As confidentially submitted to the U.S. Securities and Exchange Commission on December 9, 2022. This draft registration statement has not been filed, publicly or otherwise, with the U.S. Securities and Exchange Commission, and all information contained herein remains strictly confidential.

Registration No. 333-

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

AMENDMENT NO. 2 TO

FORM S-1/A

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

NEURAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3845**	**45-5079684**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

11550 N. Meridian Street, Suite 325
Carmel, IN 46032
Telephone: 812-689-0791
(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

Brian Carrico
Chief Executive Officer
Neuraxis, Inc.
11550 N. Meridian Street, Suite 325
Carmel, IN 46032
Telephone: 812-689-0791
(Name, address, including zip code and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

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(732) 395-4496

Ross D. Carmel, Esq.
Barry P. Biggar, Esq.
Carmel, Milazzo & Feil LLP
55 West 39th Street, 18th Floor
New York, NY 10018
(212) 658-0458

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 ☐
Non-accelerated filer ☒

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 7(a)(2)(B) of the Securities Act. ☒

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities included in this Registration Statement, of which this prospectus, are subject to an effective Registration Statement. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBMER [ ], 2022

PRELIMINARY PROSPECTUS

NEURAXIS, INC.

[●]
Shares of Common Stock

We are offering [●] shares of common stock, par value $0.001 per share, of Neuraxis, Inc. at an initial public offering price of $[●] per share.

Prior to this offering, there has been no public market for our common stock. We have applied to have our common stock listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "NRXS". We will not proceed with this offering in the event the common stock is not approved for listing on Nasdaq.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 12 of this prospectus. You should carefully consider these risk factors, as well as the information contained in this prospectus, before purchasing any of the securities offered by this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	
Underwriting discounts and commissions (1)	$	
Proceeds to us, before expenses	$	

(1) We have agreed to pay Alexander Capital L.P., as the underwriter named in this prospectus (the "Underwriter"), an Underwriter's fee of seven percent (7%) of the amount raised in the offering. We have agreed to issue to the Underwriter, on the closing date of this offering, warrants in an amount equal to six percent (6%) of the aggregate number of shares of common stock sold by us in this offering and exercisable at a price per share equal to one hundred and twenty percent (120%) of the public offering price (the "Underwriter's Warrants"). For a description of compensation to be received by the Underwriter, see "*Underwriting*" for more information.

We have granted the Underwriter an option, exercisable for up to 45 days from the date of this prospectus, to purchase a maximum of [●] shares of common stock (equal to fifteen percent (15%) of the aggregate number of shares of common stock sold in this offering) on the same terms as the other shares of common stock being purchased by the Underwriter from us.

This offering is being conducted on a firm commitment basis. The Underwriter is obligated to take and purchase all of the shares of common stock offered under this prospectus if any such shares are taken.

The Underwriter expects to deliver the securities to purchasers in the offering on or about [●], 2022.

Sole Book Running Manager

ALEXANDER CAPITAL L.P.

Prospectus dated [●], 2022.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus we have prepared. We take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date. You should also read this prospectus together with the additional information described under "Additional Information."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements". Forward-looking statements discuss matters that are not historical facts. Because they discuss future events or conditions, forward-looking statements may include words such as "anticipate," "believe," "estimate," "intend," "could," "should," "would," "may," "seek," "plan," "might," "will," "expect," "anticipate," "predict," "project," "forecast," "potential," and "continue" or the negatives thereof or similar expressions. Forward-looking statements speak only as of the date they are made, are based on various underlying assumptions and current expectations about the future and are not guarantees of future performance. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, level of activity, performance or achievement to be materially different from the results of operations or plans expressed or implied by such forward-looking statements. You are cautioned to not place undue reliance on these forward-looking statements, which speak only as of their dates.

We cannot predict all the risks and uncertainties that may impact our business, financial condition, or results of operations. Accordingly, the forward-looking statements in this prospectus should not be regarded as representations that the results or conditions described in such statements will occur or that our objectives and plans will be achieved. These forward-looking statements are found at various places throughout this prospectus and include information concerning possible or projected future results of our operations, including statements about potential acquisition or merger targets, strategies or plans; business strategies; prospects; future cash flows; financing plans; plans and objectives of management; any other statements regarding future cash needs, future operations, business plans and future financial results; and any other statements that are not historical facts.

These forward-looking statements represent our intentions, plans, expectations, assumptions and beliefs about future events and are subject to a variety of factors and risks, including, but not limited to, those set forth under "*Risk Factors*" starting page 12 of this prospectus.

Many of those risks and factors are outside of our control and could cause actual results to differ materially from the results expressed or implied by those forward-looking statements. Considering these risks, uncertainties and assumptions, the events described in the forward-looking statements might not occur or might occur to a different extent or at a different time than we have described. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. All subsequent written and oral forward-looking statements concerning other matters addressed in this prospectus and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this prospectus.

Except to the extent required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, a change in events, conditions, circumstances or assumptions underlying such statements, or otherwise.

MARKET AND INDUSTRY DATA

This prospectus contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. While we believe the industry and market data included in this prospectus are reliable and are based on reasonable assumptions, these data involve many assumptions and limitations, and you are cautioned not to give undue weight to these estimates. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the sections titled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" included in this prospectus.

TRADEMARKS AND TRADE NAMES

We own or have rights to various trademarks, service marks and trade names that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this prospectus is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, service marks and trade names.

GLOSSARY OF CERTAIN TERMS

As a neuromodulation therapy device company, describing our business involves several technical terms and acronyms. We are providing the following glossary to assist readers with certain technical terms and acronyms and to also define certain frequently used terms.

"ACA" means the Affordable Care Act, a comprehensive reform law increases health insurance coverage for the uninsured and implements reforms to the health insurance market.

"CBT" means cognitive behavioral therapy, a form of psychological treatment that has been demonstrated to be effective for a range of problems including depression, anxiety disorders, alcohol and drug use problems, marital problems, eating disorders, and severe mental illness.

"CCPA" means the California Consumer Privacy Act, a state statute intended to enhance privacy rights and consumer protection for residents of California.

"CE" means that the manufacturer or importer of a commercial product affirms the product's conformity with European health, safety and environmental safety standards.

"CE Certificate" means the CE mark that is placed on the backside of certain products sold in the European Economic Area and the European Union.

"cGCPs" means current Good Clinical Practices, which is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

"CMS" means Centers for Medicare & Medicaid Services, a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program, and health insurance portability standards.

"CPRA" means the California Privacy Rights Act of 2020, is a California ballot proposition that expands California's consumer privacy law and builds upon the California Consumer Privacy Act of 2018.

"CPT codes" means the Common Procedural Terminology codes, a medical code set that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations.

"DHS" means designated health services.

"EEA" means the European Economic Area.

"EU" means the European Union.

"FATCA" means the Foreign Account Tax Compliance Act, which requires all non-U.S. foreign financial institutions to search their records for customers with indicia of a connection to the U.S., including indications in records of birth or prior residency in the U.S., or the like, and to report the assets and identities of such persons to the U.S. Department of the Treasury.

"FDA" means the U.S. Food and Drug Administration.

"FDCA" means the Federal Food, Drug, and Cosmetic Act, a set of laws giving authority to the U.S. Food and Drug Administration to oversee the safety of food, drugs, medical devices, and cosmetics.

"FSCA" means Field Safety Corrective Actions, which is an action taken by a manufacturer 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.

"FTC" means Federal Trade Commission, an independent agency of the United States government whose principal mission is the enforcement of civil U.S. antitrust law and the promotion of consumer protection.

"FAPD" means functional abdominal pain disorder.

“GDPR” means General Data Protection Regulation, a regulation in EU law on data protection and privacy in the EU and the EEA.

“HDE” means Humanitarian Device Exemption, a regulatory pathway for products intended for diseases or conditions that affect small, rare populations.

“HIPAA” means Health Insurance Portability and Accountability Act, which is a US law designed to provide privacy standards to protect patients’ medical records and other health information provided to health plans, doctors, hospitals and other health care providers.

“IBS” means irritable bowel syndrome, a group of symptoms that occur together, including repeated pain in abdomen and changes in bowel movements, which may be diarrhea, constipation, or both.

“IRB” means Institutional Review Board, which is any group that has been formally designated to review and monitor biomedical research involving human subjects.

“JOBS Act” means the Jumpstart Our Business Startups Act of 2012, as amended, which is a law intended to encourage funding of small businesses in the U.S. by easing many of the country’s securities regulations.

“Masimo” means Masimo Corporation, a global medical technology company that develops, manufactures, and markets a variety of noninvasive patient monitoring technologies, hospital automation solutions, home monitoring devices, ventilation solutions, and consumer products.

“MACs” means Medicare Administrative Contractors, which is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment claims for Medicare Fee-For-Service beneficiaries.

“MDR” means the medical device reporting, one of the post-market surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

“MHLW” means Ministry of Health, Labour and Welfare of Japan, a cabinet level ministry of the Japanese government that provides services on health, labor and welfare.

“NASPGHAN” means the American Academy of Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

“PENFS” means Percutaneous Electrical Nerve Field Stimulation.

“PMA” means the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

“QSR” means quality system regulations maintained by the FDA that must be followed by all medical device manufacturers who wish to sell devices in the USA.

“RCT” means Randomized Controlled Trial, which is a study in which people are allocated at random (by chance alone) to receive one of several clinical interventions, including a standard of comparison or control in for the form of a placebo (e.g., a sugar pill) or no intervention at all.

“SSRI” is a type of antidepressant drug that inhibits the reabsorption of serotonin by neurons, so increasing the availability of serotonin as a neurotransmitter.

“TCA” means the EU-UK Trade and Cooperation Agreement, a free trade agreement signed on December 30, 2020, between the EU, the European Atomic Energy Community, and the United Kingdom that provides for free trade in goods and limited mutual market access in services, as well as for cooperation mechanisms in a range of policy areas, transitional provisions about EU access to UK fisheries, and UK participation in some EU programs.

“TKBMN” means TKBMN, LLC, an Indiana company.

“UKCA” means UK conformity assessment.

“UKCA Marking” means a certification mark that indicates conformity with the applicable requirements for products sold within Great Britain.

“USPTO” means United States Patent and Trademark Office.

PROSPECTUS SUMMARY

This prospectus summary contains an overview of the information from this prospectus but may not contain all of the information that is important to you. This prospectus includes specific terms of the offering of our securities, information about our business, and financial data. We encourage you to read this prospectus, including the "Risk Factors" section beginning on page 12 and the financial statements and the notes thereto, in its entirety before making an investing decision. As used in this prospectus, the terms "we," "us,", "the Company", "our," and "Neuraxis" refer to Neuraxis, Inc., a corporation organized under the laws of Delaware, including our subsidiaries, unless the context indicates a different meaning.

Overview

We are a growth stage company focused on developing neuromodulation therapies to address chronic and debilitating conditions in children. We are dedicated to advancing the science with our proprietary PENFS technology, which we developed. We believe that superior science and evidence-based research are necessary for adoption by the medical and scientific community. With one FDA indication (functional abdominal pain associated with IBS in adolescents 11-18 years old) on the market, additional clinical trials of PENFS in multiple pediatric conditions are underway focused on unmet healthcare needs in children, see "—*Our Pipeline*" for more information.

Since our inception, we have incurred significant operating losses. Our net loss was $3.0 million and $3.7 million for the years ended December 31, 2021, and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $29.2 million. Our auditors have expressed substantial doubt about our ability to continue as a going concern paragraph 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 device 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 our IB-Stim device to treat future indications.

Our Mission

Our mission is to provide solutions that create value and provide better and safer patient outcomes. We believe in improving lives and minimizing suffering; particularly in the pediatric population, where research and therapeutics are usually lacking. Neuraxis is already cleared for its IB-Stim therapy for functional abdominal pain, associated with IBS, in children. Through innovation and research, we are reimagining the future of patient care.

Pipeline

The IB-Stim device is to be used for the indication of functional abdominal pain associated with IBS and functional nausea in children. The same underlying technology will be used for the remaining pipeline indications, but we may use a name other than "IB-Stim" for marketing and commercialization purposes.

With one FDA indication—functional abdominal pain associated with IBS in adolescents 11-18 years old—on the market, additional clinical trials of PENFS in multiple pediatric conditions are underway focused on unmet healthcare needs in children. These indications consist of chronic nausea, post-concussion syndrome, chemotherapy-induced nausea and vomiting, cyclic vomiting syndrome.

The figures below show our anticipated FDA timelines for IB-Stim and each of the following pediatric indications:

1. Chronic nausea -- RCT completed, and data being analyzed, see ClinicalTrials.gov Identifier: NCT03675321).

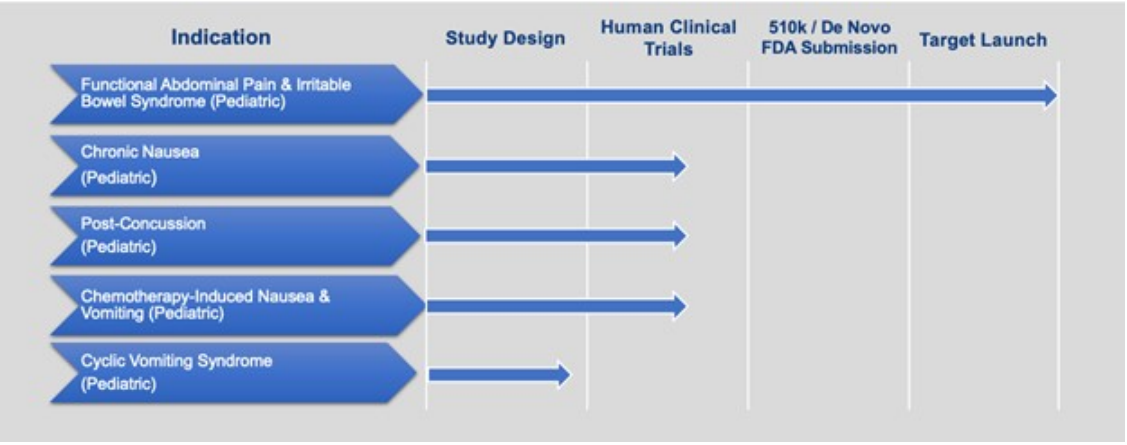
2. Post-concussion syndrome -- RCT currently enrolling patients, see ClinicalTrials.gov Identifier: NCT04978571.

3. Chemotherapy-induced nausea and vomiting -- (RCT currently enrolling patients, see ClinicalTrials.gov Identifier: NCT05143554.

4. Cyclic vomiting syndrome -- Pilot study completed, see ClinicalTrials.gov Identifier: NCT03434652; multicenter RCT is Anticipated to begin enrolling patients in the first half of 2023.

The projected timelines are management's best estimate of the FDA review process and based on past experience, as well as information available and assumptions we consider reasonable, but the 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.

FDA Pipeline Indications and Projected Timelines



Product

The IB-Stim is a PENFS system intended to be used in patients 11-18 years of age with functional abdominal pain associated with IBS. IB-Stim already has market clearance from FDA for functional abdominal pain associated with IBS in children. FDA has classified the non-implanted nerve stimulator for functional abdominal pain relief as Class II devices.

The IB-Stim is intended to be used for 120 hours per week for three consecutive weeks, and not to exceed 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. 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. See *Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomized, double-blind, sham-controlled trial*, Kovacic K, et.al., Lancet Gastroenterol Hepatol. 2017;2:727-737; *Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial*, Krasaelap A et.al., Clin Gastroenterol Hepatol. 2020;18:1987-1994; *Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders*, Santucci et.al., Neurogastroenterol Motil. 2022;34:e14358.

The ability of the 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—Technology—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—Technology—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 experience ear discomfort (three in the PENFS group, three in the sham group), three experienced adhesive allergy (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.

Medical providers are trained to place the IB-Stim through IB-Stim Training and Certification. 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 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 our IB-Stim device, patients can still attend school and extracurricular activities, exercise or play non-contact sports, shower, wear ear buds or headphones, and travel.

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

Pediatrics Industry Overview

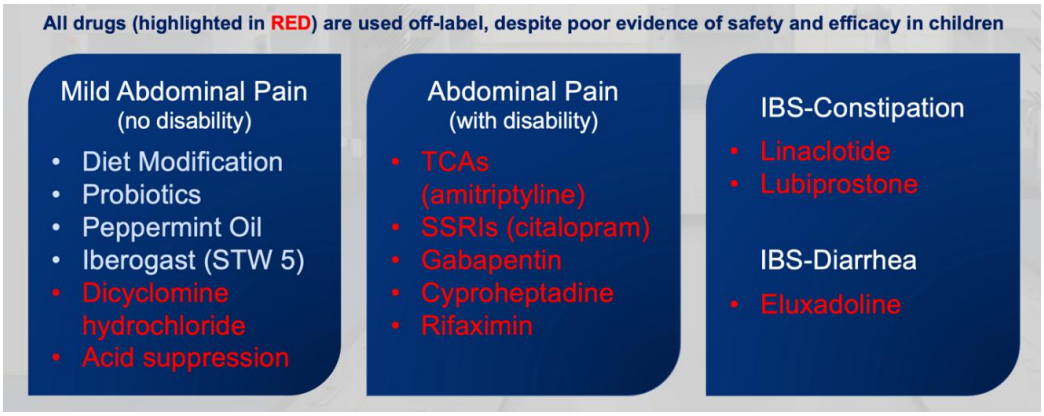
Pediatric providers, as a whole, had expressed concern about the lack of attention given to children with functional abdominal pain disorders (including IBS) and the limited treatment options available for a population that suffers from significant disabilities. With 20% of United States population under age 18, our company focus on opportunities in 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, 35-45% 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 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 therapy that is better than placebo in a randomized controlled trial and received FDA clearance for pediatric IBS.

Our Opportunity

The total addressable market ("TAM") for our target pediatric indications is $9 billion. The TAM is calculated by the total number of patients we target to treat multiplied by the revenue potential from each patient. This TAM is broken down into five (5) pipeline indications. The first pipeline indication is functional abdominal pain associated with irritable bowel syndrome which has a TAM of $1.48 billion followed by functional nausea in children which has a TAM of $2.26 billion, cyclic vomiting syndrome which has a TAM of $2.8 billion, followed by post-concussion syndrome which has a TAM of $1.9 billion, and finally chemo-therapy induced nausea and vomiting in children which has a TAM of $0.72 billion and this pipeline totals over $9 billion in TAM.

For years, physicians and qualified healthcare professionals have resorted to the use 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 SSRIs) failed to beat placebos in clinical trials, but new studies also suggest significant risks with the potential for serious side effects with these drugs. For example, significant risk of TCA side effects in children include increased risk of suicidal ideation, mood changes, EKG disturbance, and long-term risk of dementia. Other side effects of pharmaceuticals given are depression and weight gain. 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.



Our Solutions

We entered the pediatric market with clinical evidence, coverage and payment, and key opinion leaders and society endorsement, including a signed letter from the American Academy of Pediatrics and NASPGHAN supporting our request for insurers to pay for our IB-Stim device. Our 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). The FDA created a new classification of PENFS for the IB-Stim device. This is based on pre-clinical and clinical studies demonstrating the mechanism of action and efficacy. Based on this new class of devices, the 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 CNS. 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 more information, see "Business—Our Solutions." We have only submitted one FDA De Novo request and have not submitted any additional 510(k) premarket notifications for our pipeline indications to date.

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, 95% of adolescents who used IB-Stim said that they would recommend this treatment to family and friends. Many children's hospitals across the country are already treating children with IB-Stim successfully, since it provides a better alternative for therapy in children with IBS and disability and allows them to treat them safely and effectively.

We have concentrated our marketing focus on 260 children's hospitals. To date, we have sold our IB-Stim product to approximately 50 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. Current treatments treat locally and peripheral whereas IB-Stim treats at the level of the brain gut axis. It also includes devices that could theoretically be used, but do not have supporting data or FDA clearance for functional bowel disorders or IBS. Our method patents also limit other devices from targeting IBS through stimulation of cranial nerve branches in the ear.

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

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 of 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 Support
- Lower capital expenditures in nurse, trainers, and representatives for first line therapy
- Strong clinical data carried out in leading academic institutions in the US

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 and pediatric clinics

Corporate Development

Neuraxis, Inc. was established in 2011 and incorporated in the state of Indiana on April 17, 2012, under the name of Innovative Health Solutions, Inc. The name was changed to Neuraxis, Inc. in March of 2022. Additionally, the Company filed a Certificate of Conversion to become a Delaware corporation on June 23, 2022.

On September 7, 2021, the Company’s board of directors authorized a 4-for-1 stock split and increased the number of authorized common stock shares from 2,700,000 to 10,800,000. On September 9, 2021, the board authorized another increase of authorized shares of common stock from 10,800,000 to 13,400,000 in anticipation of this offering. All share and per share amounts for our common stock in this prospectus, including the financial statements, have been retroactively restated to give effect to the split.

As part of the conversion to a Delaware corporation, the total number of shares of all classes of stock which we have authority to issue was set at 101,120, 000 shares, consisting of (1) 100,000,000 shares of common stock, par value $0.001 per share and (ii) 1,120,000 shares of preferred stock, par value $0.001 per share 1,000,000 of which was designated as “Series A Preferred Stock” and 120,000 of which was designated as “Series Seed Preferred Stock”.

Recent Development

From June 3, 2022 to November 30, 2022, we entered into Securities Purchase Agreements (the "SPAs") with Leonite Fund I, Emmis Capital II, LLC, Bigger Capital Fund, LP, District 2 Capital Fund, LP, and Exchange Listing, LLC, which provide for advances of up to $2.9 million in proceeds to us, subject to our satisfaction of certain conditions. Pursuant to the SPAs, from June 3, 2022 to November 30, 2022, we issued the Senior Secured Convertible Promissory Notes ("Notes") with an aggregate principal amount of $2,777,777, which amount included original issue discount ("OID") of $222,223, and legal fees for $130,000, resulting in advance proceeds to us of $2.370 million. In connection with the issuance of the Notes, we also issued five-year warrants exercisable for an aggregate of 588,514 shares of common stock with an exercise price of the lower of (a) $5.90 and (b) a 12% discount to the price per share in any subsequent offering by the Company, and we entered into a Pledge and Security Agreement with Leonite Fund I, LP, dated June 3, 2022. Pursuant to the Pledge and Security Agreement, the Company granted a security interest in all of its assets in favor of Leonite Fund I, LP, in its capacity as collateral agent for the purchaser's parties under the SPAs.

The Notes were issued with OID of 10% of the principal amount and bear interest at the greater of (a) the prime rate of interest, as published by the Wall Street Journal, plus 8.5% per annum, or (b) 12%. The Notes will mature in twelve (12) months from their respective issue dates. Any amount of principal, interest, other amounts due hereunder or penalties on this Note, which is not paid by maturity date, shall bear interest at the lesser of the rate of twenty four percent (24%) per annum or the maximum legal amount permitted by law, from the due date thereof until the same is paid in full, including following the entry of a judgment in favor of Holder. The Notes are convertible into shares of common stock at the lower of (a) $4.72 per share, or (b) a discount of 30% to the price per share in any subsequent offering, subject to adjustment in the event of common stock distribution, stock splits, fundamental transactions, dilutive issuances or similar events affecting our common stock and the conversion price. Interest accrues on the aggregate principal amount (which includes OID) and is payable monthly, at the Company's election, in cash or in-kind.

Upon the advance of the consideration under the SPAs, the Company is required to issue to the noteholders a number of shares of common stock, calculated based on the value of 10% of the principal amount of the Notes issued in such advance, at a value per share equal to the conversion price of the Notes. Accordingly, from June 3, 2022 to November 30, 2022, in connection with the initial advance and issuance of Notes, we also issued 58,855 shares of common stock to the noteholders.

The Notes have certain restrictions on the Company's issuance of securities, including (i) the Company shall not without the noteholder's written consent (a) pay, declare or set apart for such payment, any dividend or other distribution (whether in cash, property or other securities) on the common stock of the Company other than dividends on common stock solely in the form of additional common stock, or (b) directly or indirectly or through any subsidiary make any other payment or distribution in respect of common stock or equivalents, (ii) unless approved by the noteholders in writing, the Company shall not enter into an agreement or amend an existing agreement to effect any sale of securities involving, or convert any securities previously issued under, a variable rate transaction, which means a transaction in which the Company (A) issues or sells any convertible securities either (a) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the common stock, or (b) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company, or the market for the common stock, or (B) enters into any agreement whereby the Company may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights), (iii) the noteholders have the right, but not the obligation, to participate in the purchase of the securities being offered up to an amount equal to thirty percent (30%) of the principal amount of the Notes (the " Participation Right") when the Company or its subsidiary proposes to offer and sell its securities, whether in the form of debt, equity financing, or any other financing transaction (each a "Future Offering"); provided that, the Participation Right shall not exceed the lesser of (i) one-third of the aggregate amount of the Future Offering, and (ii) an amount equal to the principal amount (allocated to the noteholder's pro-rata to their portion of the principal amount).

We have agreed to pay to the noteholders any outstanding principal amount of the Notes, all accrued and unpaid interest, and fees and penalties, if any, from any future financing proceeds (which includes proceeds to us from this offering) and other future receipts, at the noteholder's discretion, except for the right of the Company to make bona fide payments to vendors with common stock.

In addition, pursuant to the SPAs, so long as no event of default has occurred under the Notes, the closing of additional tranches, consisting of Notes in the aggregate advance amount of up to $400,000 and an aggregate principal amount (including the OID of $44,444.44) of up to $444,444.44, shall occur (i) upon the Company filing a registration statement with the Securities and Exchange Commission (the "SEC") on Form S-1.

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 equaled or exceeded $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 Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We will remain an emerging growth company until the earlier of (1) December 31, 2024, (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 (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, or Sarbanes-Oxley;
- provide reduced disclosure about our executive compensation arrangements;
- not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements;
- defer complying with certain changes in accounting standards; and
- not comply with requirements of PCAOB regarding communications of critical audit matters (CAMS) in the auditor's report on the financial statements.

