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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38546

NEURONETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-1051425**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3222 Phoenixville Pike, Malvern, Pennsylvania 19355

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (610) 640-4202

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	**STIM**	The Nasdaq Stock Market LLC

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2023) was approximately $56.5 million.

The number of shares of Registrant's Common Stock outstanding as of February 29, 2024 was 29,756,053.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2024 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Report.

NEURONETICS, INC.
Annual Report on Form 10-K for the year ended December 31, 2023
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "would," "should," "expect," "plan," "design," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" "outlook" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere herein. These risks and uncertainties include, without limitation, risks and uncertainties related to: the impact of public health crises on the Company's operations, manufacturing and supply chain interruptions or delays; the Company's ability to execute its business strategy; the Company's ability to achieve or sustain profitable operations due to its history of losses; the Company's reliance on the sale and use of its NeuroStar Advanced Therapy system to generate revenues; the scale and efficacy of the Company's salesforce; the Company's ability to retain talent; availability of coverage and reimbursement from third-party payors for treatments using the Company's products; physician and patient demand for treatments using the Company's products; developments in competing technologies and therapies for the indications that the Company's products treat; product defects; the Company's ability to obtain and maintain intellectual property protection for its technology; developments in clinical trials or regulatory review of NeuroStar Advanced Therapy system for additional indications; developments in regulation in the U.S. and other applicable jurisdictions; our ability to successfully roll-out our Better Me Guarantee Provider Program on the planned timeline; our self-sustainability and existing cash balances; and our ability to achieve cash flow break-even in the fourth quarter of 2024 and on a full-year basis in 2025. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. The Company cautions investors not to place undue reliance on these forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this Annual Report on Form 10-K, whether as a result of any new information, future events, changed circumstances or otherwise.

Disclosure Channels to Disseminate Information

The Company announces material information to the public about the Company, its products and services and other matters through a variety of means, including filings with the United States Securities and Exchange Commission (the "SEC"), press releases, public conference calls, the Company's website (https://neurostar.com/neuronetics/), including the Investors section thereof, and/or social media, including its Facebook page (https://www.facebook.com/NeuroStarAdvancedTMS/), X (formerly Twitter) account (@TMSTherapy), Instagram account (@NeurostarAdvancedTMS), YouTube account (https://www.youtube.com/user/NeuroStarTMSTherapy) and/or LinkedIn account (https://www.linkedin.com/company/neuronetics-inc./), in order to achieve broad, non-exclusionary distribution

of information to the public. The Company encourages investors and others to review the information it makes public in these locations, as such information could be deemed to be material information. Please note that this list may be updated from time to time. Our website, Facebook page, X account, Instagram account, YouTube account and LinkedIn account, and the information contained therein or connected thereto, shall not be and is not intended to be incorporated by reference into this Annual Report on Form 10-K or our other filings with the SEC unless otherwise expressly provided.

PART I

Item 1. Business.

Overview

We are a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from neurohealth disorders. Our first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation ("TMS") to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the United States Food and Drug Administration (the "FDA") to treat adult patients with major depressive disorder ("MDD") who have failed to achieve satisfactory improvement from at least one prior antidepressant medication in the current MDD episode. It is also cleared by the FDA as an adjunct for adults with obsessive-compulsive disorder ("OCD"), and to decrease anxiety symptoms in adult patients with MDD that may exhibit comorbid anxiety symptoms (anxious depression). NeuroStar Advanced Therapy System is safe, clinically effective, reproducible and precise and we believe is supported by the largest clinical data set of any competing TMS system. We believe we are the market leader in TMS therapy based on the estimated 169,068 global patients treated with over 6.1 million of our treatment sessions through December 31, 2023. We generated revenues of $71.3 million for the year ended December 31, 2023.

MDD is a mood disorder characterized by the presence of one or both of two major diagnostic criteria: a depressed mood or loss of interest in pleasure that continues for at least two weeks. The presence of at least one of these diagnostic symptoms must be accompanied by several of the following additional symptoms: sleep disturbance, changes in appetite, sexual dysfunction, anxiety, fatigue, difficulty concentrating and suicidal thinking. MDD is a recurrent disease and follows a fluctuating course over an individual's lifetime. It can be characterized by periods of remission and relapse.

