Carrico Brian Carrico	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2026
/s/ Timothy R. Henrichs Timothy R. Henrichs	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 19, 2026
/s/ Christopher Robin Brown Christopher Robin Brown	Director	March 19, 2026
/s/ Bradley Mitch Watkins Bradley Mitch Watkins	Director	March 19, 2026
/s/ Beth Keyser Beth Keyser	Director	March 19, 2026
/s/ Kristin Ferge Kristin Ferge	Director	March 19, 2026
/s/ Gilad Aharon Gilad Aharon	Director	March 19, 2026

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 19, 2026, with respect to the financial statements included in the Annual Report of Neuraxis, Inc. on Form 10-K for the year ended December 31, 2025. We consent to the incorporation by reference of said report in the Registration Statements of Neuraxis, Inc. on Form S-8 (File No. 333-290774) and on Form S-3 (File No. 333-283798).

/s/ Rosenberg Rich Baker Berman, P.A.

Somerset, New Jersey
March 19, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Carrico, certify that:

1. I have reviewed this annual report on Form 10-K of Neuraxis, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2026

By: */s/ Brian Carrico*
Brian Carrico
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy R. Henrichs, certify that:

1. I have reviewed this annual report on Form 10-K of Neuraxis, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2026

By: */s/ Timothy R. Henrichs*
Timothy R. Henrichs
Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Neuraxis, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Carrico, Chief Executive Officer of the Company and I, Timothy R. Henrichs, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: March 19, 2026

By: */s/ Brian Carrico*
Brian Carrico
Chief Executive Officer (Principal Executive Officer)

Dated: March 19, 2026

By: */s/ Timothy R. Henrichs*
Timothy R. Henrichs
Chief Financial Officer (Principal Accounting and Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350,and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.