We are an emerging growth company, and 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.

Corporate Information

We incorporated in Indiana on April 17, 2012, under the name Innovative Health Solutions, Inc. On March 11, 2022, we amended our Articles of Incorporation to change our name to Neuraxis, Inc. On June 23, 2022, our state of incorporation changed from Indiana to Delaware.

Our principal executive offices are located at 11550 N. Meridian Street, Suite 325, Carmel, IN 46032, and our telephone number is (812)-689-0791.

SUMMARY OF THE OFFERING

Issuer:	Neuraxis, Inc.
Securities Offered:	[●] shares of common stock, at a public offering price of $ [●] per share of common stock.
Over-allotment option:	We have granted the Underwriter a 45-day option to purchase up to a total of [●] shares of common stock (equal to fifteen percent (15%) of the aggregate number of shares of common stock sold in this offering) at a public offering price of $[●] per share, less the underwriting discounts payable by us, solely to cover over-allotments, if any.
Underwriter's warrants:	We have agreed to issue to Alexander Capital L.P., as the Underwriter, the Underwriter's Warrants to purchase a number of shares of common stock equal in the aggregate to six percent (6%) of the total number of shares issued in this offering. The Underwriter's Warrants will be exercisable at a per share exercise price equal to one hundred and twenty percent (120%) of the public offering price per share of common stock sold in this offering. The Underwriter's Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing 180 days after the date the registration statement, of which this prospectus forms a part, is declared effective. The registration statement also registers the shares of common stock issuable upon exercise of the Underwriter's Warrants. See "*Underwriting*" for more information.
Common stock issued and outstanding before this offering (1):	[●] shares.
Common stock issued and outstanding after the offering:	[●] shares.
Use of proceeds:	We estimate that the net proceeds to us from this offering will be approximately $[●] million, or approximately $[●] million if the Underwriter exercises its over-allotment option in full, assuming an offering price of $[●] per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering primarily for sales and marketing activities, research and development, repayment of our convertible notes and general corporate purposes. See "*Use of Proceeds*" for additional information.
Proposed Nasdaq Capital Market Trading Symbol and Listing:	We have applied to list our common stock on the Nasdaq Capital Market under the symbol "NRXS". We believe that upon the completion of this offering, we will meet the standards for listing on Nasdaq. The closing of this offering is contingent upon the successful listing of our common stock on the Nasdaq Capital Market.
Risk Factors:	See "*Risk Factors*" beginning on page 12 and the other information contained in this prospectus for a discussion of factors you should carefully consider before investing in our securities.
Lock-up:	We, our directors, executive officers, and stockholders who own five percent (5%) or more of our outstanding common stock have agreed with the Underwriter not to offer for sale, issue, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, in the case of the Company for a period of 180 days after the date of this prospectus, and in the case of our directors and executive officers and our five percent (5%) and greater stockholders for a period of 180 days after the date of this prospectus, without the prior written consent of the Underwriter. See "*Underwriting*" for additional information.

(1) The total number of shares of common stock that will be outstanding after this offering is based on [●] shares of common stock outstanding as of September 30, 2022. Unless otherwise indicated, the shares outstanding after this offering excludes the following:

- [●] shares of our common stock issuable upon exercise of warrants to purchase common stock held by Masimo and Brian P. Hannasch;
  [●] shares of our common stock issuable upon exercise of the Underwriter's Warrants to purchase common stock;
- [●] shares of our common stock issuable upon conversion of our convertible notes;
- [●] shares of our common stock issuable upon the exercise of options to purchase common stock.

Unless otherwise indicated, this prospectus reflects and assumes no exercise by the Underwriter of its over-allotment option.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks and uncertainties of which you should be aware before making an investment decision. You should consider all of the information set forth in this prospectus and, in particular, the specific factors set forth under "*Risk Factors*" in deciding whether to invest in our securities. These risks include, without limitation, the following:

Risks Relating to Our Business and Our Product

- Our business and prospects depend entirely on our current product, IB-Stim. Even though we have received FDA clearance for our product, 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.

- 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.

- 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, and therefore substantial doubt is deemed to exist about the Company's ability to continue as a going concern.

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

- 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.

- 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.

- 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 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.

- 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.

- 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.

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

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

- 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.

- 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.

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

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

- 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.

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.

- 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.

- 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 from cyber security breaches and data leakage.

- 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.

- 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 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.

- 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.

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

- 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.

- 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.

- 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.

- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our devices.
- Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products.
- We depend extensively on our patents and proprietary technology and the patents, and we must protect those assets in order to preserve our business.
- 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.
- 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.

Risks Related to Our Common Stock and This Offering

- There has been no public market for our common stock prior to this offering, and an active market in which investors can resell their shares of our common stock may not develop.
- The market price of our common stock may fluctuate, and you could lose all or part of your investment.
- We may not be able to satisfy listing requirements of Nasdaq or maintain a listing of our common stock on Nasdaq.
- We have considerable discretion as to the use of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.
- You will experience immediate and substantial dilution as a result of this offering.
- We do not expect to declare or pay dividends in the foreseeable future.
- If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then 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.
- If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.
- We will be 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.
- 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.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider and evaluate all of the information contained in this prospectus before you decide to purchase our common stock. The risks and uncertainties described in this prospectus are not the only ones we may face. Additional risks and uncertainties that we do not presently know about or that we currently believe are not material may also adversely affect our business, business prospects, results of operations or financial condition. Any of the risks and uncertainties set forth herein, could materially and adversely affect our business, results of operations and financial condition. This could cause the market price of our common stock to decline, perhaps significantly, and you may lose part or all of your investment.

Risks Relating to Our Business and Our Product

Our business and prospects depend entirely on our current product, IB-Stim. Even though we have received FDA clearance for our product, 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. 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;
- difficulties and delays in clinical studies that may occur as a result of the COVID-19 pandemic;
- 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 three (3) consecutive weeks, and not to exceed four (4) 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 technology specific CAT III CPT Code (0720T) was published on December 30, 2021 and effective on July 1, 2022. 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 a sole manufacturer for the production of our product. Any significant disruption to the sole manufacturer's operations or facilities could have a material adverse effect on our business, financial condition and results of operations.

We rely on a sole manufacturer for the production of our products. We do not have control over the operations of the facilities of the third-party manufacturer that we use. A significant disruption to our manufacturer could have a material adverse effect on our business, financial condition and results of operations. Our reliance on our manufacturer 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 manufacturer 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 prospectus relating to, among other things, the expected growth in the market for our 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 our IB-Stim device 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.

The COVID-19 pandemic could materially adversely impact our business.

As the COVID-19 pandemic continues around the globe, we have experienced and will likely continue to experience disruptions that could severely 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 the COVID-19 outbreak 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 the COVID-19 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 global status of the COVID-19 pandemic continues to rapidly evolve. The extent to which the 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 the pandemic may result in permanent changes to the environment in which we operate as described above in ways we are unable to predict. The COVID-19 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 have material weaknesses in our internal control over financing reporting. 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. Prior to this offering, due to accounting resource constraints, we have had limited review controls. These constraints have resulted in (1) a lack of segregation of duties, since we have a limited administrative staff, and (2) lack of internal controls structure review. As a result of these constraints, we have a material weakness in our internal control over financing reporting.

Our management is composed of a small number of individuals resulting in a situation where limitations on segregation of duties exist. **[Company to review/revise this risk factor as appropriate based on audit committee meeting.] All responsibility for accounting entries and the creation of financial statements is held by a single person, though the Company has previously employed additional accounting staff and currently engages multiple accounting consultants for accounting, tax and audit support. To remedy this situation, we would need to hire additional staff or financial consultant support. Currently, we are unable to hire additional staff to facilitate greater segregation of duties but will reassess our capabilities after completion of the offering.

In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, which will require 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, and will take additional actions, such as remediating the material weaknesses described above, implementing additional internal controls and procedures and hiring internal audit staff or financial consultants. 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 additional 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 material weakness, including the material weaknesses described above, 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.

We restated our previously issued consolidated financial statements.

We determined that a restatement of our December 31, 2021 audited financial statements was required after discussions among management and our independent registered public account firm, Rosenberg Rich Baker Berman, P.A., for certain disclosures that have been expanded or have added clarifications.

You should consult with a tax expert before investing in our Company.

You should consult with your own tax advisor about the tax consequences of investing in the Company through the purchase of its securities.

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 from 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 $1,000,000, 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 the 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 and this Offering

There has been no public market for our common stock prior to this offering, and an active market in which investors can resell their shares of our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on Nasdaq under the symbol "NRXS." The closing of this offering is contingent upon the successful listing of our common stock on the Nasdaq Capital Market. There is no guarantee that Nasdaq, or any other exchange or quotation system, will permit our common stock to be listed and traded.

Even if our common stock is approved for listing on Nasdaq, a liquid public market for our common stock may not develop. The initial public offering price for our common stock has been determined by negotiation between us and the Underwriter based upon several factors, including prevailing market conditions, our historical performance, estimates of our business potential and earnings prospects, and the market valuations of similar companies. The price at which the common stock is traded after this offering may decline below the initial public offering price, meaning that you may experience a decrease in the value of your common stock regardless of our operating performance or prospects.

Volatility in the market price of our common stock may prevent investors from being able to sell their common stock at or above the initial public offering price.

After this offering, the market price for our common stock is likely to be volatile, in part because our shares have not been traded publicly. In addition, the market price of our common stock may fluctuate significantly in response to several factors, most of which we cannot control, including:

- actual or anticipated variations in our periodic operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- increases in market interest rates that lead investors of our common stock to demand a higher investment return;
- changes in earnings estimates;
- changes in market valuations of similar companies;
- actions or announcements by our competitors;
- adverse market reaction to any increased indebtedness we may incur in the future;
- sales of our common stock by our officers, directors, or significant stockholders;
- additions or departures of key personnel;
- our progress toward developing our products;
- the commencement, enrollment and results of our future clinical trials;
- adverse results from, delays in or termination of our clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts, if any;
- perceptions about the market acceptance of our products and the recognition of our brand;
- threatened or actual litigation and governmental investigations;
- actions by stockholders;
- speculation in the media, online forums, or investment community; and
- our intentions and ability to list our common stock on Nasdaq and our subsequent ability to maintain such listing.

The public offering price of our common stock has been determined by negotiations between us and the underwriter based upon many factors and may not be indicative of prices that will prevail following the closing of this offering. In addition, the stock market in general, and the stock of early-stage companies like ours in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Such rapid and substantial price volatility, including any stock run-up, may be unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for investors to assess the rapidly changing value of our stock. Volatility in the market price of our common stock may prevent investors from being able to sell their common stock at or above the initial public offering price. As a result, you may suffer a loss on your investment.

We may not be able to satisfy listing requirements of Nasdaq or maintain a listing of our common stock on Nasdaq.

If our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, or if we fail to meet any of Nasdaq'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 Nasdaq 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 have considerable discretion as to the use of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.

We intend to use the proceeds from this offering for working capital, sales and marketing activities, research and development, and repayment of our convertible notes. However, we have considerable discretion in the application of the proceeds. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of this offering. The net proceeds may be used for corporate or other purposes with which you do not agree or that do not improve our profitability or increase our share price. The net proceeds from this offering may also be placed in investments that do not produce income or that lose value. Please see "*Use of Proceeds*" below for more information.

You will experience immediate and substantial dilution as a result of this offering.

As of September 30, 2022, our net tangible book value was approximately $[●], or approximately $[●] per share. Since the effective price per share of our common stock being offered in this offering is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on the assumed public offering price of $[●] per share of common stock being sold in this offering, which is the midpoint of the estimated offering range set forth on the cover page of this prospectus, and our net tangible book value per share as of September 30, 2022, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $[●] per share (or $[●] per share if the Underwriter exercises the over-allotment option in full) with respect to the net tangible book value of the common stock. See the section titled "*Dilution*" for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

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 do not publish research reports on us, or 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. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such 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 connection with this offering, we will enter into a lock-up agreement that prevents us, subject to certain exceptions, from offering additional shares of capital stock for up to six months after the closing of this offering, as further described in the section titled "*Underwriting*." 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 Nasdaq 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 will be 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.

Upon the completion of this offering, we will be 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 will be 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 Nasdaq 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 Nasdaq. 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 Nasdaq requirements that are or may be afforded to smaller reporting companies while we will seek to maintain our shares on Nasdaq, 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 Nasdaq from which we would not be exempt, including minimum stock price requirements.

USE OF PROCEEDS

Based upon an assumed public offering price of $[●] per share, we estimate that we will receive net proceeds from this offering, after deducting the underwriting discounts and the estimated offering expenses payable by us, of approximately $[●] million assuming the Underwriter does not exercise its over-allotment option.

We plan to use the net proceeds we receive from this offering for the following purposes:

	Use of Net Proceeds	
Sales and Marketing	$	[●]
Research and Development[(1)]	$	[●]
Repayment of Convertible Notes[(2)]	$	[●]
General Corporate Purposes	$	[●]

(1) Includes all funding of our IB-Stim device through the 510(k) De Novo FDA review for functional abdominal pain and IBS in children, as well as anticipated funding needed to achieve the regulatory milestones for our technology in respect of other indications as set forth in the chart captioned "FDA Pipeline Indications and Projected Timelines" under "*Prospectus Summary—Pipeline*."

(2) Includes OID accreted through September 30, 2022. The Notes were issued an OID of 10% of the principal amount and bear interest at the greater of (a) the prime rate of interest, as published by the Wall Street Journal, plus 8.5% per annum, or (b) 12%. The Notes mature twelve (12) months from their respective issue dates. For additional information, see "*Prospectus Summary–Recent Development*".

We believe that our existing cash and cash equivalents, together with proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. The foregoing represents our current intentions based upon our present plans and business conditions to use and allocate the net proceeds of this offering. However, the nature, amounts and timing of our actual expenditures may vary significantly depending on numerous factors. As a result, our management has and will retain broad discretion over the allocation of the net proceeds from this offering. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of net proceeds from this offering. To the extent that the net proceeds we receive from this offering are not immediately used for the above purposes, we intend to invest our net proceeds in short-term, interest-bearing bank deposits or debt instruments.

DIVIDEND POLICY

The Company has not declared or paid any cash dividend on its common stock, and it currently intends to retain future earnings, if any, to finance the expansion of its business, and the Company does not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on its common stock will be made by its board of directors, in their discretion, and will depend on the Company's financial condition, results of operations, capital requirements and other factors that its board of directors considers significant.

CAPITALIZATION

Set forth below is our cash and capitalization as of December 31, 2021:

- on an actual basis;
- on a pro forma basis to reflect conversion of the Series A and Series Seed Preferred Stock in connection with this offering;
- on a pro forma as adjusted basis to reflect the issuance and sale of the shares by us in this offering at the public offering price of $[●] per share, after deducting the estimated underwriting discounts and the estimated offering expenses payable by us.

You should read the information in the below table together with our financial statements and related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations," each included elsewhere in this prospectus.

	As of December 31, 2021		
	Actual (1)	Pro Forma (2)	Pro Forma As Adjusted
Cash and cash equivalents	$ 320,858	$ [●]	$ [●]
Convertible debt, net of discount	[●]	[●]	[●]
Total stockholders' equity:			
Common stock, par value $0.001 per share, 100,000,000 shares authorized, 3,856,008 shares issued and outstanding as of December 31, 2021;	3,856	[●]	[●]
Convertible Series A Preferred Stock, par value $0.001 per share, 1,000,000 shares authorized, 506,637 shares issued and outstanding as of December 31, 2021;	507	[●]	[●]
Convertible Series Seed Preferred Stock, par value $0.001 per share, 120,000 shares authorized, 115,477 shares issued and outstanding as of December 31, 2021;	115	[●]	[●]
Additional paid in capital	28,321,229	[●]	[●]
Accumulated (deficit)	(29,151,367)	[●]	[●]
Total stockholders' (deficit) equity	(825,660)	[●]	[●]
Capitalization	$ (825,660)	$ [●]	$ [●]

The table above is based on 3,856,008 shares of common stock outstanding as of December 31, 2021, and excludes, as of such date:

- 685,262 shares of our common stock issuable upon exercise of warrants to purchase common stock held by Masimo and Brian P. Hannasch;
- [●] shares of our common stock issuable upon exercise of the Underwriter's Warrants to purchase common stock;
- [●] shares of our common stock issuable upon conversion of the Notes (see "*Prospectus Summary—Recent Development*" for more information);
- 988,710 shares of our common stock issuable upon conversion of our convertible notes; and
- 659,697 shares of our common stock issuable upon exercise of options to purchase common stock.

DILUTION

If you invest in the Company's shares in this offering, your ownership interest will be diluted to the extent of the difference between the offering price per share of its common stock and the as-adjusted net tangible book value per share of its common stock immediately after the offering. Historical net tangible book value per share represents the amount of the Company's total tangible assets less total liabilities, divided by the number of shares of its common stock outstanding.

The historical net tangible book value (deficit) of the Company's common stock as of September 30, 2022, was approximately $([●] million) or $([●]) per share based upon shares of common stock outstanding on such date. Historical net tangible book value (deficit) per share represents the amount of its total tangible assets reduced by the amount of its total liabilities, divided by the total number of shares of common stock outstanding. The pro forma historical net tangible book value (deficit) was $([●]) per share based upon shares of common stock outstanding as of September 30, 2022.

After giving effect to the Company's sale of all of the [●] shares of common stock offered in this offering at a public offering price of $[●] per share after deducting estimated underwriting discounts and commissions and the Company's estimated offering expenses, the Company's pro forma as adjusted net tangible book value as of September 30, 2022 would have been $[●] or $[●] per share. This represents an immediate increase in net tangible book value of $[●] per share to the Company's existing stockholders, and an immediate dilution in net tangible book value of $[●] per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per share	$	[●]
Historical net tangible book value (deficit) per share as of	$	[●]
Pro forma historical net tangible book value (deficit) per share as of attributable to the pro forma transaction described above	$	[●]
Increase in pro forma net tangible book value per share as of attributable to the pro forma transactions described above	$	[●]
Pro forma net tangible book value per share as of	$	[●]
Dilution per share to new investors in this offering	$	[●]

The information discussed above is illustrative only, and the dilution information following this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed public offering price of $[●] per share would increase (decrease) the pro forma as adjusted net tangible book value by $[●] per share and increase the dilution to new investors by $[●] per share and decrease the dilution to new investors by $[●] per share, assuming the number of shares offered by the Company, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by the Company. The Company may also increase or decrease the number of shares it is offering. An increase of 100,000 shares offered by it would increase the pro forma as adjusted net tangible book value by $[●] per share and decrease the dilution to new investors by $[●] per share, assuming the assumed public offering price of $[●] per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by the Company. Similarly, a decrease of 100,000 shares offered by the Company would decrease the pro forma as adjusted net tangible book value by $[●] per share and increase the dilution to new investors by $[●] per share, assuming the assumed public offering price of $[●] per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by the Company.

If the Underwriter's over-allotment option to purchase additional shares from the Company is exercised in full, and based on the assumed public offering price of $[●] per share, the pro forma as adjusted net tangible book value per share after this offering would be $[●] per share, the increase in as adjusted net tangible book value per share to existing stockholders would be $[●] per share and the dilution to new investors purchasing shares in this offering would be $[●] per share.

The number of shares of common stock outstanding is based on [●] shares of common stock issued and outstanding as of September 30, 2022, and excludes the following:

- [●] shares of our common stock issuable upon exercise of warrants to purchase common stock held by Masimo and Brian P. Hannasch;
- [●] shares of our common stock issuable upon exercise of the Underwriter's Warrants to purchase common stock;
- [●] shares of our common stock issuable upon conversion of our convertible notes; and
- [●] shares of our common stock issuable upon the exercise of options to purchase common stock.

Except as otherwise indicated herein, all information in this prospectus assumes:

- no exercise of the outstanding options or warrants, or conversion of the convertible notes, described above; and
- no exercise of the Underwriter's option to purchase up to an additional [●] shares of common stock to cover over-allotments, if any, or any warrants issued to the Underwriter as compensation.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties, and assumptions. You should read the "Certain Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a growth stage company focused on developing neuromodulation therapies to address chronic and debilitating conditions in children. Our mission is to provide solutions that create value and provide better and safer patient outcomes. Our IB-Stim device is a PENFS system intended to be used in patients 11-18 years of age with functional abdominal pain associated with IBS. Our device already has market clearance from FDA for functional abdominal pain associated with IBS in children. Other indications in our pipeline are comprised of functional nausea in children, post-concussion syndrome in children, and cyclic vomiting syndrome in children. For more information, see "*Business—Our Pipeline*" and *"—Products*."

Since our inception, we have incurred significant operating losses. Our net loss was $3.0 million and $3.7 million for the years ended December 31, 2021, and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $29.2 million. Our auditors have expressed substantial doubt about our ability to continue as a going concern paragraph 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 device 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 our IB-Stim device to treat future indications.

Factors Affecting our Business and Results of Operations

Revenue

Our revenue is derived from the sale of our IB-Stim device to healthcare companies, primarily hospitals and clinics. Sales generally are not seasonal and only mildly correlated with economic cycles. Our IB-Stim device costs $1,195 per device, and each child being treated for functional abdominal pain associated with IBS will use three to four devices. Potential patients with future indications are expected to use six or more devices per patient

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 devices 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 that payment is due within 30 to 90 days. Our largest sales were to four hospitals representing approximately 58% and 67% of total sales for the years ended December 31, 2021 and 2020, 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.

Expenses

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

Costs of goods sold consists of costs paid for the IB-Stim device to our contract manufacturer along with periodic inventory adjustments and expired inventory write-offs. We ramped up production in 2018 and 2019 to meet expected demand and avoid any inventory shortages. This resulted in some excess inventory that did expire. The costs of expired inventory were $0.5 million and $0.1 million for the years ended December 31, 2021 and 2020, respectively, representing 10.4% and 3.0% of our costs of goods sold, respectively. Expired inventory expense is related to our FDA clearance for our device in the treatment of functional abdominal pain associated with IBS in children. Specifically, a certain component of our IB-Stim device is cleared for two-year period after the date the device is manufactured, and if the device is not sold in such period, we must take the device out of inventory and write it off. Expired inventory was 1.8% of sales for the year ended December 31, 2021 sales. Accordingly, expired inventory has not been material to our results, averaging less than 1.0% of revenue over the past three years. We have a fixed-price contract with the manufacturer of our IB-Stim device to produce the device. We expect production costs to remain relatively constant and only nominal inventory expirations in the foreseeable future.

Our core selling expenses primarily consist of commissions and shipping costs. These expense items are generally correlated with sales.

R&D expense is attributable to our clinical trials and related efforts to have our IB-Stim device cleared by the FDA for other indications. We expect to spend approximately $0.3 million for research and development in 2022, and we anticipate that these costs will increase in 2023 as clinical trials for post-concussion syndrome in children, and cyclic vomiting syndrome in children are completed, although we cannot assure that these trials will be completed on time, will be successful, or that trial results will lead to FDA clearance for any particular indication.

G&A expense consists of payroll and professional fees and is our most significant expense category. Payroll and professional fees account for approximately 90% of our G&A expenses. The balance of the expenses are normal operating expenses for facility expenses, utilities, travel, etc. We expect G&A expenses to increase as we transition to operating as a public company, but we expect G&A expense to stabilize within two years of completion of this offering.

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 revenue less cost of goods sold, and gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily the average selling price of our IB-Stim device, production volume, order flows, change in mix of customers, third-party manufacturing costs related to components of our IB-Stim device, and cost-reduction strategies. We expect our gross profit to increase for the foreseeable future as our revenue grows, both through broader insurer acceptance of our IB-Stim device 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, particularly as we introduce enhancements to our IB-Stim device and new products to address other indications, and as we adopt new manufacturing processes and technologies.

Results of Operations

Comparison of Year Ended December 31, 2021, and Year Ended December 31, 2020

	Years Ended December 31,	
	2021	**2020**
Net sales	$ 2,721,286	$ 1,930,228
Costs of goods sold	467,656	481,089
Gross profit	2,253,630	1,449,139
Selling expenses	455,879	521,034
Research and development	203,414	166,798
General and administrative	4,564,371	4,882,045
Operating loss	$ (2,970,034)	$ (4,120,738)
Other income (expense):		
Interest expense	(36,928)	(75,711)
Interest income	—	37
License revenue	—	250,000
Gain on loan forgiveness	—	220,000
Change in fair value of derivative financial instruments	(29,342)	1,911
Other expense	—	(1,923)
Other income	8,272	275
Total other income (expense)	(57,998)	394,589
Net loss	**$ (3,028,032)**	**$ (3,726,149)**

Net Sales

Net sales increased approximately $0.8 million, or 41%, from $1.9 million for the year ended December 31, 2020, to $2.7 million for the year ended December 31, 2021. The increase was primarily due to certain insurance carriers covering the cost of our device for the treatment of functional abdominal pain associated with IBS in children.

Costs of Goods Sold

Costs of goods sold decreased slightly, approximately 3%, in the year ended December 31, 2021, as compared to the year ended December 31, 2020, mainly because of a transition from our previous contract manufacturer to our current manufacturer. There were inefficiencies in the inventory process in 2020 that were remedied in 2021.

Gross Profit

Gross profit increased approximately $0.8 million, from $1.5 million for the year ended December 31, 2020, to $2.3 million for the year ended December 31, 2021, representing 82.8% of revenue in 2021 and 75.1% of revenue in 2020. The increase was primarily due to the decrease in cost of goods sold combined with higher sales in 2021.

Gross Margin

Gross margin increased approximately 7.7%, from 75.1% for the year ended December 31, 2020, to 82.8% for the year ended December 31, 2021. The increase was primarily due to an increase in sales and cost efficiencies from increased sales in 2021.