The World Health Organization (the "WHO") ranks MDD as the largest contributor to global disability and a major contributor to suicide worldwide. According to a study published in the Journal of PharmacoEconomics in 2021, the economic burden of MDD was estimated to be $326.2 billion, an increase of 37.9% relative to 2010. The WHO estimates indicate the proportion of the global population with depression to be 4.4% and that there are over 300 million people in the world living with depression. Based on U.S. Census Bureau data and a study published in the *Journal of the American Medical Association,* we estimate that approximately 21 million people between the ages of 22 and 70 years in the United States suffer from MDD annually, of whom an estimated 13.9 million, based on data from the *Journal of the American Medical Association*, are being treated by a psychiatrist. We estimate, based on data from the Sequenced Treatment Alternatives to Relieve Depression study (the "STAR*D Study") that approximately 6.4 million of these patients have failed to achieve remission of their MDD from their prior antidepressant medication therapy and that approximately 3.8 million of those patients have commercial insurance or federal healthcare programs coverage for NeuroStar Advanced Therapy System. As a result, based on our expected revenues for a standard course of treatment, we believe our total annual addressable market opportunity for treatment sessions in the United States is approximately $8.9 billion.

Initial treatment options for MDD often consist of antidepressant medication prescribed by a primary care physician. Although a variety of antidepressant medications are available, drug therapy has at least two primary limitations: limited effectiveness and treatment-emergent side effects. These limitations were demonstrated in the STAR*D Study, a large clinical trial funded by the U.S. National Institute of Mental Health that enrolled more than 4,000 adult MDD patients at 41 clinical sites to examine the outcomes to a sequenced series of antidepressant medication attempts that mimicked best practices. In the STAR*D Study, only approximately 28% and 21% of patients achieved remission in their first and second medication attempts, respectively. Many patients taking antidepressant medications experience intolerable or troubling side effects that contribute to a delay or failure in attaining an effective or optimal antidepressant dose, poor patient

treatment adherence or discontinuation of treatment therapy. The likelihood of achieving remission is limited and declines with each successive medication attempt.

TMS is considered an appropriate therapy for the treatment of MDD patients who have failed to achieve satisfactory improvement from at least one prior antidepressant medication. TMS is typically performed as an office-based procedure using a capital equipment system designed to deliver the magnetic pulses necessary to stimulate the areas of the brain associated with mood. A course of treatment typically requires treatment sessions five times per week for up to six weeks and can last from as short as three to as long as forty-five minutes per session. We believe the effectiveness of TMS depends on the healthcare provider's ability to deliver a precise amount of magnetic pulses to a specific area of the brain in a manner that can be consistently repeated during each treatment session.

We designed the NeuroStar Advanced Therapy System as a non-invasive therapeutic alternative to treat patients who suffer from MDD and to address many of the key limitations of existing treatment options. We believe our NeuroStar Advanced Therapy System provides our psychiatrist customers and their patients with several benefits, including clinically demonstrated response and remission with durable results, a demonstrated safety profile with limited treatment-emergent side effects and high patient adherence. Additionally, NeuroStar Advanced Therapy System was designed to provide a precise and reproducible office-based therapy that is efficient and convenient. Our therapy is delivered without general anesthesia or sedation, enabling the patient to drive and resume normal activities immediately following each treatment session. We couple our product's clinical benefits with significant practice development resources, on-site clinical training and reimbursement and service support to help our psychiatrist customers develop a successful NeuroStar Advanced Therapy System practice. We also provide cloud-based practice management solutions that enhance convenience for both psychiatrists and patients. Based on our commercial data, we believe psychiatrists can recoup their initial capital investment in our system by providing a standard course of treatment to approximately 12 patients, assuming these patients receive reimbursement from federal healthcare programs or commercial insurance at rates that are similar to what our customers have observed for existing and prior patients. We believe psychiatrists can generate approximately $8,500 of average revenue per patient for a standard course of treatment, which may provide meaningful incremental income to their practices. We believe that the NeuroStar Advanced Therapy System coupled with these advantages offer significant improvement over competing TMS, which lack the ability to reproduce consistent treatments, significant clinical data from randomized outcome trials, practice development resources, and a cloud-based practice management system.

The safety, effectiveness and durability of NeuroStar Advanced Therapy System is supported by a large clinical data set published in 31 articles in peer-reviewed medical journals, including from 15 clinical studies that have collectively enrolled more than 1,000 adult patients suffering from MDD. Dunner, et. al. published results of a naturalistic, prospective, observational trial conducted at 42 U.S. clinical sites in 257 patients who had tried and failed to receive relief from one or more medication trials in their current MDD episode who were treated with an acute course of NeuroStar Advanced Therapy. Response and remission rates at 12 months were 68% and 45% respectively as measured by CGI-S.