Selling Expenses

Selling expenses were down slightly in the year ended December 31, 2021, as compared to the year ended December 31, 2020. This was primarily due to a decrease in promotional inventory distributed. Commission and shipping costs both increased in the year ended December 31, 2021, and these increases were directly attributable to the increase in net sales.

Research and Development

R&D expense increased 22% in the year ended December 31, 2021, as compared to the year ended December 31, 2020, and this increase was due to our support and expansion of clinical trials to get our IB-Stim device cleared for other indications. R&D costs remained at 7.5% of net sales and 8.6% of net sales in 2021 and 2020, respectively.

General and Administrative

G&A expense decreased approximately 6.5% in the year ended December 31, 2021, as compared to the year ended December 31, 2020. This was due primarily to reduced payroll cost. We expect G&A expense to increase in 2022 primarily because of costs incurred in connection with this offering.

Operating Loss

Our operating loss decreased $1.2 million, or 27.9%, for the year ended December 31, 2021, as compared to the year ended December 31, 2020, primarily due to increased net sales and reduced payroll expense.

Other Income (Expense)

Other expense for the year ended December 31, 2021, was primarily attributable to interest expense. We recorded other income of $0.4 million for the year ended December 31, 2020, due to a one-time license fee payment of $250,000 from Masimo and forgiveness of a $220,000 loan we received under Paycheck Protection Program established as part of the Coronavirus Aid, Relief and Economic Security Act in 2020 ("PPP Loan"), partially offset by higher interest expense in 2020. For more information regarding the Masimo license, see "*Business—License Agreements—Masimo License and Collaboration Agreement*."

Net Loss

Our net loss decreased approximately $0.7 million, or 18.7%, in the year ended December 31, 2021, as compared to the year ended December 31, 2020. The change was primarily attributable to increased net sales, reduced payroll expense, partially offset by other income from the Masimo license fee and the PPP Loan forgiveness.

Liquidity and Capital Resources

We had cash on hand of approximately $0.3 million at December 31, 2021, as compared to cash-on-hand of approximately $1.9 million at December 31, 2020. Working capital at December 30, 2021 was $(0.9) million, as compared to working capital of $1.5 million at December 31, 2020. The decrease in working capital was due to cash used by operating activities of $2.2 million, partially offset by capital raised in 2021 of $0.7 million.

We anticipate our sales over the next 12 months to be approximately $5.0 million, assuming our expectations with respect to acceptance by insurance providers are generally correct, and we anticipate our liquidity needs over this period to be approximately $7.0 million. To bridge the gap, we intend to seek debt or equity financing, such as the arrangement described under "*—Recent Development*" below, as well as proceeds from this offering. We expect proceeds from this offering to fund our capital needs for the following 12 months.

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. We anticipate over the next 12 months the cost of being a reporting public company will be approximately $0.5 million.

The following table summarizes our cash flows from operating, investing, and financing activities for the years ended December 31, 2021 and 2020:

	Years Ended December 31,	
	2021	**2020**
Net cash used in operating activities	$ (2,234,326)	$ (4,139,329)
Net cash used by investing activities	(1,390)	(27,719)
Net cash provided by financing activities	661,099	6,054,023

Operating Activities – Cash used in operating activities primarily consisted of general and administrative expense that more than offset sales, resulting in a net loss for the year. The net loss was partially offset by favorable changes in accounts receivable and accounts payable in 2021, and net loss was negatively impacted with changes in accounts receivable and accounts receivable in 2020.

Investing Activities – Net cash used in investing activities primarily consisted of equipment additions.

Financing Activities

Net cash provided by financing activities in 2021 primarily consisted of proceeds from the sale of preferred stock. We also borrowed $250,000 from a third party in December 2021.

Net cash provided by financing activities in 2020 primarily consisted of proceeds from the sale of preferred stock to Masimo. For more information, see "*Business—License Agreements—Masimo License and Collaboration Agreement*." We also borrowed $220,000 under a PPP Loan. Our PPP Loan was approved for total forgiveness in December 2020.

Founder's Stock Issuance

In connection with the founding of the Company, Christopher Robin Brown and Gary Peterson, each a member of our board of directors, each received 468,000 of shares of our common stock, and each executed and delivered a promissory note, dated January 1, 2016, for $548,448 and $548,320, respectively, which amounts include accrued and unpaid interest through September 30, 2022. The promissory notes are unsecured and payable on demand by the Company. As of December 31, 2019, the Company recorded a collection allowance against the promissory notes and accrued interest receivable and, therefore, the promissory notes and related accrued interest are no longer itemized as an asset on our balance sheet.

Recent Development

From June 3, 2022 to November 30, 2022, we entered into Securities Purchase Agreements (the "SPAs") with Leonite Fund I, Emmis Capital II, LLC, Bigger Capital Fund, LP, District 2 Capital Fund, LP, and Exchange Listing, LLC, which provide for advances of up to $2.9 million in proceeds to us, subject to our satisfaction of certain conditions. Pursuant to the SPAs, from June 3, 2022 to November 30, 2022, we issued the Senior Secured Convertible Promissory Notes ("Notes") with an aggregate principal amount of $2,777,777, which amount included original issue discount ("OID") of $222,223, and legal fees for $130,000, resulting in advance proceeds to us of $2.370 million. In connection with the issuance of the Notes, we also issued five-year warrants exercisable for an aggregate of 588,514 shares of common stock with an exercise price of the lower of (a) $5.90 and (b) a 12% discount to the price per share in any subsequent offering by the Company, and we entered into a Pledge and Security Agreement with Leonite Fund I, LP, dated June 3, 2022. Pursuant to the Pledge and Security Agreement, the Company granted a security interest in all of its assets in favor of Leonite Fund I, LP, in its capacity as collateral agent for the purchaser's parties under the SPAs.

The Notes were issued with OID of 10% of the principal amount and bear interest at the greater of (a) the prime rate of interest, as published by the Wall Street Journal, plus 8.5% per annum, or (b) 12%. The Notes will mature in twelve (12) months from their respective issue dates. Any amount of principal, interest, other amounts due hereunder or penalties on this Note, which is not paid by maturity date, shall bear interest at the lesser of the rate of twenty four percent (24%) per annum or the maximum legal amount permitted by law, from the due date thereof until the same is paid in full, including following the entry of a judgment in favor of Holder. The Notes are convertible into shares of common stock at the lower of (a) $4.72 per share, or (b) a discount of 30% to the price per share in any subsequent offering, subject to adjustment in the event of common stock distribution, stock splits, fundamental transactions, dilutive issuances or similar events affecting our common stock and the conversion price. Interest accrues on the aggregate principal amount (which includes OID) and is payable monthly, at the Company's election, in cash or in-kind.

Upon the advance of the consideration under the SPAs, the Company is required to issue to the noteholders a number of shares of common stock, calculated based on the value of 10% of the principal amount of the Notes issued in such advance, at a value per share equal to the conversion price of the Notes. Accordingly, from June 3, 2022 to November 30, 2022, in connection with the initial advance and issuance of Notes, we will be issuing 58,855 shares of common stock to the noteholders.

The Notes have certain restrictions on the Company's issuance of securities, including (i) the Company shall not without the noteholder's written consent (a) pay, declare or set apart for such payment, any dividend or other distribution (whether in cash, property or other securities) on the common stock of the Company other than dividends on common stock solely in the form of additional common stock, or (b) directly or indirectly or through any subsidiary make any other payment or distribution in respect of common stock or equivalents, (ii) unless approved by the noteholders in writing, the Company shall not enter into an agreement or amend an existing agreement to effect any sale of securities involving, or convert any securities previously issued under, a variable rate transaction, which means a transaction in which the Company (A) issues or sells any convertible securities either (a) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the common stock, or (b) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company, or the market for the common stock, or (B) enters into any agreement whereby the Company may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights), (iii) the noteholders have the right, but not the obligation, to participate in the purchase of the securities being offered up to an amount equal to thirty percent (30%) of the principal amount of the Notes (the " Participation Right") when the Company or its subsidiary proposes to offer and sell its securities, whether in the form of debt, equity financing, or any other financing transaction (each a "Future Offering"); provided that, the Participation Right shall not exceed the lesser of (i) one-third of the aggregate amount of the Future Offering, and (ii) an amount equal to the principal amount (allocated to the noteholder's pro-rata to their portion of the principal amount).

We have agreed to pay to the noteholders any outstanding principal amount of the Notes, all accrued and unpaid interest, and fees and penalties, if any, from any future financing proceeds (which includes proceeds to us from this offering) and other future receipts, at the noteholder's discretion, except for the right of the Company to make bona fide payments to vendors with common stock.

In addition, pursuant to the SPAs, so long as no event of default has occurred under the Notes, the closing of additional tranches, in each case consisting of Notes in the aggregate advance amount of up to $400,000 and an aggregate principal amount (including the) of up to $444,444, shall occur (i) upon the Company filing a registration statement with the SEC on Form S-1 and (ii) upon the effectiveness of the CPT codes issued the Company, but in any event not later than December 3, 2022.

Quantitative and Qualitative Disclosures About Market Risk

We have not utilized any derivative financial instruments such as futures contracts, options and swaps, forward foreign exchange contracts or interest rate swaps and futures. We believe that adequate controls are in place to monitor any hedging activities. We do not intend to hedge any existing or future borrowings and, consequently, we do not expect to be affected by changes in market interest rates. We do not currently have any sales or own assets and operate facilities in countries outside the United States and, consequently, we are not affected by foreign currency fluctuations or exchange rate changes. Overall, we believe that our exposure to interest rate risk and foreign currency exchange rate changes is not material to our financial condition or results of operations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"), which requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities on the date of the financial statements and the reported amounts of revenues and expenses during the financial reporting period. We continually evaluate these estimates and assumptions based on the most recently available information, our own historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from those estimates. Some of our accounting policies require higher degrees of judgment than others in their application. We consider the policies discussed below to be critical to an understanding of our financial statements.

The SEC defines critical accounting policies as those that are, in management's view, most important to the portrayal of our financial condition and results of operations and those that require significant judgments and estimates.

The accounting principles we utilized in preparing our financial statements conform in all material respects to U.S GAAP.

Inventories

Inventories are valued at the lower of cost or net realizable value. Our inventory is comprised of finished medical devices on hand. Certain components within the devices have an expiration date and are removed from current inventory and expensed at the date of expiration.

Leases

We account for our leases under Accounting Standards Update No. 2016-02, *Leases*. We do not record an operating lease right of use ("ROU") asset and corresponding lease liability for leases with an expected term of 12 months or less and recognize lease expense for these leases as incurred over the lease term. Operating lease ROU assets and operating lease liabilities for leases with an expected term of more than 12 months are recognized based on the present value of lease payments over the lease term. For lease present value calculations, absent a rate implicit in the lease, we determine a comparable incremental borrowing rate. The present value is then recognized as lease expense on a straight-line basis over the lease term.

Derivative Financial Instruments

We evaluate our financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with Accounting Standards Codification 815, *Derivatives and Hedging* ("ASC 815"). The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. As of December 31, 2020, our derivative financial instruments were comprised of warrants issued in connection with capital raising transactions. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is reassessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instruments will be classified in the balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

Revenue Recognition

Revenue is recognized in one major product segment – commercial products. The timing of revenue recognition for this product segment occurs as goods are transferred at a point in time.

We estimate credit losses on accounts receivable by estimating expected credit losses over the contractual term of the receivable using a discounted cash flow method. When developing this estimate of expected credit losses, we consider all available information (past, current, and future) relevant to assessing the collectability of cash flows. The Company has concluded that realization losses on balances outstanding at year-end will be immaterial.

Recent Accounting Pronouncements

There are several recently issued accounting pronouncements that have been reviewed and adopted. The pronouncements regarding leases had a material impact on our financial statements. There are no other recently issued accounting pronouncements that we have not yet adopted that we believe are applicable or would have a material impact on our financial statements. For more information regarding recent accounting pronouncements, refer to Note 1 to our audited financial statements contained elsewhere in this prospectus.

We are an emerging growth company, and 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.

BUSINESS

Overview

We are a growth stage company focused on developing neuromodulation therapies to address chronic and debilitating conditions in children. We are dedicated to advancing the science with our proprietary Percutaneous Electrical Nerve Field Stimulation (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. With one FDA indication (functional abdominal pain associated with IBS in adolescents 11-18 years old) on the market, additional clinical trials of PENFS in multiple pediatric conditions are underway focused on unmet healthcare needs in children, see "—*Our Pipeline*" for more information.

Our first product, IB-Stim, is a PENFS system intended to be used in patients 11-18 years of age with functional abdominal pain associated with IBS. IB-Stim is a US FDA Class II medical device that has received one regulatory clearance: DEN180057, under the regulation name of "non-implanted nerve stimulator for functional abdominal pain relief."

Our Mission

Our mission is to provide solutions that create value and provide better and safer patient outcomes. We believe in improving lives and minimizing suffering; particularly in the pediatric population, where research and therapeutics are usually lacking. The Company already has market clearance for its IB-Stim ® that targets functional abdominal pain associated with IBS, in children, with a total addressable market of up to 6 million children. Through innovation and research, we are reimagining the future of patient care.

Our Corporate History

Neuraxis, Inc. ("we," "us," the "Company," or "Neuraxis") was established in 2011 and incorporated in the state of Indiana on April 17, 2012, under the name of Innovative Health Solutions, Inc. The name was changed to Neuraxis, Inc. in March of 2022. Additionally, the Company filed a Certificate of Conversion to become a Delaware corporation on June 23, 2022. The authorized shares were increased, and a par value established. On September 7, 2021, the Company's board of directors authorized a 4-for-1 stock split. They also increased the number of authorized common stock shares from 2,700,000 to 10,800,000. Furthermore, on September 9, 2021, the board authorized and increase of authorized shares of common stock from 10,800,000 to 13,400,000 in anticipation of a capital offering.

As part of the conversion to a Delaware corporation, the total number of shares of all classes of stock which the Corporation shall have authority to issue is 101,120,000 share, consisting of (1) 100,000,000 shares of Common Stock, par value $0.001 per share ("Common Stock") and (ii) 1,120,000 shares of Preferred Stock, par value $0.001 per share ("Preferred Stock"), 1,000,000 of which is designated as "Series A Preferred Stock" and 120,000 of which is designated as "Series Seed Preferred Stock".

We have developed three FDA cleared products, the IB-Stim (DEN180057, 2019), the NSS-2 Bridge (DEN170018, 2017), and the original 510(K) clearance (K140530, 2014), all of which were developed internally by the Company.

- The IB-Stim is a PENFS device that is indicated in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome. The IB-Stim currently is the only product marketed and sold by the Company.

- The NSS-2 Bridge is a percutaneous nerve field stimulator, or PNFS, device indicated for use in the reduction of the symptoms of opioid withdrawal. The NSS-2 Bridge device was licensed to Masimo in April 2020, and we received a one-time licensing fee of $250,000 from Masimo. Masimo markets and sells this product as its *Masimo Bridge*, and we will not receive any further licensing payments or other revenue from this product.

- 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, had expressed concern about the lack of attention given to children with functional abdominal pain disorders (including IBS) and the limited treatment options available for a population that suffers from significant disabilities. With 20% of United States population under age 18, our company focus on opportunities in 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, 35-45% 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 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 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 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 SSRIs) 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 to for Neuraxis. Below are the current standard treatments in Children with functional abdominal pain and IBS.

Our Solutions

We entered into the pediatric market with clinical evidence, coverage and payment, and key opinion leaders and society endorsement, including a signed letter from the American Academy of Pediatrics and NASPGHAN supporting our request for insurers to pay for our IB-Stim device. Our 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). The FDA created a new classification of PENFS for the IB-Stim device. This is based on pre-clinical and clinical studies demonstrating the mechanism of action and efficacy. Based on this new class of devices, the 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 CNS. 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

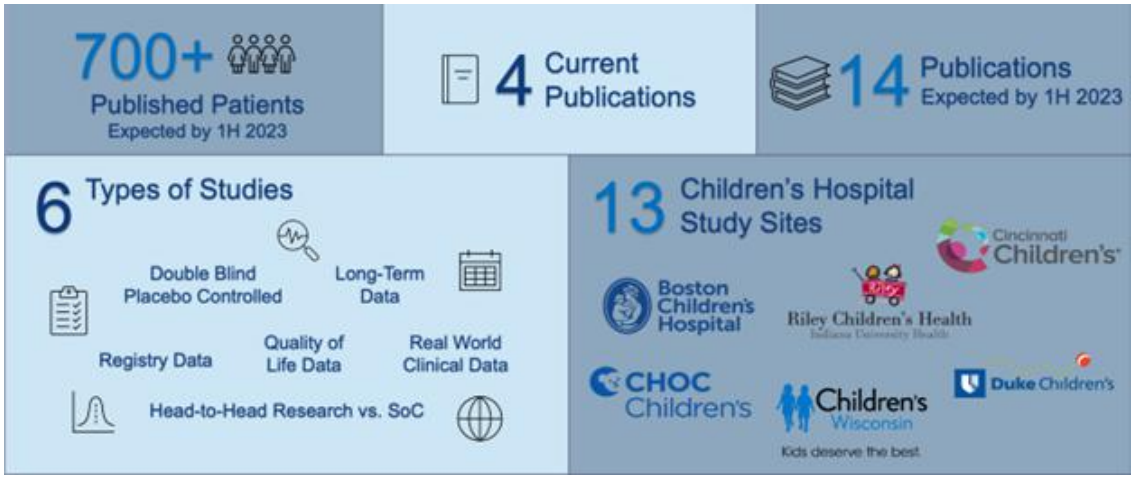
Parameters	Baseline	Penfs				p value[3]	Follow-up	p value[4]
		Week 1	Week 2	Week 3	Week 4			
GI Symptoms								
Resting VAS								
Pain Intensity	2.2 ± 0.52	1.72 ± 0.52	1.75 ± 0.53	1.73 ± 0.53	1.61 ± 0.53	0.06	-	-
Pain Unpleasantness	2.05 ± 0.5	1.21 ± 0.5	1.33 ± 0.51	1.28 ± 0.51	1.28 ± 0.51	0.03	-	-
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	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	47.85 ± 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; [3]p for Week 4 vs. Week 0; [4]p for long-term follow-up vs. Week 0

We have only submitted one FDA De Novo request and have not submitted any additional 510(k) premarket notifications for our pipeline indications to date.

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, 95% of adolescents who used IB-Stim said that they would recommend this treatment to family and friends. Many children's hospitals across the country are already treating children with IB-Stim successfully since it provides a better alternative for therapy in children with IBS and disability and allows them to treat them safely and effectively.

We have concentrated our marketing focus on the 260 children's hospitals. To date, we have sold our IB-Stim product to approximately 50 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. It also includes devices that could theoretically be used, but do not have supporting data or FDA clearance for functional bowel disorders or IBS. Our method patents also limit other devices from targeting IBS through stimulation of cranial nerve branches in the ear.

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

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 of 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 Support
- Lower capital expenditures in nurse, trainers, and representatives for first line therapy
- Strong clinical data carried out in leading academic institutions in the United States

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 and pediatric clinics

Our Pipeline

The IB-Stim device is intended to be used for the first indication of functional abdominal pain associated with IBS and functional nausea in children. The same underlying technology will be used for the remaining pipeline indications, but we may use a name other than "IB-Stim" for marketing and commercialization purposes.

With one FDA indication—functional abdominal pain associated with IBS in adolescents 11-18 years old—on the market, additional clinical trials of PENFS in multiple pediatric conditions are underway focused on unmet healthcare needs in children. These indications include chronic nausea, post-concussion syndrome, chemotherapy-induced nausea and vomiting, cyclic vomiting syndrome.

The figures below show our anticipated FDA timelines for IB-Stim and each of the following pediatric indications:

1. Chronic nausea—RCT completed, and data being analyzed. ClinicalTrials.gov Identifier: NCT03675321. *Defining Adolescent Nausea Through Brain-Gut Physiology and Non-Invasive Neurostimulation Response.* A randomized, double blind, placebo-controlled trial to evaluate the efficacy of IB-Stim in children with functional nausea. The primary endpoint was to measure improvements in nausea using the Nausea Severity Scale after IB-Stim therapy compared to a placebo device. The study will enrolled 110 participants and was conducted at Children's Wisconsin/Medical College of Wisconsin.

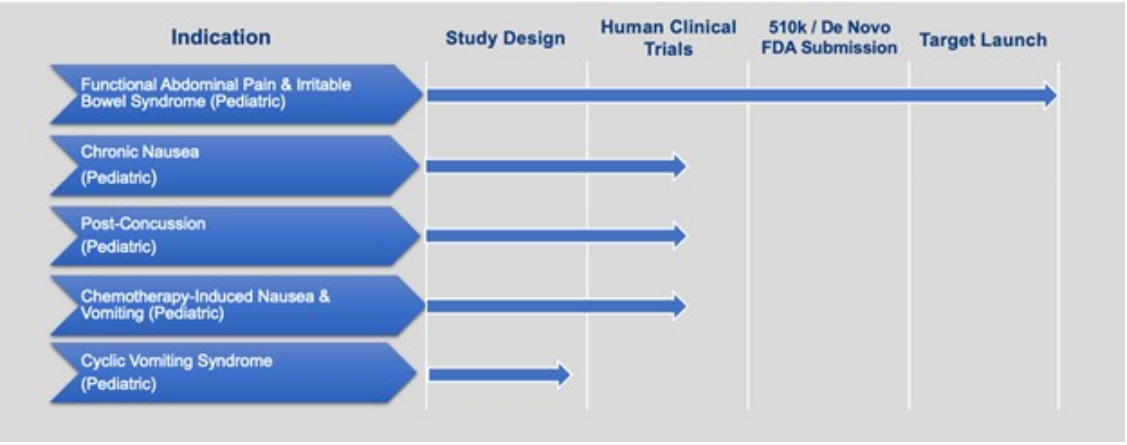
2. Post-concussion syndrome—RCT currently enrolling patients. ClinicalTrials.gov Identifier: NCT04978571. *A Prospective Study on the Effect of Auricular Percutaneous Electrical Nerve Field Stimulation (PENFS) in Patients with Post-Concussion Syndrome (PCS).* A randomized, double blind, placebo-controlled 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 compered to placebo. The study will enroll 100 participants and is being conducted at Children's Hospital of Orange County.

3. Chemotherapy-induced nausea and vomiting—RCT currently enrolling patients. ClinicalTrials.gov Identifier: NCT05143554. *Efficacy of Auricular Neurostimulation for Children Adolescents and Young Adults with Chemotherapy Induced Nausea and Vomiting.* Subject will be randomized to 5 days of active vs placebo device during administered chemotherapy known to cause moderate to severe nausea/vomiting. With the next scheduled identical chemotherapy cycle, each subject will cross over to the other device (active vs placebo). The primary endpoint will be to measure improvements in validated measures of nausea and vomiting including the Baxter Retching Faces Scale, Rhodes Index of Nausea, Vomiting and Retching, and also assessment of rescue medication. The study will enroll 50 participants and is being conducted at Children's Wisconsin/Medical College of Wisconsin.

4. Cyclic vomiting syndrome—Pilot study completed, see ClinicalTrials.gov Identifier: NCT03434652, multicenter RCT not yet started. *Auricular Neurostimulation for Children with Cyclic Vomiting Syndrome: A randomized, placebo-controlled trial.* This will be a multi-center, randomized, 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 the 3 sites are yet to be finalized.

The projected timelines are management's best estimate of the FDA review process and based on past experience, as well as information available and assumptions we consider reasonable, but the 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.

FDA Pipeline Indications and Projected Timelines



Products

The IB-Stim is a percutaneous PENFS system intended to be used in patients 11-18 years of age with functional abdominal pain associated with IBS. IB-Stim already has market clearance from FDA for functional abdominal pain associated with IBS in children. FDA has classified the non-implanted nerve stimulator for functional abdominal pain relief as Class II devices.

The IB-Stim is intended to be used for 120 hours per week for three (3) consecutive weeks, and not to exceed four (4) 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. 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. See *Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomized, double-blind, sham-controlled trial*, Kovacic K, et.al., Lancet Gastroenterol Hepatol. 2017;2:727-737; *Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial*, Krasaelap A et.al., Clin Gastroenterol Hepatol. 2020;18:1987-1994; *Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders*, Santucci et.al., Neurogastroenterol Motil. 2022;34:e14358.

The ability of the IB-Stim to produce systemic effects by modulating the central nervous system has been demonstrated in a pre-clinical animal model of IBS (see "*Pre-Clinical Data*" in the section titled "*Technology*"). 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 "*Clinical Data*" in the section titled "*Technology*"). 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 allergy (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.