Our growth strategy includes expanding our commercialization efforts in the United States, expanding international opportunities and pursuing pipeline development of our therapy for additional indications. Outside the United States, our products have received marketing authorizations in the European Union and Japan. Our initial international commercial focus is Japan, which has the third largest healthcare spend globally. We have entered into an exclusive distribution agreement with Teijin Pharma Limited ("Teijin") a leading Japanese healthcare company, to further expand our commercialization efforts in this market. We are also evaluating the use of enhancements to our NeuroStar Advanced Therapy System to treat additional indications.

As of December 31, 2023, we had 1,145 active sites utilizing our NeuroStar Advanced Therapy Systems in the United States. We currently sell our NeuroStar Advanced Therapy System and recurring treatment sessions in the United States with the collaborative support of our 203 employees as of December 31, 2023.

We generate revenues from initial capital sales of our systems, sales of our recurring treatment sessions and service and repair and extended warranty contracts. We derive the majority of our revenues from recurring treatment sessions. For the year ended December 31, 2023, we generated revenues of $71.3 million and had a net loss of $30.2 million. Our revenues increased 9% during the year ended December 31, 2023 compared to the year ended December 31, 2022. For the year ended December 31, 2023, our U.S. revenues were $69.3 million, compared to $63.4 million for the year ended December 31, 2022, which represented an increase of 9% compared to the prior period. Revenues from treatment sessions represented 73% of our U.S. revenues for the year ended December 31, 2023 compared to 71% of our U.S. revenues for the prior year.

Our Strategy

Our goal is to maintain and extend our leadership position in TMS therapy for patients with neurohealth disorders. The key elements of our strategy include:

- ***Improve customer targeting and expand our direct sales and customer support team to accelerate growth.*** To capture new psychiatrist customers, we plan to expand our specialized, direct sales organization that targets MDD treating psychiatric practices that accept reimbursement from private insurance and Medicare. Symphony Health estimates that there are approximately 26,300 group and solo practice sites in the United States with psychiatrists that prescribe antidepressant medications. Our direct sales force primarily targets 53,000 psychiatrists at 26,000 psychiatric practices that treat approximately 13.9 million patients based on data from the *Journal of the American Medical Association*. We estimate, based on data from the Sequenced Treatment Alternatives to Relieve Depression study (the "STAR*D Study") that approximately 6.4 million of these patients have failed to achieve remission of their MDD from their prior antidepressant medication therapy and that approximately 3.8 million of those patients have commercial insurance or federal healthcare programs coverage for NeuroStar Advanced Therapy System. As a result, based on our expected revenues for a standard course of treatment, we believe our total annual addressable market opportunity for treatment sessions in the United States is approximately $8.9 billion.We intend to continue to expand our team of business development managers that are responsible for driving new customer acquisitions. To reach our target practices, we also plan to expand our advertising efforts, both online and through more traditional approaches, such as targeting leading psychiatric journals, practice outreach and education through webinars and in person events, attendance at key psychiatric trade shows and sponsoring clinical symposiums and product theaters.

- ***Increase utilization of our new and existing active customer sites of NeuroStar Advanced Therapy Systems.*** We plan to expand our sales and customer support team to increase the number of patients treated at new and existing active customer sites using our NeuroStar Advanced Therapy Systems in the United States. We currently have 1,145 active customer sites in the United States. We currently have 47 NeuroStar practice development managers in 2023 ("PDMs"), to focus exclusively on helping increase patient utilization of NeuroStar Advanced Therapy System in a practice. We intend to add to this team to support our revenue growth. Our NeuroStar practice consultants focus their efforts on helping psychiatrist customers implement our Better Me Guarantee Provider pilot program and our 5 Stars Solution for Practice Success. We intend to make further investments in marketing resources, such as our marketing portal, which consists of customizable practice development and advertising materials, and digital patient outreach tools all of which are designed to drive patient awareness and help identify patients who can benefit from NeuroStar TMS within an existing practice and in the local community. We also plan to invest further in our direct to consumer marketing programs, which is comprised of paid search, display advertising, social media, billboards, radio and public relations.