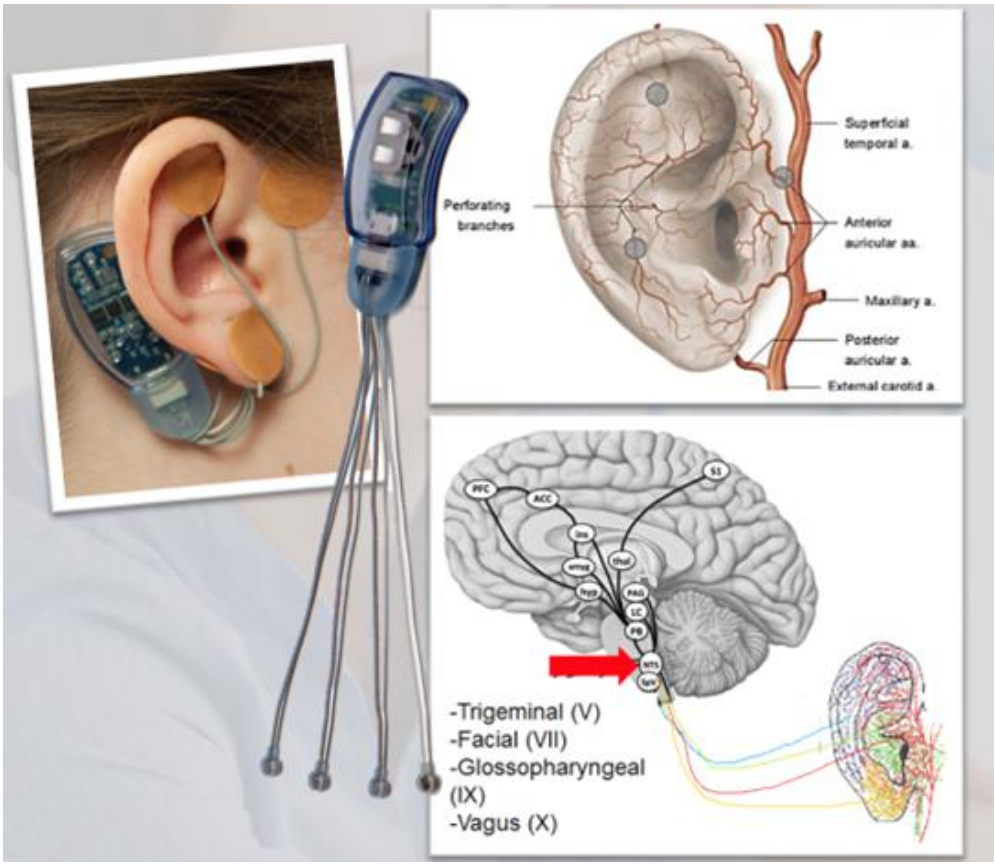
Medical providers are trained to place the IB-Stim through IB-Stim Training and Certification. Once the provider is trained, the device can be placed in the outpatient clinic and can be removed by the provider in the clinic or the patient at home. IB-Stim stays on for a total of five-days to allow delivery 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 our IB-Stim device, patients can still attend school and extracurricular activities, exercise or play non-contact sports, shower, wear ear buds or headphones, and travel.

Our IB-Stim device 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.

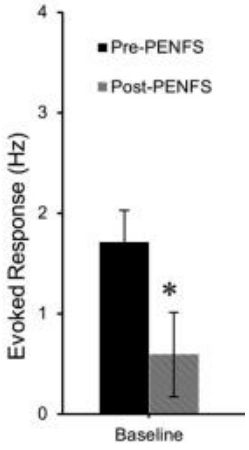
Technology

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. The 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 the IB-Stim technology. A recent human study in adults with pain related to fibromyalgia suggested that the IB-Stim technology 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

Our goal is to have over 700 published patients specific to our first FDA indication which is functional abdominal pain associated with irritable bowel syndrome in patients 11-18 years of age by July 1, 2023. A published patient is defined as a patient who went through a study and 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).

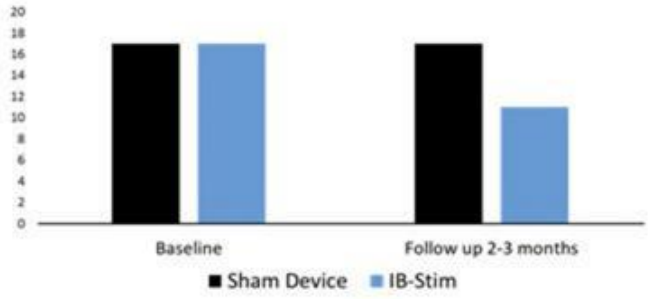
At long-term follow-up, median PFSD composite scores were 12.6 (IQR 3.6–22.5) in the PENFS group and 16.8 (4.8–33.6) in the control group. A comparison of changes in PFSD composite scores (baseline to follow-up) showed that patients in the PENFS group reported significantly greater improvement in pain (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

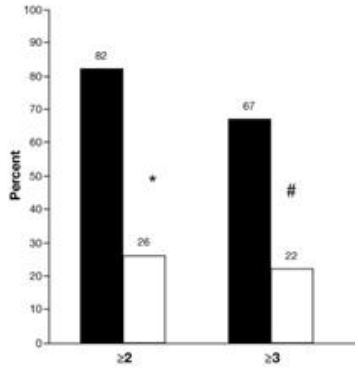
PFSD=Pain-Frequency-Severity-Duration. PENFS=percutaneous electrical nerve field stimulation.

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).



A more recent 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

		Penfs						
Parameters	**Baseline**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	***p* value[†]**	**Follow-up**	***p* value[‡]**
GI Symptoms								
Resting VAS								
Pain Intensity	2.2 ± 0.52	1.72 ± 0.52	1.75 ± 0.53	1.73 ± 0.53	1.61 ± 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	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	47.85 ± 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; [†]p for Week 4 vs. Week 0; [‡]p for long-term follow-up vs. Week 0

A clinically meaningful endpoint is the number needed to treat (NNT) used in treatment for abdominal pain-related functional gastrointestinal disorders in adolescents. NNT means the number of patients that need to be treated for one patient to get the targeted improvement (≥30% improvement).

Reimbursement

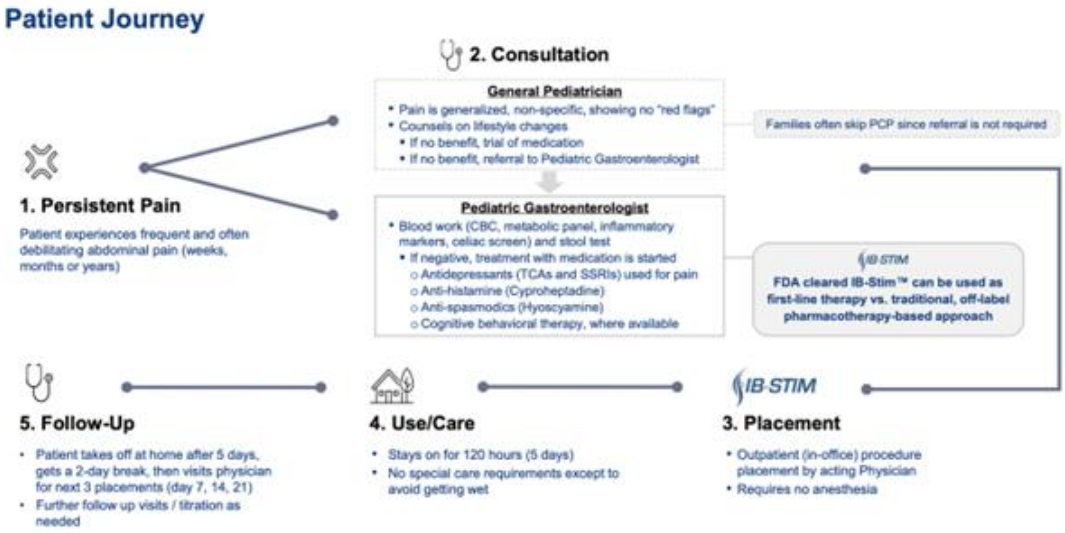
Our technology specific CAT III CPT Code (0720T) was published on December 30, 2021 and effective on July 1, 2022. A CAT III CPT code is viewed as a temporary CPT code, and we expect to submit for our permanent CAT I CPT code in 2023. As of the date of this prospectus, there are three (3) commercial written insurance coverage policies that cover our CPT Code, including BCBS Nebraska, BCBS Massachusetts, and Quartz Wisconsin.

Marketing

We market our products through search engine optimization, or SEO, internet channels and to physicians via the academic society. We plan to extensively ramp-up our marketing efforts to patients and physicians as we gain additional indications.

Patients/Customers

Our current patient base is children, who ages 11-18 and suffering from functional abdominal pain. Our customers are primarily children's hospitals who serve these children.



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 10 registered trademarks, eight (8) of which are being used in commerce:

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	THE NEURO-STIM SYSTEM and Design	5105258	20-Dec-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	5978412	04-Feb-2020	10 Int. medical apparatus, namely, electrical nerve stimulators;	Registered

AURICULAR STIMULATOR and Design	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

US	NEURAXIS	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	Filed
US	NEURAXIS (STYLIZED)	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	Filed

The Company has no unregistered trademarks.

Patents

The Company has eight (8) granted patents and nine (9) applied for patent applications in the United States and nine (9) 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	
CN	Neuraxis, Inc.	201980027574.9	25-Apr-2019				AURICULAR NERVE FIELD STIMULATION DEVICE	applied for	
EP	Neuraxis, Inc.	19850021.7	25-Apr-2019				AURICULAR NERVE FIELD STIMULATION DEVICE	applied for	
JP	Neuraxis, Inc.	2021-509961	23-Oct-2020				AURICULAR NERVE FIELD STIMULATION DEVICE	applied for	
KR	Neuraxis, Inc.	10-2020-7034010	25-Apr-2019				AURICULAR NERVE FIELD STIMULATION DEVICE	applied for	
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				AURICULAR NERVE FIELD STIMULATION DEVICE	applied for	
US	Neuraxis, Inc.	63/314028	25-Feb-2022				AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	applied for	
US	Neuraxis, Inc.	63/315371	01-Mar-2022				AURICULAR NERVE FIELD STIMULATION DEVICE AND METHODS FOR USING THE SAME	applied for	
US	Neuraxis, Inc.	16/014169	21-Jun-2018	10322062	18-Jun-2019	14-May-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR	granted	Out-licensed

							AND METHOD OF OPERATING SAME		
US	Neuraxis, Inc.	16/408004	09-May-2019	11077019	03-Aug-2021	14-May-2034	AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	granted	Out-licensed
US	Neuraxis, Inc.	17/363620	30-Jun-2021				AURICULAR PERIPHERAL NERVE FIELD STIMULATOR AND METHOD OF OPERATING SAME	applied for	
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	
CA	Neuraxis, Inc.	3143304	10-Dec-2021				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION DEVICE	applied for	
CN	Neuraxis, Inc.	202080060202.9	23-Jun-2020				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION DEVICE	applied for	
EP	Neuraxis, Inc.	20830917.9	10-Dec-2021				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION DEVICE	applied for	
JP	Neuraxis, Inc.	2021-576915	24-Dec-2021				EXTERNAL AUDITORY CANAL PHOTOBIOMODULATION 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-April-2037	METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION	granted	Out-licensed
US	Neuraxis, Inc.	16/534159	07-Aug-2019	11331473	17-May-2022	14-April-2037	METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION	granted	
US	Neuraxis, Inc.	17/725761	21-Apr-2022				METHODS OF TREATING DISEASE USING AURICULAR PERIPHERAL NERVE FIELD STIMULATION	applied for	
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	Out-licensed
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	Out-licensed
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	Out-licensed

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 rights to "Systems and Methods for Electro-Therapy Treatment," US Patent No. 10,792,500 (the "TKBMN Patent"). The expiration date of the TKBMN Patent is Oct 18, 2037, if all maintenance fees remain paid. Thomas Carrico is the author and inventor of the TKBMN Patent and has assigned the auricular portion of the TKBMN Patent to the Company.

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 Patent.

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. 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 equaled or exceeded $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, 2024, (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, or Sarbanes-Oxley;
- 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.

More recently, 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. PMA applications are also subject to the payment of user fees, which for fiscal year 2021 includes a standard application fee of $365,657.

- 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 the Centers for Medicare & Medicaid Services, or 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 [only if the patient meets the established medical necessity criteria for surgery]. 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, or 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 Agreement

On August 21, 2020, the Company entered into a Manufacturing Services Agreement with GMI Corporation ("GMI"), dated as of August 21, 2020 ("MSA"), for the manufacture and supply of the Company's IB-STIM device based upon the Company's product specifications as set forth in the MSA.

The Company provides the necessary equipment to GMI and retains ownership. GMI bears the risk of loss of and damage to the equipment and consigned materials. Performance under the MSA is initiated by orders issued by the Company and accepted by GMI.

The initial term of the MSA was 24 months and automatically renews for terms of twelve months unless either party provides a written termination notice to the other party within 180 days prior to the end of the then-current term.

GMI was established in 1990 and manufactures our IB-Stim device in its 69,000 square foot facility, of which approximately 1,000 square feet is dedicated to producing our product, located in Indiana.

In connection with the MSA, the Company entered into a quality agreement with GMI, dated as of August 24, 2020, for GMI to test product provided by the Company and perform quality assurance services.

Employees

As of September 30, 2022, we had 16 full-time employees and one part-time employee.

Facilities

Our corporate headquarter is located in Carmel, Indiana, where we leased an office space for employees, pursuant to a lease agreement with SEPRO DEVELOPMENT COMPANY II, LLC. The three-year term of this lease commenced March 1, 2021 and is scheduled to end on February 28, 2023. Over the term of this lease, base rent is $1,675.88 through March 2023, and $1,716.75 thereafter. The lease may be extended for one year with an annual base rent of $21.50 per rentable square foot.

We also lease 981 rentable square feet of space in Versailles, Indiana, where we lease a total of 3,825 rentable square feet of office space pursuant to two lease agreements with Hashbo Properties, LLC. The lease term of each lease agreement commenced January 1, 2022 and is scheduled to end December 31, 2023, with an automatic one year renewal. Rents are payable monthly at a rate of $1,664 and $469.85, respectively.

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 September 30, 2022, 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 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 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. The Company filed a motion to dismiss. The Court suspended briefing on the merits while it considers the Company's motion to dismiss the appeal. While it is too early to predict the ultimate outcome of this matter, we continue to believe we have meritorious defenses, that the dismissal of the Complaint should be upheld, and intend to continue to defend this matter vigorously.

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.

The Company has filed a motion to dismiss all claims, but no ruling has been issued. While it is too early to predict the ultimate outcome of this matter, we believe we have meritorious defenses and intend to defend this matter vigorously.

MANAGEMENT

Our directors were elected to serve until the next annual meeting of stockholders and until their respective successors will have been elected and will and will have qualified. The following table sets forth the name, age, and position held with respect to our present executive officers and directors and our director nominees.

Directors and Executive Officers

The following table sets forth certain information with respect to our directors and executive officers:

Name	Age	Position
Brian Carrico	41	President, Chief Executive Officer, and Director
John Seale	62	Chief Financial Officer
Dan Clarence*	63	Chief Operating Officer
Adrian Miranda*	53	Chief Medical Officer, Senior Vice President of Science and Technology
Thomas Carrico*	66	Chief Regulatory Officer
Christopher Robin Brown	68	Director of Innovation and Director
Gary Peterson*	56	Director of Design and Engineering and Director
Timothy Henrichs**	50	Director
Bradley Mitch Watkins**	47	Director
Beth Keyser**	54	Director

*Dan Clarence, Adrian Miranda, Thomas Carrico and Gary Peterson are current members of our board of directors and have effectively resigned from the board of directors immediately upon the effectiveness of the registration statement of which this prospectus forms a part.

**Timothy Henrichs, Bradley Mitch Watkins, and Beth Keyser have accepted nomination to our board of directors and will become members of our board of directors immediately upon the effectiveness of the registration statement of which this prospectus forms a part.

Brian Carrico, President, Chief Executive Officer and Director

Brian Carrico joined the Company in 2012. During his tenure, Mr. Carrico has held multiple leadership positions of increasing responsibility, including Vice President of Sales and President before becoming CEO on January 1, 2018. As an early employee in the Company's life cycle, Mr. Carrico was instrumental in setting the strategic agenda for the Company, raising start-up capital, championing new product development, and bringing the Company's technology to market. Prior to joining Neuraxis, Mr. Carrico worked selling in the operating room at Bard Medical and in the Cath lab at St. Jude Medical. He attended Indiana State University and holds a Bachelor of Science in Business Marketing.

John Seale, Chief Financial Officer

John Seale is a certified public accountant and a certified information technology professional. He has served as our Chief Financial Officer since August 2022 and is also the managing partner of RBSK Partners PC ("RBSK"), a CPA firm that offers a blend of accounting, audit, tax and specialized advisory services to individuals and business clients and has been with RBSK since 1984. Mr. Seale, through RBSK, has prepared the Company's financial statements since 2017. Mr. Seale specializes in delivering services to clients in a variety of industries, including health care, manufacturing, professional services, agriculture, warehousing, real estate and not-for-profits. Mr. Seale is also a qualified to perform peer reviews of CPA firms in accordance with standards established by the Peer Review Board of the AICPA.

Mr. Seale is a member of the American Institute of CPAs (AICPA), the Indiana CPA Society, the Ohio CPA Society and the Association of Certified Fraud Examiners. He formerly served on the Indiana Society's Peer Review Committee and the Review Acceptance Board, is a former member of the AICPA Information Technology Executive Committee and was the designated audit committee financial expert on the board of directors of MainSource Financial Group.

Dan Clarence, Chief Operating Officer

Dan Clarence, a proven senior executive with results oriented general management skills and a consistent track record of successful sales and marketing initiatives over his career of thirty plus years, has served as our COO since 2018. Mr. Clarence attained a bachelor's degree from Central Michigan University, followed by Graduate Studies at the University of Chicago MBA program.

In his role as VP of Sales and Senior Director of Sales at Euro-Pro/Shark Ninja, a multi-Billion dollar privately held corporation, from 2011 to 2018, Mr. Clarence was responsible for pioneering the Wal-Mart/Sam's Club business.

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

Adrian Miranda has served as our Chief Medical Officer since 2018 and brings a unique background of research and clinical expertise to his role. Prior to joining Neuraxis, Dr Miranda was an Assistant professor at the Medical College of Wisconsin. He is a board-certified pediatric gastroenterologist. He obtained his undergraduate degree in Biology from San Diego State University and obtained his medical degree from the Medical College of Wisconsin. He completed his residency and subspecialty training in pediatric gastroenterology at Children's Hospital of Wisconsin.

As a physician scientist, he has spent the past 20 years of his career investigating the pathophysiology of visceral and somatic pain, as well as exploring new therapeutic options. His focus has been on studying the effects of adverse early life events, neuroplasticity and the development of chronic pain. He has an extensive publication record and has lectured nationally and internationally.

Thomas Carrico, Chief Regulatory Officer

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.

Christopher Robin Brown, Director of Innovation, Founder and Director

Dr. Brown is a co-founder of the Company. He developed clinical protocol, initial practice guidelines, designed and implemented the practitioner certification program, initiated the company 401K, 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 establish initial communications with Dr. Thomas Carrico (Chief Regulatory Officer), Dr. Adrian Miranda (Chief Medical Officer), John Seale (Accountant & CFO) and our IP attorneys at Barnes and Thornburg. 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 5000. 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, 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.

Gary Peterson, Director of Design and Engineering

Gary Peterson is our founder, Director of Design and Engineering, and Director. Mr. Peterson was the Chief Executive Officer of the Company from the time of founding in 2011 until January 1, 2018. Mr. Peterson then moved to a member of the board of directors and Director of Design and Engineering of the Company.

Timothy Henrichs, Director

Timothy Henrichs has been a finance executive for the last 14 years. Mr. Henrichs currently serves as the Chief Financial Officer of HomeRenew Buyer, Inc. (d/b/a Renovo Home Partners), a privately held short-term home improvement installer of bathrooms, kitchens, windows, doors, cabinets, roofing and siding across the United States. Prior to joining Renovo Home Partners, Mr. Henrichs served as the Executive Vice President and Chief Financial Officer from 2008 to 2022 of Follett Corporation, a privately held retailer and distributor of print and digital course materials, textbooks, trade books, library books and general merchandise and developer of software technology to the educational market including 80,000 schools. From 2005 to 2008, Mr. Henrichs served as the Global Controller of General Electric Company's Healthcare Clinical Systems division responsible for the manufacture and distribution of patient monitoring, maternal and infant care, ultrasound, diagnostic cardiology and anesthesiology equipment. From 2003 to 2005, Mr. Henrichs served as the Financial Reporting Manager at Federal Signal Corporation. From 1995 to 2003, Mr. Henrichs served in various roles of increasing responsibility at Ernst & Young LLP in Chicago, Illinois and Frankfurt, Germany including Capital Markets and Mergers and Acquisitions Transaction Support, ultimately serving as a Senior Manager in the Audit and Assurance practice. Mr. Henrichs holds a B.B.A in Accounting from the University of Notre Dame and is a Certified Public Accountant with an inactive license in the State of Illinois.

Bradley Mitch Watkins, Director

Bradley Mitch Watkins has overseen four companies through their early commercialization periods within the medical device sector over the last 12 years. He has reported to the CEO or BOD directly and operated as the lead for all field operations. These duties have groomed Mr. Watkins with a wide array of responsibilities beyond sales, including marketing, clinical study design, manufacturing, research and development, FDA submissions as well as fiscal oversight are all areas of experience and competence. 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. He now manages corporate accounts and GPO contracts for the Cardiovascular line of products. Over his 18 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 reported directly to CEOs and Board of Directors and has thrived in early commercialization, recruitment, and strategic company direction. Mr. Watkins received his bachelor's degree in Behavioral Science from the University of Maryland. Mr. Watkins agreed to join the Company's board of directors with proven expertise in commercial operational efficiency and sales effectiveness for startups and large corporations.

Beth Keyser, Director

With more than 20 years' experience in executive roles in population health, Beth Keyser is skilled at understanding the unique, complex needs of multiple market segments and devises solutions that meet their specific goals. Ms. Keyser is the President, BCBS of Indiana at Anthem, Inc. since 2020. From 2018 to 2020, Ms. Keyser served as the President, Create at Brighton Health Plan Solutions. From 2015 to 2020, Ms. Keyser served as the Senior Vice President, International and Hawaii Markets at Sharecare, Inc. Ms. Keyser received her master's degree in Executive Master of Science, Health Administration, from University of Alabama at Birmingham.

Family Relationships

Brian Carrico, our Chief Executive Officer and Director, is the son of Thomas 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 has and plans on maintaining 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 Articles of Incorporation and Bylaws.

Director Independence

The listing rules of Nasdaq require that independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of Nasdaq 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 Nasdaq, 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 three are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. 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 the effectiveness of the registration statement of which this prospectus forms a part, the following three standing committees will be established: audit committee; compensation committee; and nominating and governance committee, or nominating committee. Each of our independent directors, Timothy Henrichs, Bradley Mitch Watkins, and Beth Keyser, will serve on each committee. Our board has adopted written charters for each of these committees, and those charters will be effective upon the effectiveness of the registration statement of which this prospectus forms a part. Upon completion of this offering, copies of the charters will be 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, will be 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 Nasdaq listing rules. Effective upon the completion of this offering the board of directors will adopt 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 Mr. Henrichs meets the qualifications of an Audit Committee financial expert.

The Audit Committee will consist of Timothy Henrichs, Bradley Mitch Watkins, and Beth Keyser. Mr. Henrichs will chair the Audit Committee. We believe that, after consummation of this offering, the functioning of the Audit Committee will comply with the applicable requirements of the rules and regulations of the Nasdaq listing rules and the SEC.

Compensation Committee

The Compensation Committee will be 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 will consist of Timothy Henrichs, Bradley Mitch Watkins, and Beth Keyser, and Mr. Watkins will serve 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 Nasdaq listing rules. The Company believes that, after the consummation of the offering, the composition of the Compensation Committee will meet the requirements for independence under, and the functioning of such Compensation Committee will comply with, any applicable requirements of the rules and regulations of Nasdaq listing rules and the SEC.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee, among other things, will be 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 will consist of Timothy Henrichs, Bradley Mitch Watkins, and Ms. Keyser will serve as chair. 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 guidelines of Nasdaq listing rules.

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 Nasdaq. The Code of Conduct will be effective upon the effectiveness of the registration statement of which this prospectus forms a part and publicly available on the Company's website following completion of this offering. 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 Nasdaq.

EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Executive Officers Compensation

Summary Compensation Table

The following table sets forth information concerning all compensation earned by or paid to our Chief Executive Officer and two other persons who served as executive officers as, at, or during the year ended December 31, 2021, and who earned compensation exceeding $100,000 during 2021 (the "Named Executive Officers"), for services as executive officers for the last two years.

Name and Principal Position	Year	Salary ($)
Brian Carrico	2021	369,231
Chief Executive Officer	2020	419,615
Thomas Carrico	2021	297,347
Chief Regulatory Officer	2020	318,582
Adrian Miranda	2021	254,231
Chief Medical Officer	2020	201,538

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, 2021.

Name	Number of Securities Underlying Unexercised Options, Exercisable (#)	Number of Securities Underlying Unexercised Options, Not Exercisable (#)	Option Exercise Price ($)	Option Expiration Date
Brian Carrico	640,000	—	3.47	09/13/29
Thomas Carrico	612,472	—	3.47	09/13/29
Adrian Miranda	674,408	—	3.47	09/13/29

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

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 (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 2,638,788. Cancelled and forfeited stock options and stock awards may again become available for grant under the 2017 Plan. As of the date of September 30, 2022, options to purchase 2,638,788 shares of common stock have been granted under the 2017 Plan and remain outstanding, and 0 shares remain available for issuance under the 2017nPlan. 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 2,638,788 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 2017n 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

On November 1, 2022, the Company adopted the Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan (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 numbers of shares of common stock that may be issued pursuant to awards granted are 600,000. Cancelled and forfeited stock options and stock awards may again become available for grant under the 2022 Plan. As of the date of this prospectus, no options to purchase shares of common stock have been granted under the 2022 Plan and remain outstanding, and 600,000 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 600,000 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 is 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 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, 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 an one-time incentive payment in the amount of $494,732 to reward past service and incentivize Mr. Carrico to remain with the Company for future service, to be paid in a single lump sum within two and one-half months. 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 640,000 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 on January 2 on each of 2024, 2025, 2026, 2027, and 2028, with a condition that on or before each scheduled payment date, Mr. Carrico shall exercise at least 128,000 of the stock options.

If the employment agreement is terminated by the Company without cause, 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 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.

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.

Dan Clarence, our Chief Operating Officer, entered into an employment agreement with the Company, dated August 9, 2022, which provides has a two-year initial term and provides for a base salary of $275,000 with annual compensation increase. Mr. Clarence also will receive a one-time incentive payment in the amount of $116,897.24 to reward past service and incentivize Mr. Clarence to remain with the Company for future service, to be paid in a single lump sum within two and one-half months. In addition, Mr. Clarence 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 137,636 unexercised options to purchase stock or shares of the Company held by Mr. Clarence (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 on January 2 on each of 2024, 2025, 2026, 2027, and 2028, with a condition that on or before each scheduled payment date, Mr. Clarence shall exercise at least 27,527 of the stock options.

If the employment agreement is terminated by the Company without cause occurs during the term of the agreement, Mr. Clarence 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 Mr. Clarence 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 Mr. Clarence'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 Mr. Clarence 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, Mr. Clarence 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. Clarence's termination date; and accrued and unused PTO, if any, in accordance with the Company's PTO policy in effect on Mr. Clarence's termination date.

Mr. Clarence 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. Clarence 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. Clarence 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. Clarence 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.

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 674,408 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 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 134,881 of the stock options.

If the employment agreement is terminated by the Company without cause 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 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.

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.

Thomas Carrico, Chief Regulatory Officer, entered into an employment agreement with the Company, dated August 9, 2022, which has a two-year initial term and provides for a base salary of $275,000 with annual compensation increase. Mr. Carrico will also receive a one-time incentive payment in the amount of $141,243.17 to reward past service and incentivize Mr. Carrico to remain with the Company for future service, to be paid in a single lump sum within two and one-half months. In addition, Mr. 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 612,472 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 on January 2 on each of 2024, 2025, 2026, 2027, and 2028, with a condition that on or before each scheduled payment date, Mr. Carrico shall exercise at least 122,494 of the stock options.

If the employment agreement is terminated by the Company without cause occurs during the term of the agreement, Mr. 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 Mr. 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 Mr. 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 Mr. 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, Mr. Carrico 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 (iii) accrued and unused 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 special deferred bonus.

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) 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.

Christopher Robin Brown, our Director of Innovation, entered into an employment agreement with the Company, dated August 9, 2022, which has a two-year initial term and provides for a base salary of $200,000 with annual compensation increase. Mr. Brown also will receive a one-time incentive payment in the amount of $250,843.88 to reward past service and incentivize Mr. Brown to remain with the Company for future service, to be paid in a single lump sum within two and one-half months.

If the employment agreement is terminated by the Company without cause, Mr. Brown 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 Mr. Brown with severance compensation in the form of salary continuation at his Base Salary as of the termination date and ending the later of (i) 3 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 fourth (1/4th) of Mr. Brown'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 Mr. Brown reimbursement of his Medicare, Medicare Supplement and prescription drug coverage insurance premiums for continuation of health coverage for eighteen (18) months post termination.

If the employment agreement is terminated by the Company for cause, Mr. Brown 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. Brown's termination date; and accrued and unused PTO, if any, in accordance with the Company's PTO policy in effect on Mr. Brown's termination date.

Mr. Brown 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.

Pursuant to the employment agreement, Mr. Brown 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 Mr. Brown 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. Brown 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.

Gary Peterson, our Director of Design and Engineering, entered into an employment agreement with the Company, dated August 9, 2022, which has a two-year initial term and provides for a base salary of $200,000 with annual compensation increase and a one-time incentive payment in the amount of $53,277.01 to reward past service and incentivize Mr. Carrico to remain with the Company for future service, to be paid in a single lump sum within two and one-half months.

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

- If termination occurs during the initial term, the Company shall provide Mr. Peterson 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 Mr. Peterson'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 Mr. Peterson reimbursement of his COBRA premiums for continuation of health coverage for 18 months post termination.

If the employment agreement terminates for any reason except termination by the Company for cause occurs, Mr. Peterson 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. Peterson's termination date; and accrued and unused PTO, if any, in accordance with the Company's PTO policy in effect on Mr. Peterson's termination date.

Mr. Peterson 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.

Pursuant to the employment agreement, Mr. Peterson 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 Mr. Peterson 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. Peterson 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.

Director Compensation

Currently, none of our directors is compensated for their service as directors, and we do not expect to compensate our current directors in the future. Following completion of this offering, we do expect to compensate our independent directors $80,000 annually apportioned equally between cash and stock options and payable [●]. The number of stock options granted will be determined at the discretion of the Compensation Committee based on one or more accepted valuation methodologies, such as the Black-Scholes model. The options will vest immediately upon issuance, have an exercise price set at the closing price of our common stock on Nasdaq as of the grant date, and expire seven years from the grant date.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of October 31, 2022, with respect to the holdings of: (i) each person who is the beneficial owner of more than 5% of our common stock, (ii) each of our directors, (iii) each executive officer, and (iv) all of our executive officers and directors as a group.

Beneficial ownership of the common stock is determined in accordance with the rules of the SEC and includes any shares of our common stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of October 31, 2022. Applicable percentage ownership in the following table is based on (i) 3,856,008 shares of common stock issued and outstanding on October 31, 2022, plus an aggregate of 2,026,540 shares of common stock issuable upon conversion of our Series A Preferred Stock and an aggregate of 461,907 shares of common stock issuable upon conversion of our Series Seed Preferred Stock, as all shares of our preferred stock are expected to convert into shares of common stock in connection with this offering, and (ii) after the offering, assumes the issuance of [●] shares of common stock in the offering, which excludes shares of common stock which may be sold upon exercise of the Underwriter's over-allotment option, (iii) plus, for each individual, any securities that person has the right to acquire within 60 days of October 31, 2022 through exercise of warrants, stock options or otherwise.

To the best of our knowledge, each of the persons named in the table has sole voting and investment power with respect to the shares of our common stock beneficially owned by such person, except to the extent such power may be shared with a spouse. To our knowledge, none of the shares listed below are held under a voting trust or similar agreement. To our knowledge, there is no arrangement, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

Name of Owner	Shares of Common Stock Owned Beneficially	Percent of Class Before the Offering	Percent of Class After the Offering
5% Holders			
Masimo Corporation (1)	1,642,654	23.7%	[●]%
Brian P. Hannasch (2)	674,991	10.5%	[●]%
Executive Officers and Directors (3)			
Brian Carrico (4)	694,236	9.9%	[●]%
John Seale	—	—	—
Dan Clarence (5)	551,417	8.5%	[●]%
Adrian Miranda (6)	674,408	9.6%	[●]%
Thomas Carrico (7)	632,472	9.1%	[●]%
Christopher Robin Brown	1,585,673	25.0%	[●]%
Gary Peterson	1,086,240	17.1%	[●]%
Timothy Henrichs*	—	—	—
Bradley Mitch Watkins*	—	—	—
Beth Keyser*	—	—	—
Officers and directors as a group (10 persons)	5,224,446	62.1%	[●]%

*Timothy Henrichs, Bradley Mitch Watkins, Beth Keyser have accepted nomination to our board of directors and will become members of our board of directors immediately upon the effectiveness of the registration statement of which this prospectus forms a part.

(1) The business address for Masimo Corporation is 52 Discovery, Irvine, California 92618. Shares of common stock beneficially owned includes 1,063,096 shares of common stock issuable upon the conversion of Series A Preferred Stock, and 579,558 shares of common stock issuable upon the exercise of prefunded warrants.

(2) The business address for Mr. Hannasch is 8815 West State Road 46, Columbus, Indiana 47201. Shares of common stock beneficially owned includes 491,419 shares of common stock issuable upon the conversion of Series A Preferred Stock, and 105,704 shares of common stock issuable upon the exercise of warrants.

(3) The business address for each executive officer and director is 11550 N. Meridian Street, Suite 325 Carmel, IN. 46032.

(4) Shares of common stock beneficially owned includes 640,000 shares of common stock issuable upon the exercise of stock options.

(5) Shares of common stock beneficially owned consists of 10,598 shares of common stock issuable upon the conversion of Series A Preferred Stock, 56,137 shares of common stock issuable upon conversion of Series Seed Preferred Stock, and 137,636 shares of common stock issuable upon the exercise of stock options.

(6) Shares of common stock beneficially owned consists of 674,408 shares of common stock issuable upon the exercise of stock options.

(7) Shares of common stock beneficially owned includes 612,472 shares of common stock issuable upon the exercise of stock options.

CERTAIN RELATIONSHIPS AND RELATED PERSONS TRANSACTIONS

SEC rules require us to disclose any transaction since the beginning of our last fiscal year or any currently proposed transaction in which we are a participant in which the amount involved exceeded or will exceed $120,000 and in which any related person has or will have a direct or indirect material interest. A related person is any executive officer, director, nominee for director, or holder of 5% or more of our common stock, or an immediate family member of any of those persons.

The Company has two demand notes receivable from two 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. As of September 30, 2022, the balances of both notes were $[●].

The Company has loans payable to three shareholders related to funding needs for operations in the amount of $[●], $[●], and $[●], with due dates of [●], [●], and [●], and interest rates of 12%, 15%, and 15%, respectively. As of September 30, 2022, the balances of loans are $[●], $[●], and $[●].

John Seale, our Chief Financial Officer, is also the managing partner of RBSK. Mr. Seale, through RBSK, has prepared the Company's financial statements since 2017. For the nine months ended September 30, 2022, and the fiscal years ended December 31, 2021 and 2020, the Company paid RBSK $[●], $83,548 and $118,095, respectively, for accounting services.

DESCRIPTION OF OUR SECURITIES

General

Our certificate of incorporation authorizes us to issue up to 101,120,000 shares of capital stock, consisting of 100,000,000 shares of common stock, par value $0.001 per share, and 1,120,000 shares of preferred stock, par value $0.001 per share, 1,000,000 of which are designated as Series A Preferred Stock and 120,000 of which are designated as Series Seed Preferred Stock.

As of September 30, 2022, there were 3,856,008 shares of our common stock, 506,367 shares of our Convertible Series A Preferred Stock, and 115,477 shares of our Convertible Series Seed Preferred Stock issued outstanding. Our Company is authorized, without stockholder approval, to issue additional shares of authorized but unissued capital stock.

Common Stock

Our certificate of incorporation authorizes the issuance of 100,000,000 shares of common stock, par value $0.001 per share. The holders of common stock are entitled to one vote per share on each matter submitted to a vote at any meeting of stockholders. Shares of common stock do not carry cumulative voting rights and, therefore, a majority of the shares of outstanding common stock will be able to elect the entire board of directors and, if they do so, minority stockholders would not be able to elect any persons to the board of directors. Our bylaws provide that a majority of our issued and outstanding shares constitutes a quorum for stockholders' meetings, except respecting certain matters for which a greater percentage quorum is required by statute or the bylaws.

Our stockholders have no pre-emptive rights to acquire additional shares of common stock or other securities. The common stock is not subject to redemption and carries no subscription or conversion rights. In the event of our liquidation, the shares of common stock are entitled to share equally in corporate assets after satisfaction of all liabilities.

Holders of common stock are entitled to receive such dividends as the board of directors may, from time to time, declare out of funds legally available for the payment of dividends. We seek growth and expansion of our business through the reinvestment of profits, if any, and do not anticipate that we will pay dividends in the foreseeable future.

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our Board, in its discretion, determines to declare and pay dividends and then only at the times and in the amounts that our Board may determine.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters properly submitted to a vote of stockholders on which holders of common stock are entitled to vote. We have not provided for cumulative voting for the election of directors in our Certificate of Incorporation.

No Pre-emptive or Similar Rights

Our common stock is not entitled to pre-emptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

If we become subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time [preferred stock to be paid first], subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Our certificate of incorporation authorizes the issuance of 1,120,000 shares of preferred stock, par value $0.001 per share, 1,000,000 of which are designated as Series A Preferred Stock and 120,000 of which are designated as Series Seed Preferred Stock. As of the date of hereof, there are [●] share of preferred stock outstanding.

Voting Rights

The Series A Preferred Stock and Series Seed Preferred Stock shall vote together with the Common Stock on an as-converted basis, and not as separate classes.

Conversion

The Series A Preferred and Series Seed initially convert 1:1 to Common Stock at any time at option of holder, subject to adjustments for stock dividends, splits, combinations, and similar events and as described below under "Anti-dilution Provisions."

Dividends

The Series A Preferred will carry an annual 8% cumulative dividend, payable upon any liquidation, dissolution or winding up of the Company (the "Accruing Dividend"). For any other dividends or distributions, participation with Common Stock on an as-converted basis.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, the proceeds shall be paid in the following priority:

- First, to the Series A Preferred in proportion to each holder's respective pro rata Series A Original Purchase Price, plus any pro rata share of the Accruing Dividend until the entire Series A Original Purchase Price and Accruing Dividend are paid;
- Second, to the Series Seed Preferred Stock in proportion to each holder's respective pro rata Series Seed Original Purchase Price until the entire amount of the Series Seed Original Purchase Price is paid;
- Thereafter, the Series A Preferred Stock and Series Seed Preferred Stock participate with the Common Stock pro rata on an as-converted basis.

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 (a "Deemed Liquidation Event"), thereby triggering payment of the liquidation preferences described.

Anti-dilution Provisions

The Series A Preferred have full-ratchet anti-dilution protection so that the conversion price will be reduced to 80% of the price at which any future shares are issued, if less than the Series A Original Purchase Price.

Investor Agreements

Masimo Side Letters

On April 9, 2020, the Company entered into a side letter with Masimo (the "Masimo Side Letter") in connection with Masimo's purchase of shares of our Series A Preferred Stock under certain purchase agreement (the "Masimo Series A Purchase Agreement"). Pursuant to the Masimo Side Letter, Masimo is entitled to specify one individual to serve as a non-voting observer at all meetings of the board of directors and certain information and inspection rights. The Company also agreed to not to enter into any agreement or arrangement with any investor providing for rights, benefits, powers, preferences, priorities or privileges more favorable to such investor than rights, benefits, powers, preferences, priorities or privileges provided to Masimo under the Masimo Series A Purchase Agreement, unless Massimo is offered such opportunity.

The Company plans to enter into an agreement with Masimo that Masimo will relinquish its rights under the Masimo Side Letter immediately upon the effectiveness of the registration statement of which this prospectus forms a part.

Brian Hannasch Side Letters

On September 6, 2019, the Company entered into an investor rights agreement with Brian Hannasch (the "Investor Rights Agreement") in connection with Brian Hannasch's purchase of shares of our Series A Preferred Stock under certain purchase agreements (the "Series A Purchase Agreement"). Pursuant to the Investor Rights Agreement, Mr. Hannasch is entitled to certain information and inspection rights. Major investors who hold at least 125 shares of Series A Preferred Stock are entitled to right of first offer if the Company proposes to sell any new securities, which shall terminate immediately before the consummation of this offering, or when the Company becomes subject to periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or upon the closing of a deemed liquidation event, and may appoint one (1) observer to attend and be present at the meeting of board of directors. The Company also agreed not to, without major investors' approval, (i) make any loan to any person, subsidiarity or other entity except expenditures in the ordinary course of business or under an employee stock option plan, (ii) own any securities of any subsidiarity or other entity unless it is wholly owned by the Company, (iii) guarantee any indebtedness except for trade accounts arising in the ordinary course of business, make any investment inconsistent with any investment policy approved by the board of directors, (iv) enter into any material transaction with insiders of the Company outside the ordinary and usual course of business, (v) authorize any plan for the issuance of any employee incentive equity rights, management incentive plans payable on the basis of equity process or amend the 2017 Stock Compensation plan, and (vi) allow previous common stockholders who own more than $100,000 of common stock, except for certain common stockholders as indicated in the Investor Rights Agreement, to participate in the purchase of Series A Preferred Stock, unless such common stockholder purchases at least $100,000 of Series A Preferred Stock valued at the Series A Original Issue Price.

The Company plans to enter into an agreement with Brian Hannasch that Mr. Hannasch will relinquish his rights under the Investor Rights Agreement immediately upon the effectiveness of the registration statement of which this prospectus forms a part.

Warrants

As of September 30, 2022, warrants to purchase an aggregate of [●] shares of our common stock were outstanding, with a weighted average exercise price of $[●] per share.

On September 6, 2019, we issued warrants to purchase 20,000 shares of common stock to Brian P. Hannasch, in connection with certain Series A Preferred Stock Purchase Agreement. Pursuant to the terms of the warrants, the warrant exercise price is equal to $0.01 per share. If unexercised, these warrants will expire on the 10th anniversary of their issuance dates. The warrants will [neither expire nor be automatically exercised upon the closing of this offering.] The warrants provide that the holder thereof may elect to exercise the warrant on a net "cashless" basis at any time prior to the expiration thereof. Assuming the closing of this offering occurs, the fair market value of one share of our common stock in connection with any cashless exercise shall be the based on the average of the daily closing prices per share for the 30 consecutive trading day period ending on the second trading day prior to such date.

On April 9, 2020, we issued pre-funded warrants to purchase 144,890 shares of Series A Preferred Stock to Masimo, in connection with certain Series A Preferred Stock Purchase Agreement. Pursuant to the terms of the warrants, the warrant exercise price is equal to $0.0001 per share, subject to adjustments, and these warrants will not expire. The aggregate purchase price of this Warrant, in the amount of$2,734,340.40, equating to $18.87 per warrant share, was pre-funded to the Company and, consequently, no additional consideration shall be required to be paid by Masimo to any Person to effect any exercise of this Warrant, except for the payment of the exercise price. The warrants will [neither expire nor be automatically exercised upon the closing of this offering.] The warrants provide that Masimo thereof may elect to exercise the warrant on a net "cashless" basis at any time prior to the expiration thereof. Assuming the closing of this offering occurs, the fair market value of one share of our Series A Preferred Stock in connection with any cashless exercise shall be the closing price or last sale price of a share of common stock reported for the business day immediately before the date on which Masimo delivers this warrant together with its notice of exercise to the Company, multiplied by the number of shares of common stock into which a share of Series A Preferred Stock is then convertible, if the common stock is then traded on a trading market, or (ii) the fair market value of Series A Preferred Stock, as mutually determined in writing by the Company and Masimo. Masimo may not exercise the warrant in excess of that number of shares which would cause the aggregate number of shares of common stock beneficially owned by Masimo to exceed 19.99% of the total number of issued and outstanding shares of common stock following such exercise, or the combined voting power of the securities beneficially owned by Masimo to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise.

Certain Anti-Takeover Provisions of Delaware Law, Our Certificate of Incorporation and Our Bylaws

Section 203 of the DGCL provides that if a person acquires 15% or more of the voting stock of a Delaware corporation, such person becomes an "interested stockholder" and may not engage in certain "Business Combinations" with such corporation for a period of three years from the time such person acquired 15% or more of such corporation's voting stock, unless: (1) the board of directors of such corporation approves the acquisition of stock or the merger transaction before the time that the person becomes an interested stockholder, (2) the interested stockholder owns at least 85% of the outstanding voting stock of such corporation at the time the merger transaction commences (excluding voting stock owned by directors who are also officers and certain employee stock plans), or (3) the merger transaction is approved by the board of directors and at a meeting of stockholders, not by written consent, by the affirmative vote of 2/3 of the outstanding voting stock which is not owned by the interested stockholder. A Delaware corporation may elect in its certificate of incorporation or Bylaws not to be governed by this particular Delaware law.

Our certificate of incorporation, our bylaws and the DGCL contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the members of our board of directors or taking other corporate actions, including effecting changes in our management. For instance, our certificate of incorporation does not provide for cumulative voting in the election of directors. Our board of directors are empowered to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director in certain circumstances; and our advance notice provisions in our bylaws require that stockholders must comply with certain procedures in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting.

Our authorized but unissued common stock will be available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Certificate of incorporation and Bylaws

Among other things, our certificate of incorporation and our bylaws:

- do not provide for cumulative voting in the election of directors;
- provides for the exclusive right of the board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director by stockholders;
- Requires that a special meeting of stockholders may be called only by the Board of Directors, or by a committee of the Board of Directors that has been designated by the Board of Directors;
- limits the liability of, and providing indemnification to, our directors and officers;
- controls the procedures for the conduct and scheduling of stockholder meetings;
- grants the ability to remove directors only for cause by the affirmative vote of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Company entitled to vote at an election of directors;
- provides for advance notice procedures that stockholders must comply with in order to nominate candidates to the board of directors or to propose matters to be acted upon at a stockholders' meeting.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares of common stock and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our common stock.

Forum for Litigation

Article VIII of our Certificate of Incorporation identifies the Court of Chancery of the State of Delaware (referring to Delaware State Courts) as the exclusive forum for certain litigation, including any derivative action. To the extent that the applicability such provision may be sought in connection with actions arising under the Securities Act or Exchange Act, pursuant to Section 27 of the Exchange Act, exclusive federal jurisdiction is created over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, which would result in federal courts instead having jurisdiction over such claims. Pursuant to Section 22 of the Securities Act, concurrent jurisdiction is created for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such provision in an action arising under the Securities Act or Exchange Act.

The Company does not intend for such exclusive forum provision to apply to claims arising under the Securities Act or the Exchange Act. With respect to claims arising under the Securities Act, note that investors cannot waive compliance with the federal securities laws and rules and regulations thereunder.

Limitation of Liability and Indemnification

Our bylaws provide that we will indemnify our directors to the fullest extent authorized or permitted by applicable law. Under our Bylaws, we are required to indemnify each of our directors and officers if the basis of the indemnitee's involvement was by reason of the fact that the indemnitee is or was our director or officer or was serving at our request as a director, officer, employee or agent for another entity. We must indemnify our officers and directors against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the indemnitee in connection with such action, suit or proceeding if the indemnitee acted in good faith and in a manner the indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the indemnitee's conduct was unlawful. Our bylaws also require us to advance expenses (including attorneys' fees) incurred by a director or officer in defending any civil, criminal, administrative or investigative action, suit or proceeding, provided that such person will repay any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Transfer Agent and Registrar

Vstock Transfer LLC is the Company's transfer agent with respect of our common stock. The principal business address of 18 Lafayette Place, Woodmere, NY 11598. Phone: 212-828-8436.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has no public market for the Company's common stock, and a liquid trading market for its common stock may not develop or be sustained after this offering. Future sales of substantial amounts of the Company's common stock in the public market, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time, and could impair the Company's ability to raise capital through sales of equity or equity-related securities.

Only a limited number of shares of the Company's common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of the Company's common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of its common stock. Although the Company intends to list its common stock on the Nasdaq, the Company cannot assure you that there will be an active market for its common stock.

Of the shares to be outstanding immediately after the completion of this offering, we expect that the shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act; these restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once the Company has been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of the Company's affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of its common stock proposed to be sold for at least six months is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than Company affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, the Company's affiliates or persons selling shares of its common stock on behalf of its affiliates are entitled to sell upon expiration of the market standoff agreements and lock-up agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

(a) 1% of the number of shares of the Company's capital stock then outstanding; or

(b) the average weekly trading volume of the Company's common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by the Company's affiliates or persons selling shares of its common stock on behalf of its affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about the Company.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of the Company's common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of the Company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of the Company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the lock-up period described below.

Lock-Up Agreements

In connection with this offering, the Company, and its officers, directors and 5% stockholders have agreed to a "lock-up" period, in the case of the Company, a period of 180 days after the date the registration statement, of which this prospectus forms a part is declared effective, and in the case of our directors and executive officers and our 5% and greater stockholders, a period of 180 days after the date the registration statement, of which this prospectus forms a part, is declared effective, with respect to the shares that they beneficially own, including shares issuable upon the exercise of convertible securities and options that are currently outstanding or which may be issued. This means that, for a period of 180 days following the closing of this offering, such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of the Underwriter. Officers' and directors' 180-day restricted period is subject to extension upon certain events and the terms of the lock-up agreements may be waived at the Underwriter's discretion. The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under "Underwriting."

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of some of the possible U.S. tax consequences that should be anticipated in connection with an investment in our common stock. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), the U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. There can be no assurance that their Internal Revenue Service (the "IRS") will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax considerations relating to the purchase, ownership, or disposition of our common stock. **Each prospective investor is urged to consult their own tax advisor about the tax consequences of an investment in our common stock in light of the investor's own circumstances**.

Consequences For U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our common stock by U.S. Holders. As used in this discussion, the term "U.S. Holder" means a beneficial owner of our common stock that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source, or (4) a trust (i) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions, or (ii) that has elected to be treated as a domestic trust for U.S. federal income tax purposes.

This discussion applies to U.S. Holders that purchase our common stock pursuant to this offering and hold such common stock as capital assets. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances, or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain former citizens or residents of the United States, persons who hold our common stock as part of a "straddle", "hedge", "conversion transaction", "synthetic security" or integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own directly, indirectly or through attribution 10% or more of the voting power of our common stock, corporations that accumulate earnings to avoid U.S. federal income tax, persons subject to special tax accounting rules under Section 451(b) of the Code, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences. If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax consequences relating to an investment in our common stock will depend in part upon the status and activities of such entity and the particular partner. Any such entity should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of our common stock.

Distributions

A U.S. Holder that receives a distribution with respect to our common stock generally will be required to include the gross amount of such distribution in income as a dividend when actually or constructively received, to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's common stock. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's common stock, the remainder will be taxed as capital gain.

Sale, Exchange or Other Disposition of our Common Stock

A U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of our common stock in an amount equal to the difference, if any, between the amount realized (i.e., the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition, and such U.S. Holder's adjusted tax basis in the shares that were transferred. Such capital gain or loss generally will be long-term capital gain or long-term capital loss if, on the date of sale, exchange or other disposition, the transferred shares were held by the U.S. Holder for more than one year. Long-term capital gains of individual investors are generally subject to lower tax rates than those imposed on ordinary income. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. Capital losses might not be permitted to offset the full amount of an individual's ordinary income.

Medicare Tax on Net Investment Income

Certain U.S. Holders who are individuals, estates or trusts are subject to an additional 3.8% U.S. federal income tax on all or a portion of their "net investment income," which generally includes dividends on the shares, and net gains from the disposition of common stock. U.S. Holders that are individuals, estates or trusts should consult their tax advisors regarding the applicability of the Medicare tax.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS (with a copy of such report provided to you) the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. Backup withholding may apply to amounts subject to reporting if the U.S. Holder (1) fails to provide an accurate United States taxpayer identification number or otherwise establish a basis for exemption, or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

Foreign Account Tax Compliance Act

The Foreign Account Tax Compliance Act ("FATCA") generally imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of securities that are beneficially owned by certain U.S. persons where held in a "foreign financial institution" (as specially defined under those rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners), or otherwise establishes an exemption. If a U.S. Holder owns our common stock in a foreign financial institution, they should obtain specific advice from an expert on the implications of FATCA.

Consequences to Non-U.S. Holders

The following is a summary of the material U.S. federal income tax considerations for Non-U.S. Holders relating to the purchase, ownership and disposition of the common stock purchased in this offering. A "Non-U.S. Holder" is a beneficial owner of our securities (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that, for U.S. federal income tax purposes, is not a U.S. holder. This summary is for general information purposes only and does not purport to be a complete analysis of all the potential tax considerations.

Distributions

Subject to the discussion below regarding effectively connected income, any dividend (including any taxable constructive stock dividend) paid to a Non-U.S. Holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend, or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a Non-U.S. Holder must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other applicable IRS Form W-8 properly certifying qualification for the reduced rate. These forms must be updated periodically. A Non-U.S. Holder eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If a Non-U.S. Holder holds our common stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, which then may be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by a Non-U.S. Holder that are effectively connected with its conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States) are generally exempt from such withholding tax if the Non-U.S. Holder satisfies certain certification and disclosure requirements. In order to obtain this exemption, the Non-U.S. Holder must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated U.S. federal income tax rates applicable to U.S. holders, net of certain deductions and credits. In addition, dividends received by a corporate Non-U.S. Holder that are effectively connected with its conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. Non-U.S. Holders should consult their own tax advisors regarding any applicable tax treaties that may provide for different rules.

Gain on Sale, Exchange or Other Taxable Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale, exchange or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States);

- the Non-U.S. Holder is a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs, and certain other conditions are met; or

- shares of our common stock constitute U.S. real property interests by reason of our status as a "United States real property holding corporation" (a USRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the Non-U.S. Holder's disposition of, or the non- U.S. holder's holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the Non-U.S. Holder actually or constructively holds more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding the Non-U.S. Holder's disposition of, or the Non-U.S. Holder's holding period for, our common stock.

If the Non-U.S. Holder is described in the first bullet above, they will be required to pay tax on the net gain derived from the sale, exchange or other taxable disposition under regular graduated U.S. federal income tax rates, and a corporate Non-U.S. Holder described in the first bullet above also may be subject to the branch profits tax at a rate of 30%, or such lower rate as may be specified by an applicable income tax treaty. An individual Non-U.S. Holder described in the second bullet above will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, exchange or other taxable disposition, which gain may be offset by U.S. source capital losses for the year (provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses). Non-U.S. Holders should consult their own tax advisors regarding any applicable income tax or other treaties that may provide for different rules.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS (with a copy of such report provided to you) the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock made to you may be subject to backup withholding unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN or IRS Form W-8BEN-E or other applicable IRS Form W-8. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person. Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

UNDERWRITING

In connection with this offering, we will enter into an underwriting agreement with Alexander Capital L.P. as the Underwriter of this offering. The Underwriter, and each other underwriter named in the underwriting agreement, if any, has severally agreed to purchase from us, on a firm commitment basis, the number of shares, set forth opposite its name below, at the public offering price, less the underwriting discount set forth on the cover page of this prospectus.

Underwriter	Number of Shares
Alexander Capital L.P.	[●]
Total	[●]

The Underwriter is committed to purchase all of the shares offered by us other than those covered by the option to purchase additional securities described below, if they purchase any such securities. The obligations of the Underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the Underwriter's obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the Underwriter of the officers' certificates and legal opinions.

The Company has agreed to indemnify the Underwriter against specified liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the Underwriter may be required to make in respect thereof.

The Underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The Underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option

We have granted the Underwriter an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the Underwriter to purchase up to a total of [●] shares of common stock (equal to fifteen percent (15%) of the aggregate number of shares of common stock sold in this offering) and exercisable at a price per share equal to the public offering price less the underwriting discounts and commissions set forth on the cover of this prospectus in any combination thereof. We will be obligated, pursuant to the option, to sell these additional shares of common stock to the Underwriter to the extent the option is exercised.

Discount

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the Underwriter of its over-allotment option.

	Per Share	Total Without Over-Allotment Option	Total With Over Allotment Option
Public offering price	$ [●]	$ [●]	$ [●]
Underwriting discount ([●]%)	$ [●]	$ [●]	$ [●]
Proceeds, before expenses, to us	$ [●]	$ [●]	$ [●]

The Underwriter proposes to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the Underwriter may offer some of the shares to other securities dealers at such price less a concession of $[●] per share.

The Company will pay the out-of-pocket accountable expenses of the Underwriter in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, any advance expense deposits paid to the Underwriter will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

The Company has agreed to pay the Underwriter an Underwriter's fee of seven percent (7%) of the amount raised in the Offering. If any capital is raised in a pre-Offering bridge round, the placement fee will be equal to a nine percent (9%) cash fee, plus the Underwriter's Warrants. The Company has agreed to pay for a certain amount of the Underwriter's accountable expenses including actual accountable road show expenses for the offering; prospectus tracking and compliance software for the offering; the reasonable and documented fees and disbursements of the Underwriter's counsel up to an amount of $[●]; background checks of the Company's officers and directors; preparation of bound volumes and cube mementos in such quantities as the Underwriter may reasonably request.

The Company estimates that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately $[●].

We have been advised by the Underwriter that it proposes to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the Underwriter may offer some of the Shares to other securities dealers at such price less a concession of $[●] per Share. After the initial offering, the public offering price and concession to dealers may be changed.

Underwriter Warrants

Upon the closing of this offering, we have agreed to issue to the Underwriter a five-year warrant to purchase up to six percent (6%) of the common stock sold by us in this offering. The Underwriter's Warrants will be exercisable at a per share exercise price equal to one hundred twenty percent (120%) of the public offering price per share). The Underwriter's Warrants will be exercisable at any time, and from time to time, in whole or in part, during the period from the effective date of the offering, which period shall not extend further than five years from the date of commencement of sales in this offering in compliance with Financial Industry Regulatory Authority, or FINRA, Rule 5110. The Underwriter's Warrants are also exercisable on a cashless basis. The Underwriter's Warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110. Except as permitted by Rule 5110, the Underwriter (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate the Underwriter's Warrants or the securities underlying the Underwriter's Warrants, nor will any of them engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the option or the underlying securities for a period of 180 days from the commencement of sales under this prospectus. The exercise price and number of securities upon exercise of the Warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the Underwriter's Warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the Underwriter's Warrant exercise price.

The Underwriter's Warrants include piggy-back registration and mandatory registration rights in favor of the Underwriter. The piggy-back registration rights provide that the Company will, subject to certain limitations, include common stock underlying the Underwriter's Warrants in any registration statement filed by the Company while the Underwriter's Warrants are exercisable. The mandatory registration rights require the Company to prepare and file at the written request of the warrant holder, on a one-time basis, a registration statement on Form F-3 covering any remaining unregistered common stock underlying the Underwriter's Warrants so long as such warrants are exercisable. The underwriting agreement and the accompanying exhibits, including the form of the Underwriter's Warrant agreement, have been filed with this offering's registration statement as Exhibit No. 1.1.

Discretionary Accounts

The Underwriter does not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

Pursuant to the underwriting agreement and certain "lock-up" agreements, the Company, its executive officers, directors and certain holders of the Company's common stock and securities exercisable for or convertible into its common stock outstanding immediately upon the closing of this offering, have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the Underwriter, for a period of 180 days from the date of effectiveness of the registration statement, of which this prospectus forms a part.

Right of First Refusal

We have granted the Underwriter a right of first refusal, for a period of 12 months from the closing of this offering, to act as sole investment banker, sole book runner and/or sole Underwriter at the Underwriter's discretion, for each and every future public or private equity financing for the Company, or any successor to or subsidiary of the Company. The right of first refusal may be terminated by the Company for cause, which including a material breach by the Underwriter or a material failure by the Underwriter to provide services as contemplated.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by the Underwriter, if any, participating in this offering and the Underwriter participating in this offering may distribute prospectuses electronically. The Underwriter may agree to allocate a number of shares for sale to its online brokerage account holders. Internet distributions will be allocated by the Underwriter that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the Underwriter in its capacity as the Underwriter, and should not be relied upon by investors.

Stabilization

In connection with this offering, the Underwriter may engage in stabilizing transactions, over-allotment transactions, covered transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.

- Over-allotment transactions involve sales by the Underwriter of shares of common stock in excess of the number of shares of common stock the Underwriter is obligated to purchase. This creates a covered short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the Underwriter is not greater than the number of shares of common stock that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares of common stock in the over-allotment option. The Underwriter may close out any short position by exercising its over-allotment option and/or purchasing shares of common stock in the open market.

- Covered transactions involve purchases of shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares of common stock to close out the short position, the Underwriter will consider, among other things, the price of shares of common stock available for purchase in the open market as compared with the price at which it may purchase shares of common stock through exercise of the over- allotment option. If the Underwriter sells more shares of common stock than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares of common stock in the open market. A naked short position is more likely to be created if the Underwriter is concerned that after pricing there could be downward pressure on the price of the shares of common stock in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permits the Underwriter to reclaim a selling concession from a syndicate member when the shares of common stock originally sold by the Underwriter are purchased in stabilizing or covered transactions to cover short positions.

These stabilizing transactions, covered transactions and penalty bids may have the effect of raising or maintaining the market price of the shares of common stock or preventing or retarding a decline in the market price of its shares of common stock. As a result, the price of the common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither the Company nor the Underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of the Company's common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the Underwriter may engage in passive market making transactions in the Company's common stock on The Nasdaq Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

The Underwriter and their respective affiliates may, in the future provide various investment banking, commercial banking and other financial services for the Company and its affiliates for which they have received, and may in the future receive, customary fees. However, except as disclosed in this prospectus, the Company has no present arrangements with the Underwriter for any further services.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the Underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the common stock offered by us in this offering will be passed upon for us by Lucosky Brookman LLP, Woodbridge, New Jersey. Certain legal matters will be passed upon for the Underwriter by Carmel, Milazzo & Feil LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2021 and 2020, included in this registration statement have been so included in reliance upon the report of Rosenberg Rich Baker Berman, P.A., an independent registered public accounting firm, given on the authority of said firm as an expert in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We are subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available on the website of the SEC referred to above. The information contained in, or that can be accessed through, our website is not part of this prospectus, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

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AUDITOR'S REPORT

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, 2021 and 2020, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, 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, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Restatement

As discussed in Note 17 to the financial statements, certain disclosures in the accompanying financial statements have been restated.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has experienced operating losses and negative cash flows from operations since inception that raise substantial doubt about its 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.

Somerset, New Jersey
September 27, 2022, except for the effects of the restatement discussed in Note 17 to the financial statements, as to which the date is November 9, 2022

We have served as the Company's auditor since 2022

Neuraxis, Inc.
Balance Sheet

	December 31,	
	2021	**2020**
Assets		
Current Assets:		
Cash and cash equivalents	**$ 320,858**	$ 1,895,475
Accounts receivable, net	**115,301**	311,329
Inventories	**39,180**	106,846
Prepaids and other current assets	**15,670**	148,289
Total current assets	**491,009**	2,461,939
Property and Equipment, at cost:	**404,455**	403,065
Less - accumulated depreciation	**(286,913)**	(252,146)
Property and equipment, net	**117,542**	150,919
Other Assets:		
Operating lease right of use asset, net	**127,975**	150,786
Intangible assets, net	**23,956**	25,897
Total Assets	**$ 760,482**	$ 2,789,541

Notes to financial statements are an integral part of these statements

Neuraxis, Inc.
Balance Sheet

	December 31, 2021	December 31, 2020
Liabilities		
Current Liabilities:		
Accounts payable	**$ 483,790**	$ 164,558
Accrued expenses	**561,638**	667,004
Current portion of long-term notes payable	**192,356**	—
Notes payable - related party	**58,051**	151,005
Customer deposits	**69,337**	—
Warrant liabilities	**32,102**	2,760
Current portion of operating lease payable	**27,582**	23,311
Total current liabilities	**1,424,856**	1,008,638
Non-current Liabilities:		
Operating lease payable, net of current portion	**109,594**	137,176
Note payable, net of current portion	**51,692**	—
Total non-current liabilities	**161,286**	137,176
Total liabilities	**1,586,142**	1,145,814
Commitments and contingencies (see note 14)		
Stockholders' Equity (Deficit)		
Convertible Series A Preferred stock, $0.001 par value; 1,000,000 shares authorized; 506,637 and 479,612 issued and outstanding as of December 31, 2021 and 2020, respectively	**507**	480
Convertible Series Seed Preferred Stock, $0.001 par value; 120,000 shares authorized; 115,477 issued and outstanding as of December 31, 2021 and 2020	**115**	115
Common stock, $0.001 par value; 100,000,000 shares authorized; 3,856,008 issued and outstanding as of December 31, 2021 and 2020	**3,856**	3,856
Additional paid in capital	**28,321,229**	27,762,611
Accumulated deficit	**(29,151,367)**	(26,123,335)
Total stockholders' equity (deficit)	**(825,660)**	1,643,727
Total Liabilities and Stockholders' Equity (Deficit)	**$ 760,482**	$ 2,789,541

Notes to financial statements are an integral part of these statements

Neuraxis, Inc.
Statements of Operations

	For the Years Ended December 31,	
	2021	**2020**
Net Sales	**$ 2,721,286**	$ 1,930,228
Cost of Goods Sold	**467,656**	481,089
Gross Profit	**2,253,630**	1,449,139
Selling Expenses	**455,879**	521,034
Research and Development	**203,414**	166,798
General and Administrative	**4,564,371**	4,882,045
Operating Loss	**(2,970,034)**	(4,120,738)
Other Income (Expense):		
Interest expense	**(36,928)**	(75,711)
Interest income	**—**	37
License revenue	**—**	250,000
Gain on loan forgiveness	**—**	220,000
Change in fair value of derivative financial instruments	**(29,342)**	1,911
Other expense	**—**	(1,923)
Other income	**8,272**	275
Total other income (expense), net	**(57,998)**	394,589
Net Loss	**$ (3,028,032)**	$ (3,726,149)
Per-share Data		
Basic and diluted loss per share	**$ (0.96)**	$ (1.10)
Weighted Average Shares Outstanding		
Basic and diluted	**3,936,008**	3,936,008

Notes to financial statements are an integral part of these statements

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

For the Years Ended December 31, 2021 and 2020

	Convertible Series A Preferred Stock		Convertible Series Seed Preferred Stock		Common Stock		Additional Paid In	Accumulated	Stockholder's
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2020	189,092	$ 189	115,477	$ 115	3,856,008	$ 3,856	$ 20,943,167	$ (22,397,186)	$ (1,449,859)
Stock based compensation	—	—	—	—	—	—	48,774	—	48,774
Sale of Convertible Series A Preferred Stock, net of fees	290,520	291	—	—	—	—	4,036,330	—	4,036,621
Issuance of Pre-Funded Warrants for Preferred Stock	—	—	—	—	—	—	2,734,340	—	2,734,340
Net loss for the year ended December 31, 2020	—	—	—	—	—	—	—	(3,726,149)	(3,726,149)
Balance, December 31, 2020	**479,612**	**$ 480**	**115,477**	**$ 115**	**3,856,008**	**$ 3,856**	**$ 27,762,611**	**$ (26,123,335)**	**$ 1,643,727**
Stock based compensation	—	—	—	—	—	—	**48,641**	—	**48,641**
Sale of Convertible Series A Preferred Stock	**27,025**	**27**	—	—	—	—	**509,977**	—	**510,004**
Net loss for the year ended December 31, 2021	—	—	—	—	—	—	—	**(3,028,032)**	**(3,028,032)**
Balance, December 31, 2021	**506,637**	**$ 507**	**115,477**	**$ 115**	**3,856,008**	**$ 3,856**	**$ 28,321,229**	**$ (29,151,367)**	**$ (825,660)**

Notes to financial statements are an integral part of these statements

Neuraxis, Inc.
Statement of Cash Flows

	For the Years Ended December 31,	
	2021	**2020**
Cash Flows from Operating Activities		
Net Loss	**$ (3,028,032)**	$ (3,726,149)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	**36,708**	35,787
Provisions for losses on accounts receivable	**11,770**	—
Non-cash lease expense	**22,811**	19,620
Stock based compensation	**48,641**	48,774
Gain on loan forgiveness	**—**	(220,000)
Change in fair value of derivative liabilities	**29,342**	(1,911)
Changes in operating assets and liabilities:		
Accounts receivable	**184,258**	(223,008)
Inventory	**67,666**	323,764
Prepaids and other current assets	**132,619**	1,286
Accounts payable	**319,232**	(664,247)
Accrued expenses	**(105,367)**	286,851
Customer deposits	**69,337**	—
Payroll withholding	**—**	(467)
Operating lease liability	**(23,311)**	(19,629)
Net cash used by operating activities	**(2,234,326)**	(4,139,329)
Cash Flows from Investing Activities		
Additions to property and equipment	**(1,390)**	(27,719)
Net cash used by investing activities	**(1,390)**	(27,719)
Cash Flows from Financing Activities		
Proceeds from sale of convertible Series A Preferred Stock, net of fees of $0 and $1,446,040, respectively	**510,004**	4,036,621
Proceeds from pre-funded warrants for Series A Preferred Stock	**—**	2,734,340
Principal payments on line of credit	**—**	(150,000)
Principal payments on notes payable	**(98,905)**	(1,036,938)
Proceeds from notes payable	**250,000**	470,000
Net cash provided by financing activities	**661,099**	6,054,023
Net Increase (Decrease) in Cash and Cash Equivalents	**(1,574,617)**	1,886,975
Cash and Cash Equivalents at Beginning of Period	**1,895,475**	8,500
Cash and Cash Equivalents at End of Period	**$ 320,858**	$ 1,895,475
Supplemental Disclosure of Non-cash Cash Activities		
Cash paid for interest	**$ 31,631**	$ 74,490
Cash paid for income taxes	**—**	—
Supplemental Schedule of Non-cash Investing and Financing Activities		
Non-cash share issuance costs	**$ —**	$ 350,000

Notes to financial statements are an integral part of these statements

Neuraxis, Inc.
Notes to Financial Statements

December 31, 2021 and 2020

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 on April 17, 2012, under the name of Innovative Health Solutions, Inc. The name was changed to Neuraxis, Inc. in March of 2022. Additionally, the Company filed a Certificate of Conversion to become a Delaware corporation on June 23, 2022. The authorized shares were increased, and a par value established. See Subsequent Events footnote.

On September 7, 2021, the Company's board of directors authorized a 4-for-1 stock split. They also increased the number of authorized common stock shares from 2,700,000 to 10,800,000. Furthermore, on September 9, 2021, the board authorized and increase of authorized shares of common stock from 10,800,000 to 13,400,000 in anticipation of a capital offering. All share and per share amounts for the common stock have been retroactively restated to give effect to the split.

As part of the conversion to a Delaware corporation, the total number of shares of all classes of stock which the Corporation shall have authority to issue is (1) 100,000,000 shares of Common Stock, par value $0.001 per share ("Common Stock") and (ii) 1,120,000 shares of Preferred Stock, par value $0.001 per share ("Preferred Stock"), 1,000,000 of which is hereby designated as "Series A Preferred Stock" and 120,000 of which is hereby designated as "Series Seed Preferred Stock" with the rights, preferences, powers, privileges and restrictions, qualifications and limitations set forth in this Article IV of the Delaware Certificate of Incorporation. All share amounts have been retroactively restated to give effect to these changes.

The Company is headquartered in Versailles, Indiana. The Company specializes in the development, production, and sale of medical neuromodulation devices.

The Company has developed three FDA cleared products, the IB-STIM (DEN180057, 2019), the NSS-2 Bridge (DEN170018, 2017), and the original 510(K) clearance (K140530, 2014).

- The IB-STIM is a percutaneous electrical nerve field stimulator (PENFS) device that is indicated in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome. The IB-STIM currently is the only product marketed and sold by the Company.

- The NSS-2 Bridge is a percutaneous nerve field stimulator (PNFS) device indicated for use in the reduction of the symptoms of opioid withdrawal. The NSS-2 Bridge device was licensed to Masimo Corporation in April 2020, and the Company received a one-time licensing fee of $250,000 from Masimo. Masimo markets and sells this product as its Masimo Bridge, and the Company will not receive any further licensing payments or other revenue from this product.

- 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 is 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.

Preparing the Company's financial statements in conformity with accounting principles generally accepted in the United States of America ("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 date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

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 doubtful accounts, stock-based compensation, income tax provisions, excess and obsolete inventory reserve, and impairment of intellectual property. Actual results could differ from those estimates.

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, 2021 and 2020.

Trade Accounts Receivable

Trade accounts receivable are stated at the amount management expects to collect from balances outstanding at year-end. Management considers the following factors when determining the collectability of specific customer accounts: customer creditworthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. Based on management's assessment of the credit history with customers having outstanding balances and current relationships with them, it has concluded that realization losses on balances outstanding at year-end will be immaterial. Interest is not charged on past due customer accounts.

Allowance for Doubtful Accounts

Trade accounts receivable are stated net of an allowance for doubtful accounts. We estimate allowance for doubtful accounts by evaluating specific accounts where information indicates our customers may have an inability to meet financial obligations, such as customer payment history, credit worthiness and receivable amounts outstanding for an extended period beyond contractual terms. We use assumptions and judgment, based on the best available facts and circumstances, to record an allowance to reduce the receivable to the amount expected to be collected. The allowance for doubtful accounts was $11,770 and $0 at December 31, 2021 and 2020, respectively. During the years ended December 31, 2021 and 2020, the Company recorded $11,770 and $4,027, respectively as a bad debt expense.

Customer deposits

Customer deposits consists of billings and payments from clients in advance of revenue recognition. The Company will recognize the customer deposits over the next year. As of December 31, 2021, and 2020, the Company had customer deposits of $69,337 and $0, respectively

Inventories

Inventories are valued at the lower of cost or net realizable value. 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. For the years 2021 and 2020, $48,488 and $14,072 were expensed as expired inventory, respectively.

Prepaid inventories of $96,587 held on December 31, 2020, are comprised of device components that were acquired from the previous contract manufacturer during the switch to a new contract manufacturer. The components were utilized by the new contract manufacturer in 2021. The balance is reported on the prepaids and other current assets line of the balance sheet.

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
Leasehold Improvements	10-20
Machinery and Equipment	7-10
Furniture and Fixtures	5-10

Depreciation expense was $34,767 and $33,846 during the years ended December 31, 2021 and 2020, respectively.

Research and Development

Costs for research and development are expensed as incurred. Research and development expense consists primarily of clinical research studies, new product development, and manufacturing improvements.

Intangible Assets

Intangible assets consist of patents and 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, we amortize the capitalized patent costs 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. 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, 2021 and 2020, the Company recorded an impairment charge of $0 for intangible assets.

Amortization expense was $1,941 and $1,941 during the years ended December 31, 2021 and 2020, respectively.

Income Taxes

The Company has adopted accounting rules that prescribe when to recognize and how to measure the financial statements effect, if any, of income tax positions taken or expected to be taken on its income tax returns. These rules require management to evaluate the likelihood that, upon examination by relevant taxing jurisdictions, those income tax positions would be sustained.

Based on that evaluation, if it were more than 50% probable that a material amount of income tax would be imposed at the entity level upon examination by the relevant taxing authorities, a liability would be recognized in the accompanying balance sheet along with any interest and penalties that would result from that assessment. Should any such penalties and interest be incurred, the Company's policy would be to recognize them as operating expenses.

Based on the results of management's evaluation, adoption of the rules did not have a material effect on the Company's financial statements. Further, no interest or penalties have been accrued or charged to expense as of December 31, 2021 and 2020 and for the years then ended.

The Company's income tax returns are subject to examination by the taxing authorities until the expiration of the related statutes of limitations on those tax returns. In general, the federal and state income tax returns have a three-year statute of limitations. As of December 31, 2021, the following tax years are subject to examination:

Jurisdiction	Open Years for Filed Returns	Return to File in 2022
Federal	2018 – 2020	2021
Indiana	2018 – 2020	2021

Advertising Cost

Advertising costs are expensed as incurred and amounted to $34,316 and $89,709 for the years ended December 31, 2021 and 2020, respectively.

Derivative Financial Instruments

The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with paragraph 815-10-05-4 and Section 815-40-25 of the FASB Accounting Standards Codification. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market on each balance sheet date and recorded as either an asset or a liability. In the event that the fair value is recorded as a liability, the change in fair value is recorded in the condensed consolidated statement of operations as other income or expense. Upon conversion, exercise, or cancellation of a derivative instrument, the instrument is marked to fair value at the date of conversion, exercise, or cancellation, and then the related fair value is reclassified to equity.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

In accordance with Section 815-40-15 of the FASB Accounting Standards Codification ("Section 815-40-15") to determine whether an instrument (or an embedded feature) is indexed to the Company's own stock. Section 815-40-15 provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions.

The Company utilizes a Monte Carlo simulation model for warrants that have an option to convert at a variable number of shares 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 Monte Carlo model included a starting stock price, an expected remaining term of each warrant as of the valuation date, estimated volatility, drift, and a risk-free rate. The Company records the change in the fair value of the derivative as other income or expense in the condensed consolidated statements of operations.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, Fair Value Measurements and Disclosures ("ASC 820"). ASC 820 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 below:

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 assumptions that 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/liabilities include cash, accounts receivable, accounts payable, prepaids, and other current assets. Management believes the estimated fair value of these accounts at December 31, 2021 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 2 assets/liabilities include certain of the Company's notes payable and capital lease obligations. Their carrying value approximates their fair values based upon a comparison of the interest rate and terms of such debt given the level of risk to the rates and terms of similar debt currently available to the Company in the marketplace.

The Company's Level 3 assets/liabilities include derivative liabilities. 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. Unobservable inputs used in the models are significant to the fair values of the assets and liabilities.

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

Fair Value Measurements as of December 31, 2021

	Total	(Level 1)	(Level 2)	(Level 3)
Liabilities:				
Derivative liabilities	$ 32,102	$ -	$ -	$ 32,102
Total Liabilities	$ 32,102	$ -	$ -	$ 32,102

Fair Value Measurements as of December 31, 2020

	Total	(Level 1)	(Level 2)	(Level 3)
Liabilities:				
Derivative liabilities	$ 2,760	$ -	$ -	$ 2,760
Total Liabilities	2,760	$ -	$ -	$ 2,760

The following table shows the valuation methodology and unobservable inputs for Level 3 assets and liabilities measured at fair value on recurring basis as of December 31, 2021 and 2020:

	Fair Value As of December 31, 2021	Fair Value As of December 31, 2020	Valuation Methodology	Unobservable Inputs
Derivative liabilities	$ 32,102	$ 2,760	Monte Carlo model	Project simulated cash flows

There were no transfers between any of the levels during the years ended December 31, 2021 and 2020. In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges.

Basic and Diluted Net Income (Loss) per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss), net of preferred stock dividends, by the weighted average number of shares of common stock outstanding during the period. Diluted EPS is computed by dividing net income (loss) by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented. Preferred stock dividends (not declared or paid) were $748,832 and $589,156 for the years ended December 31, 2021 and 2020, respectively.

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, which is the case for December 31, 2021 and 2020 presented in these financial statements, the weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive.

The Company had the following potentially dilutive common stock equivalents at December 31, 2021 and 2020:

	December 31,	
	2021	**2020**
Convertible Series A Preferred Stock	506,637	479,612
Convertible Series Seed Preferred Stock	115,477	115,477
Options	2,638,788	2,638,788
Pre-Funded Warrants for Convertible Series A Preferred Stock	144,890	144,890
Warrants	25,704	25,704
Totals	3,431,496	3,404,471

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

	2021	**2020**
Numerator		
Net loss	**$ (3,028,032)**	$ (3,726,149)
Preferred stock dividends	**(748,832)**	(589,156)
	(3,776,864)	(4,315,305)
Denominator		
Weighted-average shares of common stock outstanding - basic and diluted	**3,936,008**	3,936,008
Basic and diluted net loss per share	**$ (0.96)**	$ (1.10)

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. 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 of a stock option.

The Company accounts for the granting of stock options 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 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. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance, or service condition.

Stock-based payments 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

Neuraxis, Inc. specializes in the development, production, and sale of medical neuromodulation devices to healthcare providers primarily located in the United States. Patented and trademarked neuromodulation devices is the Company's major product line. Products are generally transferred at a point in time (rather than over time). Essentially all the Company's revenue is generated from purchase order contracts.

In accordance with FASB's ASC 606, Revenue from Contracts with Customers, ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. 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 of the consideration it is entitled to in exchange for the goods or services 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 or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service 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 estimates credit losses on accounts receivable by estimating expected credit losses over the contractual term of the receivable using a discounted cash flow method. When developing this estimate of expected credit losses, the Company considers all available information (past, current, and future) relevant to assessing the collectability of cash flows.

The Company offers a Patient Assistance Program for patients without insurance coverage for IB-Stim. This program extends potential self-pay discounts for IB-Stim devices, 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 rebates 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 the IB-Stim device. The Company recognizes revenue at such a time that collection of the amount due is assured.

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

	2021	2020
Wisconsin	**$ 665,157**	$ 450,568
California	**549,466**	353,810
Ohio	**462,350**	348,666
North Carolina	**260,753**	325,155
All other states	**783,560**	452,029
	$ 2,721,286	$ 1,930,228

The following economic factors affect the nature, amount, timing, and uncertainty of the Company's revenue and cash flows as indicated:

Type of customer: Based on dollar amounts of revenue, essentially all of the goods sold by the Company are sold to healthcare customers including hospitals and clinics. Sales to healthcare customers lack seasonality and have a mild correlation with economic cycles.

Geographical location of customers: Sales to customers located within the United States represent essentially all of the Company's sales.

Type of contract: Sales contracts consist of purchase order contracts that tend to be short-term (i.e., less than or equal to one year in duration).

The opening and closing balances of trade receivables, contract assets, and contract liabilities from contracts with customers are as follows:

	Trade Receivables	Contract Assets	Contract Liabilities
Balance 1/1/2020	$ 88,321	$ 0	$ 0
Balance 12/31/20 and 1/1/2021	$ 311,329	$ 0	$ 0
Balance 12/31/2021	$ 115,301	$ 0	$ 0

Company's Performance Obligations with Customers:

Timing of Satisfaction

The Company typically satisfies its performance obligations as goods are delivered.

Goods that are shipped to customers are typically shipped FOB shipping point with freight prepaid by the Company. As such, ownership of goods in transit transfer to the customer when shipped and the customer bears the associated risks (e.g., loss, damage, delay). In some cases, a customer will take delivery directly from the Company's inventory (i.e., consigned inventory), at which point ownership and the associated risks pass to the customer at that time.

Shipping and handling costs are recorded as general and administrative expenses in the Statement of Operations.

Significant Payment Terms

Payment for goods sold by the Company is typically due, after an invoice is sent to the customer, within 30 days. However, other payment terms are frequently negotiated with customers ranging from due upon receipt to due within 90 days. Some payment terms may call for payment only after the healthcare provider receives their insurance reimbursement. Invoices for goods are typically sent to customers within three calendar days of shipment. 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.

Nature

Medical devices that the Company contracts to sell and transfer to customers are manufactured by one specific third-party manufacturer. The manufacture is located within the state of Indiana and maintains compliance with FDA manufacturing guidelines. 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).

Returns, Refunds, etc.

Orders may not be cancelled after shipment. Customers may return devices within 10 days of delivery 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 maintains appropriate accounts to reflect the effects of expected returns on the Company's financial position and periodically adjusts those accounts to reflect its actual return experience. Historically, returns have been immaterial, and the Company currently does not provide a provision for this liability.

Warranties

In most cases, goods that customers purchase from the Company are covered by manufacturers' warranties. The Company does not sell warranties separately.

The manufacturer guarantees the product for the period up to the expiration date printed on the device's label or twelve months from the date of purchase, whichever comes first. The guarantee applies to flaws of material and workmanship. The Company's warranties provide customers with assurance that purchased devices comply with published specifications, inspection standards, and workmanship. At the time revenue is recognized, the Company estimates the cost of expected future warranty claims but does not exclude any amounts from revenue. The Company maintains appropriate accounts to reflect the effects of expected future warranty claims on the Company's financial position and periodically adjusts those accounts to reflect its actual warranty claim experience. Historically, warranty claims have been immaterial, and the Company currently does not provide a provision for this liability.

The Company typically satisfies its performance obligations for goods at a point in time. In most cases, goods are shipped by common carrier to customers under "FOB Shipping Point" terms. As such, customers typically obtain control of the goods upon shipment. The Company's management exercises judgment in determining when performance obligations for goods have been satisfied. In making such judgments, management typically relies on shipping information obtained from common carriers to evaluate when the customer has obtained control of the goods.

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.

Leases

Effective January 1, 2021, the Company adopted Accounting Standards Updated ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), using the full retrospective method, the cumulative effect of the accounting change is recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. 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.

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

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 of the contract consideration to the lease component only.

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.

Risks and Uncertainties

In 2021, the World Health Organization declared Coronavirus (COVID-19) a pandemic. The continued spread of COVID-19, or any similar outbreaks in the future, may adversely impact the local, regional, national, and global economies. The extent to which COVID-19 impacts the Company's results is dependent on the breadth and duration of the pandemic and could be affected by other factors the Company is not currently able to predict. These impacts may include, but are not limited to, additional costs for responding to COVID-19, potential shortages of labor, potential shortages of material and supplies, and loss of, or reduction to, revenue. Management believes the Company is taking appropriate actions to respond to the pandemic, however, the full impact is unknown and cannot be reasonably estimated at this time.

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 balance at December 31, 2021 and 2020 of accounts receivable was $115,301 and $311,329, respectively.

The table below sets forth the Company's customers that accounted for greater than 10% of its revenues in one of the years ended December 31, 2021 and 2020, respectively.

	2021	Percentage of Sales	2020	Percentage of Sales
Hospital A	**$ 574,185**	21%	$ 430,211	22%
Hospital B	**444,965**	16%	336,627	17%
Hospital C	**321,964**	12%	231,568	12%
Hospital D	**226,293**	8%	285,717	15%
	$ 1,567,407	58%	$ 1,284,123	67%

From time to time, the Company's bank balances may exceed the FDIC limit of $250,000; however, management does not feel that this has a material impact on the financial condition. At December 31, 2021 and 2020, the Company's uninsured cash balances totaled $20,850 and $1,450,000, respectively.

Liquidity

We have incurred losses since inception and have funded our operations primarily with a combination of sales, debt, and the sale of capital stock. As of December 31, 2021, we had an stockholders' deficit of approximately $826 thousand. At December 31, 2021, we had short-term and long-term borrowings outstanding of approximately $250 thousand and $52 thousand, respectively. As of December 31, 2021, we had cash of approximately $321 thousand and a working capital deficit of approximately $934 thousand.

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 end of 2022 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 through November 2022.

Going Concern Evaluation

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.

To date, the Company has experienced operating losses and negative cash flows from operations. Management believes that increased sales and acceptance of their product by insurance providers, will allow the Company to achieve profitability in the near term.

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. Because, under current accounting standards, 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, 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 its cost structure. We may never achieve profitability, and unless and until doing so, we intend to fund future operations through additional dilutive or nondilutive financings. 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 February 2016, the FASB issued an update (ASU 2016-02, Leases) which requires lessees to record most leases on their balance sheet and recognize leasing expenses in the income statement. The guidance modifies the recognition and accounting for lessees and lessors and requires expanded disclosures regarding assumptions used to recognize revenue and expenses related to leases. The guidance is effective for annual and interim reporting periods beginning after December 15, 2019 for SEC filers, December 15, 2020 for public business entities that are not SEC filers, and December 15, 2021 for all other entities, including EGCs that have elected to defer adoption until the guidance becomes effective for non-public entities, with early adoption permitted. The Company elected to adopt early. Early adoption is permitted and modified retrospective adoption is required. The guidance is to be applied using either a full retrospective or modified retrospective method. In applying the full retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. In applying the modified retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings at the date of adoption. The Company early adopted ASU 2016-02 effective January 1, 2020, under the full retrospective approach.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company adopted this standard as of January 1, 2020, and the adoption did not have a material impact on the Company's financial statements.

In November 2018, FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020, and the adoption did not have a material impact on the Company's financial statements.

In August 2020, FASB issued ASU 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. The guidance is effective for interim and annual periods beginning after December 15, 2021. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB has specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The guidance is to be applied using either a full retrospective or modified retrospective method. In applying the full retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings in the first comparative period presented. In applying the modified retrospective method, the cumulative effect of the accounting change should be recognized as an adjustment to the opening balance of retained earnings at the date of adoption**.** The Company early adopted ASU 2020-06 effective January 1, 2021, under the modified retrospective approach. The adoption of this guidance did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued an update (ASU 2014-09, Revenue from Contracts with Customers) that supersedes most current revenue recognition and industry-specific guidance. These standards update clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP and International Financial Reporting Standards. The standards update intends to provide a more robust framework for addressing revenue issues; improve comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets; and provide more useful information to users of financial statements through improved disclosure requirements. The guidance is effective for nonpublic entities for annual reporting periods beginning after December 15, 2019. The Company adopted ASU 2014-09 effective January 1, 2020.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which amends the effective date of ASU 2016-13. Public business entities meeting the definition of an SEC filer, excluding entities eligible to be a Smaller Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The Company is evaluating the effect that ASU 2016-13 will have on its 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 provided an allowance for the entire balance of principal and interest as of December 31, 2019. The current allowance is $1,083,762 as of December 31, 2021. The current loan balances are as follows:

December 31, 2021	Loan Receivable	Interest Receivable	Interest Income
Shareholder 1	$ 506,400	$ 35,548	$ 827
Shareholder 2	506,400	35,414	827
	1,012,800	70,962	1,654
Allowance for Collection Risk	(1,012,800)	(70,962)	(1,654)
Net Balance	$ —	$ —	$ —

December 31, 2020	Loan Receivable	Interest Receivable	Interest Income
Shareholder 1	$ 506,400	$ 34,721	$ 2,921
Shareholder 2	506,400	34,587	2,921
	1,012,800	69,308	5,842
Allowance for Collection Risk	(1,012,800)	(69,308)	(5,842)
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, 2021	Due Date	Interest Rate	Loan Balance	Interest & Service Fee Accrued	Interest Paid
Shareholder 2	Demand	0.12%	$ —	$ —	$ 10
Shareholder 1	June, 2019	15.00%	20,051	5,153	—
Shareholder 1	June, 2019	15.00%	38,000	17,781	—
Shareholder 3	June, 2019	15.00%	—	—	4,582
Other Convertibles Various		5.00%	—	66,648	—
Total			$ 58,051	$ 89,582	$ 4,592

December 31, 2020	Due Date	Interest Rate	Loan Balance	Interest & Service Fee Accrued	Interest Paid
Shareholder 2	Demand	0.15%	$ 61,861	$ 8	$ 36,403
Shareholder 1	June, 2019	15.00%	20,051	2,145	9,051
Shareholder 1	June, 2019	15.00%	38,000	12,081	—
Shareholder 3	June, 2019	15.00%	31,093	3,403	9,619
Other Convertibles	Various	5.00%	—	66,648	—
Total			$ 151,005	$ 84,285	$ 55,073

The Company's Chief Financial Officer, John Seale, CPA.CITP, is contracted for services through RBSK Partners PC (RBSK). Mr. Seale is RBSK's managing partner and majority shareholder. RBSK is engaged by the Company to provide accounting and tax services on a continuous basis. Fees paid to RBSK for services were $80,394 and $167,489 for the years ended December 31, 2021 and 2020, respectively. The Company owed RBSK for open invoices of $3,386 and $6,270 as of December 31, 2021 and 2020, respectively.

4. Prepaids and Other Current Assets

The Company made cash advances to its manufacturer in the amount of $1,123,000. Production invoices from the manufacturer for the years 2017-2020 in the amount of $1,123,000 have been applied to the advance balance leaving a net balance of $0 and $38,240 as of December 31, 2021 and 2020, respectively. The vendor deposit balance is reported within prepaids and other current assets on the balance sheet.

5. Accrued Expenses

Accrued expenses consisted of the following:

	2021	2020
Wages	$ 451,970	$ 525,791
Employee benefits	11,735	5,736
Commissions	7,786	50,639
Property taxes	563	554
Interest expense	89,582	84,285
Total accrued expenses	$ 561,636	$ 667,005

6. Long-term Notes Payable

The Company borrowed $250,000 on December 16, 2021, from Channel Partners Capital. The note calls for 65 weekly payments of $4,923.08 with the final payment scheduled for March 16, 2023. The note's interest rate computes to a nominal rate of 40.856%. The principal outstanding at December 31, 2021 was $244,048.

The lender was granted and assigned a continuing security interest in all the Company's personal property assets including, but not limited to, business equipment, inventory, accounts, accounts receivable, intellectual property, chattel paper, instruments, deposit accounts, commercial tort claims, contract rights, licenses, claims, and general intangibles.

Future minimum principal payments are as follows:

2022	$ 192,356
2023	$ 51,692

7. Leases

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, 2021 and 2020.

The Company had three leases primarily consisting of office space in Versailles and Carmel Indiana. Two of the leases in Versailles started January 1, 2017. Both have an initial term of five years with an option for an additional five-year term. The monthly lease payments for these leases are $550 and $1,600 with a 3% per annum increase starting with the optional five-year term. The lease in Carmel started March 1, 2016. The initial term is five years and three months with an option for an additional three-year term. The monthly lease payment started at $1,472 with an annual increase of approximately 2.7%. On December 16, 2020, the Company entered into an amendment of the Carmel lease that extended the initial term by two years.

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.

For the years ended December 31, 2021 and 2020, the Company recognized $4,725 and $2,268 of operating lease expense, including short-term lease expense and variable lease costs, which are immaterial.

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

	2021	2020
Operating lease right-of-use assets	**$ 127,975**	$ 150,786
Other current liabilities	**27,582**	23,311
Operating lease liabilities	**109,594**	137,176
	$ 137,176	$ 160,487
Weighted-average remaining lease term (in years)	5	4
Weighted-average discount rate	15.0%	15.0%

As of December 31, 2021, the maturities of the Company's operating lease liabilities were as follows:

2022	$ 46,319
2023	46,832
2024	34,731
2025	25,800
2026	25,800
Total lease payments	179,482
Less: imputed interest	42,306
Total present value of lease payments	$ 137,176

8. Common Stock and Warrants

On September 7, 2021, the Company's board of directors authorized a 4-for-1 stock split. They also increased the number of authorized common stock shares from 2,700,000 to 10,800,000. Furthermore, on September 9, 2021, the board authorized and increase of authorized shares of common stock from 10,800,000 to 13,400,000 in anticipation of a capital offering. As part of the conversion to a Delaware Corporation in June of 2022, the total number of common stock shares authorized was increased to 100,000,000. All share and per share amounts for the common stock have been retroactively restated to give effect to the split.

In connection with a bridge loan, the Company issued a warrant to a shareholder, Brian Hannasch, on September 18, 2018. The warrant allows the holder to purchase common stock from the Company at a share price of $4.38 per share. The number of shares was based on a formula tied to the amount of loans made by the holder. The number of shares based on this formula is 25,704. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. If the fair market value of one share is greater than the warrant price, the holder may elect to receive a number of shares equal to the value of the warrant. If the exercise in in connection with the sale of the Company, the holder may, at its option, condition its exercise of the warrant upon the consummation of such transaction. The warrant expires on September 18, 2028, and can be exercisable either in whole or from time to time in part prior to the expiration date.

The Company issued a second warrant to Brian Hannasch on September 6, 2019, under similar terms. This is a penny warrant that allows the holder to purchase 80,000 shares of common stock and is subject to adjustment for certain equity events. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. The warrant expires on September 6, 2029.

The Company issued a third warrant to Masimo Corporation on April 9, 2020. This warrant was pre-funded in the amount of $2,734,340. The warrant allows the holder to purchase 144,890 shares of Series A Preferred Stock at $18.87 per share and is subject to adjustment for certain equity events. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. There will be no additional purchase price for the Warrants. In the event that all outstanding shares of Series A Preferred Stock are converted, automatically or by action of the holders thereof, into Common Stock, including, without limitation, in connection with the Company's initial, underwritten public offering and sale of its Common Stock pursuant to an effective registration statement under the Act (the "IPO"), then from and after the date on which all outstanding shares of Series A Preferred Stock have been so converted, this Warrant shall be exercisable for such number of shares of Common Stock into which the Warrant Shares would have been converted had the Warrant Shares been outstanding on the date of such conversion, and the Exercise Price shall equal the Exercise Price in effect as of immediately prior to such conversion divided by the number of shares of Common Stock into which one share of Series A Preferred Stock would have been converted, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant.

The following is a summary of warrant activity for common stock during the years ended December 31, 2021 and 2020:

	Number of Warrants for Common Stock	Weighted-Avg. Exercise Price
Outstanding as of December 31, 2019	105,704	$ 1.07
Granted	—	—
Cancelled/Expired	—	—
Exercised	—	—
Outstanding as of December 31, 2020	105,704	$ 1.07
Granted	—	—
Cancelled/Expired	—	—
Exercised	—	—
Outstanding as of December 31, 2021	105,704	$ 1.07

The following is a summary of warrant activity for preferred stock during the years ended December 31, 2021 and 2020:

	Number of Warrants for Preferred Stock	Weighted-Avg. Exercise Price
Outstanding as of December 31, 2019	—	$ —
Granted	—	—
Cancelled/Expired	—	—
Exercised	—	—
Outstanding as of December 31, 2020	—	$ —
Granted	144,890	$ 0.0001
Cancelled/Expired	—	—
Exercised	—	—
Outstanding as of December 31, 2021	144,890	$ 0.0001

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2021.

	Number of Warrants Outstanding		Exercise Price	Expiration Date
Common Stock	25,704	$	4.3800	September 18, 2028
Common Stock	80,000	$	0.0100	September 6, 2029
Preferred Stock	144,890	$	0.0001	None
	250,594			

9. Preferred Stock

The Company has authorized 1,120,000 shares of preferred stock of which 1,000,000 has been designated Series A Preferred Stock and 120,000 has been designated Series Seed Preferred Stock, of which 506,637 and 479,612 shares of Series A Preferred Stock and 115,477 shares of Series Seed Preferred Stock are issued and outstanding as of December 31, 2021 and 2020.

The aggregate purchase price of the Series A Preferred Stock was $9,321,165, of which $7,692,664 was comprised of cash and the remaining $1,628,501 was comprised of converted debt and common stock. The aggregate purchase price of the shares of Series Seed Preferred Stock was $0, as all the shares of Series Seed Stock were converted from common stock as an incentive to reinvest in Series A Preferred Stock.

The following is a summary of Preferred Stock terms:

Voting Rights - The Series A Preferred Stock and Series Seed Preferred Stock shall vote together with the Common Stock on an as-converted basis, and not as separate classes.

Conversion - The Series A Preferred Stock and Series Seed Stock initially convert 1:1 to Common Stock at any time at option of holder, subject to adjustments for stock dividends, splits, combinations, and similar events and as described below under "Anti-dilution Provisions."

Dividends - The Series A Preferred Stock will carry an annual 8% cumulative dividend, payable upon any liquidation, dissolution or winding up of the Company (the "Accruing Dividend"). For any other dividends or distributions, participation with Common Stock on an as-converted basis.

Liquidation - In the event of any liquidation, dissolution or winding up of the Company, the proceeds shall be paid in the following priority:

First, to the Series A Preferred in proportion to each holder's respective pro rata Series A Original Purchase Price, plus any pro rata share of the Accruing Dividend until the entire Series A Original Purchase Price and Accruing Dividend are paid;

Second, to the Series Seed Preferred Stock in proportion to each holder's respective pro rata Series Seed Original Purchase Price until the entire amount of the Series Seed Original Purchase Price is paid;

Thereafter, the Series A Preferred Stock and Series Seed Preferred Stock participate with the Common Stock pro rata on an as-converted basis.

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 (a "Deemed Liquidation Event"), thereby triggering payment of the liquidation preferences described.

Anti-dilution Provisions - The Series A Preferred have full-ratchet anti-dilution protection so that the conversion price will be reduced to 80% of the price at which any future shares are issued, if less than the Series A Original Purchase Price.

In consideration for shareholders to make an additional investment in the Company, upon the purchase of the Series A Preferred stock by the shareholder, the Company converted the existing common shares held by shareholders to Series Seed Preferred Stock at a $100 million valuation and at a 120% share premium. As of December 31, 2021, and 2020, there were 97,702 common shares converted into 115,477 shares of Series Seed Preferred Stock that have no par value and are outstanding.

10. Stock Options and Awards

On October 12, 2017, the Company adopted the 2017 Stock Compensation Plan authorizing the issuance of 1,435,652 shares of common stock. On September 13, 2019 the Company entered into a Stock Option Cancellation agreement with all holders of these stock options effective on that date.

This plan was then amended on September 13, 2019, to increase the share amount to 2,638,788. This plan was enacted to enable the Company to retain the services of certain key employees, officers, and directors of the Company. The Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs and restricted stock, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Assumptions as of December 31, 2019	
	Fully Vested	**Partially Vested**
Number of Shares	2,580,648	58,140
Stock price	$ 3.74	$ 3.74
Exercise price	$ 3.47	$ 3.47
Expected term	5 years	5.9 years
Expected volatility	63.69%	69.4%
Risk-free interest rate	2.17%	2.17%
Dividend rate	0%	0%

The following is a summary of stock option activity for the years ended December 31, 2021 and 2020:

	Number of Options	**Weighted Avg. Remaining Contractual Life (in years)**	**Weighted Avg. Exercise Price**	**Aggregate Intrinsic Value**
Outstanding as of December 31, 2019	2,638,788	7.78	$ 13.88	$ —
Granted	—			
Forfeited	—			
Cancelled/Expired	—			
Exercised	—			
Outstanding as of December 31, 2020	2,638,788	6.78	$ 13.88	$ —
Granted	—			
Forfeited	—			
Cancelled/Expired	—			
Exercised	—			
Outstanding as of December 31, 2021	2,638,788	5.78	$ 13.88	$ —
Vested and Exercisable as of December 31, 2021	2,619,408	5.78	$ 13.88	$ —

Stock-based compensation expense is classified in the Company's statements of operations as general and administrative expense. The amounts were $48,641 and $48,774 for years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, there was $27,319 of total unrecognized compensation expense related to unvested options granted under the Company's share-based compensation plans that is expected to be recognized over a period of approximately 0.56 years.

11. Derivative Liabilities

The Company has identified derivative instruments arising from an adjustable exercise price for warrants that are issued and outstanding as of December 31, 2021 and 2020.

The Company utilizes a Monte Carlo simulation model for warrants that have an option to convert at a variable number of shares 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 Monte Carlo model included a starting stock price, an expected remaining term of each warrant as of the valuation date, estimated volatility, drift, and a risk-free rate.

Risk-free interest rate: The Company uses the risk-free interest rate of a U.S. Treasury Note adjusted to be on a continuous return basis to align with the Black-Scholes option-pricing model.

Dividend yield: The Company uses a 0% expected dividend yield as the Company has not paid dividends to date and does not anticipate declaring dividends in the near future.

Volatility: The Company calculates the expected volatility based on comparable company's historical stock prices with a look back period commensurate with the period to maturity.

Expected term: The Company's remaining term is based on the remaining contractual maturity of the warrants.

The following are the changes in the derivative liabilities during the year ended December 31, 2021 and 2020.

	Level 1	Level 2	Level 3
Derivative liabilities as of January 1, 2020	$ —	$ —	$ 4,745
Addition	—	—	—
Changes in fair value	—	—	(1,247)
Derivative liabilities as of January 1, 2021	—	—	3,498
Addition	—	—	—
Changes in fair value	—	—	28,816
Derivative liabilities as of December 31, 2021	$ —	$ —	$ 32,314

12. Retirement Plan

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 matches the employee's contribution up to 3%. The Company can also make an optional profit-sharing contribution to the employee accounts on an annual basis. There was an expense of $22,501 and an over accrual of $7,048 for years ended December 31, 2021 and 2020, respectively.

13. **Payroll Protection Program Loan**

The Company received a loan in the amount of $220,000 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after eight or twenty-four weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the eight-week period.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company has used the proceeds for purposes consistent with the PPP.

On December 28, 2020, the Company was notified by their bank that the SBA had paid off their PPP loan which was approved for total forgiveness.

14. **Commitments and Contingencies**

License Agreement

On April 9, 2020, the Company entered into a license agreement with Masimo Corporation (Masimo) granting certain exclusive rights and licenses, access to Company's research and development capabilities, and to enable the development, manufacture, and commercialization of products in a specific "field", primarily related to pain associated with substance abuse withdrawal symptoms.

The "field" excludes the following pediatric and adult conditions (including the associated symptoms and any pain caused thereby): chronic nausea, gastroparesis, functional gastrointestinal disorders, chemotherapy induced nausea/vomiting, concussions and post-concussion syndrome, headaches (migraine or benign, non-specified), symptoms resulting from traumatic brain injury, post-traumatic stress disorder, fatty liver disease, cyclic vomiting syndrome, movement disorder including Parkinson's disease, chronic sleep disorders, inflammatory bowel disease, pancreatitis, pulmonary inflammatory disorders, dysautonomia and postural orthostatic tachycardia syndrome, tic disorders, tinnitus, TMJ disorders, autoimmune disorders, seizure disorders, diabetes, and modulation of exercise physiology and recovery.

Company also entered into a collaboration agreement with Masimo to induce Masimo to enter into the purchase of Series A Preferred Stock and Pre-funded Warrants for Series A Preferred Stock and as part of that agreement received a one-time, upfront and non-refundable fee of $250,000 for the license agreement. More information is contained in footnote 8.

Manufacturing Services Agreement

On August 21, 2020, the Company entered into a Manufacturing Services Agreement (MSA) for the manufacture and supply of the Company's IB-STIM device based upon the Company's product specifications as set forth in the MSA. This agreement terminated any prior manufacturing agreements.

The Company provides the necessary equipment to the manufacturer and retains ownership. The manufacturer bears the risk of loss of and damage to the equipment and consigned materials. Performance under the MSA is initiated by orders issued by the Company and accepted by the manufacturer.

The term of the MSA is 24 months and shall automatically renew for renewal terms of twelve months unless either party provides a written termination notice to the other party within 180 days prior to the end of the then-current term.

Litigation

From time to time in the normal course of our business operations, we may become subject to litigation that may result in liability material to our financial condition as a whole or may negatively affect our operating results if changes to our business operations are required. The cost to defend such litigation may be significant and may require a significant diversion of our resources, and there is no guarantee that we will be able to successfully defend against any such litigation regardless of particular merits. There also may be adverse publicity associated with litigation that could negatively affect customer perception of our business, regardless of whether the allegations are valid or whether we are ultimately found liable. Insurance may not be available on favorable terms, at all, or in sufficient amounts to cover any liabilities with respect to these or other matters. A judgment or other liability in excess of our insurance coverage for any claims could adversely affect our business, financial condition and the results of our operations.

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 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 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. The Company filed a motion to dismiss. The Court suspended briefing on the merits while it considers the Company's motion to dismiss the appeal.

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 Neuraxis, Inc. and others in the United States District Court for the District of Maryland. Those plaintiffs 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. While it is too early to predict the ultimate outcome of this matter, we believe we have meritorious defenses and intend to defend this matter vigorously. 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.

The Company has filed a motion to dismiss all claims, but no ruling has been issued yet. While it is too early to predict the ultimate outcome of this matter, we believe we have meritorious defenses and intend to defend this matter vigorously.

15. Income Taxes

The Company did not recognize a current provision for income taxes for 2021 and 2020 since there were net operating losses reported in both years.

Deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. Differences are primarily attributable to net operating loss carryforwards and depreciation on assets.

The Company does not reflect a deferred tax asset in its financial statements but includes that calculation and valuation in its footnotes. The net deferred tax amounts include the following components:

	2021	2020
Net deferred tax assets - Non-current		
Depreciation	**$ (22,010)**	$ (27,955)
Amortization	**(5,992)**	(6,539)
Accrual to cash	**509,743**	377,185
Stock based compensation	**3,667,546**	3,690,014
Expected income tax benefit from NOL carry-forwards	**2,409,546**	1,817,929
Less valuation allowance	**(6,558,833)**	(5,850,634)
Deferred tax assets, net of valuation allowance	**$ —**	$ —

A reconciliation of the federal statutory income tax rate and the effective income tax rate as a percentage of income before income taxes is as follows:

	2021	2020
Federal statutory income tax rate	**21.0%**	21.0%
State tax rate, net of federal benefit	**4.0**	4.3
Nondeductible expenses	**—**	1.5
Nontaxable income	—	(5.9)
Change in valuation allowance on net deferred tax assets	**(25.0)**	(20.9)
Effective income tax rate	**—%**	—%

On December 31, 2021, the Company has Federal and state net operating loss (NOL) carryforwards totaling $9,629,835 and $9,650,176, respectively. These loss carryforwards may be offset against future taxable income. There is no limitation on the number of years to utilize the Federal NOL. The Federal deduction will be limited to 80% of modified taxable income. The state deduction for NOL allows up to 100% of taxable income to be offset and can be carried forward no longer than twenty years after the year of the taxable loss.

Federal and state tax laws impose limitations on the utilization of net operating losses 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 which may have already happened or may happen in the future. Such an ownership change could result in a limitation in the use of the net operating losses in future years and possibly a reduction of the net operating losses available.

If not used, the state carryforwards will expire as follows:

2038	$ 888,389
2039	$ 1,898,067
2040	$ 4,457,495
2041	$ 2,406,225

16. Subsequent Events

The Company evaluated subsequent events through the date of issuance. The following changes occurred subsequent to the Company's year end:

Name and Entity Change - The Company changed its name from Innovative Health Solutions, Inc. to Neuraxis, Inc. by filing amended and restated articles of incorporation with the State of Indiana on March 11, 2022. Additionally, the Company filed a Certificate of Conversion to become a Delaware corporation on June 23, 2022.

Delaware Shares - The total number of shares of all classes of stock which the Corporation shall have authority to issue is (1) 100,000,000 shares of Common Stock, par value $0.001 per share ("Common Stock") and (ii) 1,120,000 shares of Preferred Stock, par value $0.001 per share ("Preferred Stock"), 1,000,000 of which is hereby designated as "Series A Preferred Stock" and 120,000 of which is hereby designated as "Series Seed Preferred Stock" with the rights, preferences, powers, privileges and restrictions, qualifications and limitations set forth in this Article IV of the Delaware Certificate of Incorporation. All share amounts have been retroactively restated to give effect to these changes.

Addition Borrowing – The Company borrowed additional funds subsequent to December 31, 2021, and up through the date of this report. From June 3, 2022 to August 15, 2022, we entered into Securities Purchase Agreements (the "SPAs") which provide for advances of up to $2.4 million in proceeds to us, subject to our satisfaction of certain conditions. Pursuant to the SPAs, from June 3, 2022 to August 15, 2022, we issued the Senior Secured Convertible Promissory Notes ("Notes") with an aggregate principal amount of $2,222,223, which amount included original issue discount ("OID") of $222,223, and legal fees for $130,000, resulting in advance proceeds to us of $1.870 million. In connection with the issuance of the Notes, we also issued five-year warrants exercisable for an aggregate of 470,810 shares of common stock with an exercise price of the lower of (a) $5.90 and (b) a 12% discount to the price per share in any subsequent offering by the Company, and we entered into a Pledge and Security Agreement dated June 3, 2022. Pursuant to a Pledge and Security Agreement, dated as of June 3, 2022, the Company granted a security interest in all of its assets in favor of the lender, in its capacity as collateral agent for the purchaser's parties under the SPAs.

The Notes carry OID of 10% of the principal amount and have an interest rate of the greater of (a) the prime rate of interest, as published by the Wall Street Journal, plus 8.5% per annum, or (b) 12%. The Notes will mature in twelve (12) months from the issue dates. Any amount of principal, interest, other amounts due hereunder or penalties on this Note, which is not paid by maturity date, shall bear interest at the lesser of the rate of twenty four percent (24%) per annum or the maximum legal amount permitted by law, from the due date thereof until the same is paid in full, including following the entry of a judgment in favor of Holder. The Notes are convertible into shares of common stock at the lower of (a) $4.72 per share, or (b) a discount of 30% to the price per share in any subsequent offering, subject to adjustment in the event of common stock distribution, stock splits, fundamental transactions, dilutive issuances or similar events affecting our common stock and the conversion price. Interest accrues on the aggregate principal amount (which includes OID) and is payable monthly, at the Company's election, in cash or in-kind.

Upon the advance of the consideration under the SPAs, the Company is required to issue to the noteholders a number of shares of common stock, calculated based on the value of 10% of the principal amount of the Notes issued in such advance, at a value per share equal to the conversion price of the Notes. Accordingly, from June 3, 2022 to August 15, 2022, in connection with the initial advance and issuance of Notes, we will be issuing 47,085 shares of common stock to the noteholders.

The Notes have certain restrictions on the Company's issuance of securities, including (i) the Company shall not without the noteholder's written consent (a) pay, declare or set apart for such payment, any dividend or other distribution (whether in cash, property or other securities) on the common stock of the Company other than dividends on common stock solely in the form of additional common stock, or (b) directly or indirectly or through any subsidiary make any other payment or distribution in respect of common stock or equivalents, (ii) unless approved by the noteholders in writing, the Company shall not enter into an agreement or amend an existing agreement to effect any sale of securities involving, or convert any securities previously issued under, a variable rate transaction, which means a transaction in which the Company (A) issues or sells any convertible securities either (a) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the common stock, or (b) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company, or the market for the common stock, or (B) enters into any agreement whereby the Company may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights), (iii) the noteholders have the right, but not the obligation, to participate in the purchase of the securities being offered up to an amount equal to thirty percent (30%) of the principal amount of the Notes (the " Participation Right") when the Company or its subsidiary proposes to offer and sell its securities, whether in the form of debt, equity financing, or any other financing transaction (each a "Future Offering"); provided that, the Participation Right shall not exceed the lesser of (i) one-third of the aggregate amount of the Future Offering, and (ii) an amount equal to the principal amount (allocated to the noteholder's pro-rata to their portion of the principal amount).

We have agreed to pay to the noteholders any outstanding principal amount of the Notes, all accrued and unpaid interest, and fees and penalties, if any, from any future financing proceeds (which includes proceeds to us from this offering) and other future receipts, at the noteholder's discretion, except for the right of the Company to make bona fide payments to vendors with common stock.

In addition, pursuant to the SPAs, so long as no event of default has occurred under the Notes, the closing of additional tranches, in each case consisting of Notes in the aggregate advance amount of up to $400,000 and an aggregate principal amount (including the) of up to $444,444, shall occur (i) upon the Company filing a registration statement with the SEC on Form S-1 and (ii) upon the effectiveness of the CPT codes issued the Company, but in any event not later than December 3, 2022.

17. Restatement

The financial statements have been restated for certain disclosures that have been expanded or have added clarifications. The restatements did not impact the balance sheet, statement of operations, equity or statement of cash flows. The following disclosures were restated:

- Note 2 – a table showing the calculation of basic and diluted net loss per share and the effect of preferred stock dividends has been included.
- Note 8 - The table has been corrected to reflect the actual weighted average exercise price and distinguish between warrants for the purchase of common stock and preferred stock.
- Note 9 - The aggregate purchase price of the Series A Preferred Stock and Series Seed Preferred Stock from cash and converted debt and common stock has been disclosed.
- Note 14 – Additional disclosure and clarification of the status of litigation was updated.

[●] Shares of Common Stock

NEURAXIS, INC.

PROSPECTUS

Sole Book Running Manager

ALEXANDER CAPITAL L.P.

[●], 2022

Through and including [●], 2022 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following is an estimate of the expenses (all of which are to be paid by the Company) that we may incur in connection with the securities being registered hereby.

Offering Expenses		
SEC registration fee	$	[●]
FINRA filing fee	$	[●]
Legal fees and expenses	$	[●]
Accounting fees and expenses	$	[●]
Miscellaneous	$	[●]
Total	$	[●]

Item 14. Indemnification of Directors and Officers.

Section 145(a) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the DGCL provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the DGCL.

Additionally, our bylaws eliminates our directors' liability to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any transaction from which the director derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for any unlawful payment of dividends or redemption of shares; or
- for any breach of a director's duty of loyalty to the corporation or its stockholders.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the Company's directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

We are also expressly authorized to carry directors' and officers' insurance to protect our directors, officers, employees and agents against liabilities for actions taken in their capacities as directors and officers.

Item 15. Recent Sales of Unregistered Securities.

The following information relates to all securities issued or sold by us within the past three years and not registered under the Securities Act.

In 2019, the Company granted stock options to purchase 659,697 shares of common stock in the aggregate under the Innovative Health Solutions, Inc. 2017 Stock Compensation Plan adopted October 12, 2017 (the "Plan") with exercise prices of $13.88 per share and a term of ten years.

From September 2019 to November 2019, we entered into Series A Preferred Stock Purchase Agreements with 16 investors. Pursuant to the Series A Preferred Stock Purchase Agreements, we issued a total of 189,092 shares of Series A Preferred Stock, at a price of $18.8719 per share, all of which will be converted into shares of common stock upon the closing of this offering. Pursuant to the Series A Preferred Stock Purchase Agreements, we issued a total of 115,477 shares of Series Seed Preferred Stock in exchange of the share of common stock held by the investors.

On September 6, 2019, in connection with the conversion of certain secured convertible promissory note, in the amount of $347,379.45, that the Company issued to Brian Hannasch on January 31, 2019, we issued 20,056 shares of Series A Preferred Stock to Brian Hannasch, at a conversion price of $17.32 per share.

On September 6, 2019, we issued warrants to purchase 20,000 shares of common stock to Brian P. Hannasch, in connection with certain Series A Preferred Stock Purchase Agreement. Pursuant to the terms of the warrants, the warrant exercise price is equal to $0.01 per share. If unexercised, these warrants will expire on the 10^{th} anniversary of their issuance dates. The warrants will neither expire nor be automatically exercised upon the closing of this offering. The warrants provide that the holder thereof may elect to exercise the warrant on a net "cashless" basis at any time prior to the expiration thereof. Assuming the closing of this offering occurs, the fair market value of one share of our common stock in connection with any cashless exercise shall be the based on the average of the daily closing prices per share for the 30 consecutive trading day period ending on the second trading day prior to such date.

From April 2020 to June 2021, we entered into 5 Series A Preferred Stock Purchase Agreements with investors. Pursuant to the Series A Preferred Stock Purchase Agreements, we issued a total of 317,545 shares of Series A Preferred Stock, at a price of $18.8719 per share, all of which will be converted into shares of common stock upon the closing of this offering.

On April 9, 2020, we entered into a Series A Preferred Stock Purchase Agreements with Masimo. Pursuant to the Series A Preferred Stock Purchase Agreement, we issued a total of 265,774 shares of Series A Preferred Stock, at a price of $18.8719 per share, all of which will be converted into shares of common stock upon the closing of this offering.

On the same day, we issued pre-funded warrants to purchase 144,890 shares of Series A Preferred Stock to Masimo, in connection with its Series A Preferred Stock Purchase Agreement. Pursuant to the terms of the warrants, the warrant exercise price is equal to $0.0001 per share, subject to adjustments, and these warrants will not expire. The aggregate purchase price of this Warrant, in the amount of $2,734,340.40, equating to $18.8719 per warrant share, was pre-funded to the Company and, consequently, no additional consideration shall be required to be paid by Masimo to any Person to effect any exercise of this Warrant, except for the payment of the exercise price. The warrants will neither expire nor be automatically exercised upon the closing of this offering. The warrants provide that Masimo thereof may elect to exercise the warrant on a net "cashless" basis at any time prior to the expiration thereof. Assuming the closing of this offering occurs, the fair market value of one share of our Series A Preferred Stock in connection with any cashless exercise shall be the closing price or last sale price of a share of common stock reported for the business day immediately before the date on which Masimo delivers this warrant together with its notice of exercise to the Company, multiplied by the number of shares of common stock into which a share of Series A Preferred Stock is then convertible, if the common stock is then traded on a trading market, or the fair market value of Series A Preferred Stock, as mutually determined in writing by the Company and Masimo. Masimo may not exercise the warrant in excess of that number of shares which would cause the aggregate number of shares of common stock beneficially owned by Masimo to exceed 19.99% of the total number of issued and outstanding shares of common stock following such exercise, or the combined voting power of the securities beneficially owned by Masimo to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise.

On October 19, 2020, the Company entered into a Series A Preferred Stock Purchase Agreement with Dresner Investment Services, Inc. d/b/a Dresner Partners ("Dresner"). Pursuant to the Series A Preferred Stock Purchase Agreement, the Company issued 18,546 shares of Series A Preferred Stock to Dresner and six (6) of its designees in consideration of the fee owed to Dresner in connection with an engagement letter, dated April 16, 2020, at a price of $18.8719 per share. We plan to convert all of the Series A Preferred Stock into shares of common stock upon the closing of this offering.

On September 9, 2021, the Company cancelled and reissued all previously issued stock options in connection with a 4-to-1 stock split that occurred on the same date. No new optionees were awarded options on this date, but all prior stock option holders received four times the number of options they had before the split, and the exercise price was divided by four due to the split.

From June 3, 2022 to November 30, 2022, the Company entered into Securities Purchase Agreements (the "SPAs") with Leonite Fund I, LP, Emmis Capital II, LLC, District 2 Capital Fund, LP, and Exchange Listing, LLC, which provide for advances of up to $2.4 million in proceeds to us, subject to our satisfaction of certain conditions. Pursuant to the SPAs, from June 3, 2022 to November 30, 2022, we (i) issued the Senior Secured Convertible Promissory Notes ("Notes") with an aggregate principal amount of $777,777, which amount included original issue discount ("OID") of $377,777.78, resulting in advance proceeds to us of $2.370 million. In connection with the issuance of the Notes, we also issued five-year warrants exercisable for 588,514 shares of common stock with an exercise price of the lower of (a) $5.90 and (b) a 12.5% discount to the price per share in any subsequent offering by the Company, and we entered into a Pledge and Security Agreement with Leonite Fund I, LP, dated June 3, 2022. The Notes carry OID of 10% of the principal amount and have an interest rate of the greater of (a) the prime rate of interest, as published by the Wall Street Journal, plus 8.5% per annum, or (b) 12%. The Notes will mature in twelve (12) months from the issue dates. The Notes are convertible into shares of common stock at the lower of (a) $4.72 per share, or (b) a discount of 30% to the price per share in any subsequent offering, subject to adjustment in the event of common stock distribution, stock splits, fundamental transactions, dilutive issuances or similar events affecting our common stock and the conversion price. Interest accrues on the aggregate principal amount (which includes OID) and is payable monthly, at the Company's election, in cash or in-kind. Upon the advance of consideration under the SPAs, the Company is required to issue to the noteholders a number of shares of common stock, calculated based on the value of 10% of the principal amount of the Notes issued in such advance, at a value per share equal to the conversion price of the Notes. Accordingly, from June 3, 2022 to November 30, 2022, in connection with the initial advance and issuance of Notes, we also issued 58,855 shares of common stock to the noteholders. For additional information, see"*Management's Discussion and Analysis of Financial Condition and Results of Operations–Recent Development*".

Unless otherwise stated above, the issuances of these securities were made in reliance upon exemptions provided by Section 4(a)(2) of the Securities Act, Regulation D promulgated thereunder, or Securities Act Rule 701 for the offer and sale of securities not involving a public offering.

No underwriter was engaged in connection with the foregoing sales of securities. The Company has reason to believe that all of the foregoing purchasers were familiar with or had access to information concerning the operations and financial conditions of the Company, and all of those individuals purchasing securities represented that they were accredited investors, acquiring the shares for investment and without a view to the distribution thereof. At the time of issuance, all of the foregoing securities were deemed to be restricted securities for purposes of the Securities Act and the certificates representing such securities bore legends to that effect**.**

Item 16. Exhibits and Financial Statement Schedules

Exhibit Number	Exhibit Description
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation
3.2*	Bylaws
4.1*	Form of warrant issued to Brian P. Hannasch
4.2*	Form of warrant issued to Masimo Corporation
4.3*	Form of warrant issued to Leonite Fund I, LP
4.4*	Form of warrant issued to Emmis Capital II, LLC
4.5*	Form of warrant issued to Exchange Listing, LLC
4.6*	Form of warrant issued to District 2 Capital Fund, LP
4.7*	Form of Underwriter Warrant
4.8*	Side Letter, dated April 9, 2020, by and between the Innovative Health Solutions, Inc. and Masimo Corporation
4.9*	Side Letter, dated August [●], 2022, by and between Neuraxis, Inc. and Masimo Corporation
4.10*	Side Letter, dated August [●], 2022, by and between Neuraxis, Inc. and Brian Hannasch
4.11*	Investor Rights Agreement, dated September 6, 2019, by and between the Innovative Health Solutions, Inc. and Brian Hannasch
5.1*	Legal opinion of Lucosky Brookman LLP
10.1*	License and Collaboration Agreement, dated April 9, 2020, by and between Neuraxis, Inc. and Masimo Corporation
10.2*	Exclusive License Agreement, dated May 7, 2020, by and between Neuraxis, Inc. and TKBMN, LLC
10.3*	Securities Purchase Agreement, dated June 3, 2022, between the Neuraxis, Inc. and Leonite Fund I, L.P.
10.4*	Securities Purchase Agreement, dated June 3, 2022, between Neuraxis, Inc. and Emmis Capital II, LLC
10.5*	Securities Purchase Agreement, dated June 3, 2022, between Neuraxis, Inc. and Exchange Listing, LLC

10.6*	Pledge and Security Agreement, dated June 3, 2022, between Neuraxis, Inc. and Leonite Fund I, LP
10.7*†	Employment Agreement between Neuraxis, Inc. and Brian Carrico, dated as of August 9, 2022
10.8*†	Employment Agreement between Neuraxis, Inc. and Adrian Miranda, dated as of [●], 2022
10.9*†	Employment Agreement between Neuraxis, Inc. and Thomas Carrico, dated as of August 9, 2022
10.10*†	Employment Agreement between Neuraxis, Inc. and Dan Clarence, dated as of August 9, 2022
10.11*†	Employment Agreement between Neuraxis, Inc. and Christopher Robin Brown, dated as of August 9, 2022
10.12*†	Employment Agreement between Neuraxis, Inc. and Gary Peterson, dated as of August 9, 2022
10.13*	Promissory note of Gary Peterson, dated as of January 1, 2016
10.14*	Promissory note of Christopher Robin Brown, dated as of January 1, 2016
10.15*†	Innovative Health Solutions, Inc. 2017 Stock Compensation Plan, as amended
10.16*†	Neuraxis, Inc. 2022 Omnibus Securities and Incentive Plan
10.17*	Manufacturing Services Agreement between Neuraxis, Inc. and GMI Corporation, dated as of August 21, 2020
10.18*	Quality Agreement between Neuraxis, Inc. and GMI Corporation, dated as of August 24, 2020
14.1*	Code of Ethics and Business Conduct
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Rosenberg Rich Baker Berman, P.A.
23.2*	Consent of Lucosky Brookman LLP (reference is made to Exhibit 5.1)
24.2	Power of Attorney (included on the signature page hereto)
99.1*	Consent of Timothy Henrichs, dated as of August 28, 2022
99.2*	Consent of Bradley Mitch Watkins, dated as of August 8, 2022
99.3*	Consent of Beth Keyser, dated as of [●], 2022
101.PRE	XBRL Instance Document
101.INS	XBRL Taxonomy Extension Schema Document
101.SCH	XBRL Taxonomy Extension Calculation Linkbase Document
101.CAL	XBRL Taxonomy Extension Definition Linkbase Document
101.DEF	XBRL Taxonomy Extension Label Linkbase Document
101.LAB	XBRL Taxonomy Extension Presentation Linkbase Document
107*	Filing Fee Table

* To be filed by amendment
† Executive compensation plan or arrangement.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, will be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement or amendment thereto to be signed on its behalf by the undersigned, thereunto duly authorized, in [●], on [●], 2022.

Neuraxis, Inc.

By: _____
Brian Carrico
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Brian Carrico, his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to sign any registration statement for the same offering covered by the Registration Statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agent, or his, her or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Brian Carrico	Chief Executive Officer and Director (principal executive officer)	, 2022
/s/ John Seale	Chief Financing Officer (principal financial officer and principal accounting officer)	, 2022
/s/ Dan Clarence	Director	, 2022
/s/ Adrian Miranda	Director	, 2022
/s/ Thomas Carrico	Director	, 2022
/s/ Christopher Robin Brown	Director	, 2022
/s/ Gary Peterson	Director	, 2022