- ***Expand our international market opportunities.*** We primarily sell our products within the United States. We also sell our products through distributors in countries where we have received regulatory approval, including Japan, Saudi Arabia, The United Arab Emirates, Singapore, and the Republic of Korea. We primarily focus our commercial efforts outside of the United States on Japan. We worked

with Teijin to obtain reimbursement approval for the NeuroStar Advanced Therapy System in June 2019 and will continue to provide sales, marketing and clinical support to ensure our commercial success. We will continue to opportunistically evaluate additional markets outside the United States and Japan for commercial expansion.

- ***Pursue enhancements of our NeuroStar Advanced Therapy System and pipeline development for additional indications.*** We plan to continue our research and development efforts to enhance the hardware and software components of our NeuroStar Advanced Therapy System for the treatment of MDD and other neurohealth disorders.

Research and Development

We invest in research and development for the use of the NeuroStar Advanced Therapy System in neurohealth disorders. Throughout our history, we have provided material support to more than 65 investigator-initiated trials and are currently considering a number of new indications for the use of the NeuroStar Advanced Therapy System related to neurohealth disorders.

Sales and Customer Support Team and Customer Training

As of December 31, 2023, our sales and customer support team consisted of 91 employees working collaboratively across the following departments: sales, marketing, field service and customer support, and reimbursement. In 2024, we plan to continue to expand our sales and customer support teams to have the largest direct sales and customer support team in the industry, including 47 NeuroStar practice development managers, 18 area sales managers, 7 clinical training managers, 18 field service and technical support specialists, 15 sales leaders, 8 customer service representatives, 4 inside sales managers and 10 reimbursement specialists and managers.

Key Customers, Sales and marketing—United States

We primarily market and sell the NeuroStar Advanced Therapy System and recurring treatment sessions to psychiatrists, with primary care physicians and pain management specialists representing a small percentage of our customer base. We are dependent upon a small number of customers, as the market for neurohealth disorder equipment is highly concentrated. In 2022, our largest customer acquired our second-largest customer. The combined entity accounted for 15% of our revenue in 2023. We executed a new long-term, exclusive agreement with the customer in 2023, which covers sales to the combined organization on what we believe are mutually beneficial terms.

We target approximately 53,000 psychiatrists across 26,000 psychiatric practices, We target these practices by the number of psychiatrists within their practices, the number of patients they treat and their acceptance of commercial insurance and Medicare. We believe that our psychiatrist targeting strategy makes for a well-defined customer base that is accessible by our direct sales organization.

We have structured our sales and customer support team with specialized roles to sell our NeuroStar Advanced Therapy Systems and recurring treatment sessions, while delivering customer service at each stage of the implementation process. Our area sales managers are responsible for identifying key customer prospects, educating them on the value of NeuroStar Advanced Therapy System, gaining their commitment for capital placement and introducing them to our PDMs. Our PDMs enhance the operational experience for providers and drive implementation of the NeuroStar Advanced Therapy System into our customers' practices. We created the role of clinical training manager to partner with our customers to conduct initial and ongoing on-site clinical training to ensure clinical and practice success.

Practice Management Support and Psychiatrist Training—United States

Our PDMs play a pivotal role in ensuring the success of our customers as they implement a new service line into their practice. In the early stages of implementation, they help the practice set goals, educate on the types of patients that can benefit from our therapy and train the office staff on how to talk with patients about TMS and how to use patient educational tools such as presentations, videos and starter kits. Once the practice begins treating patients, our PDMs will educate the psychiatrist on how to track clinical outcomes, interpret data and effectively convey results to existing and potential patients and referring physicians. Our PDMs also work with our customers to increase awareness with referring physicians and develop external marketing tactics. Our dedicated reimbursement managers help practices navigate issues regarding the reimbursement process including investigation of benefits, prior authorizations and claims documentation. This group has assisted our customers to conduct over 69,900 benefit investigations.

Psychiatrists and staff training on the NeuroStar Advanced Therapy System is a key to success within each practice. Our clinical training managers take the burden of clinical training off our NeuroStar practice consultants and provide a dedicated training resource to each customer. Clinical training managers conduct a hands-on training course that is scheduled after system installation at each practice and also provide ongoing advanced on-site clinical training.

To enhance the work our PDMs do to support customer training and education, our sales training team hosts bi-monthly *NeuroStar University* courses to educate existing customers on internal best practices that help them improve the patient experience and overall business operations. This group has trained 369 customers during the year 2023.

Field Support—United States

Our field service engineers are responsible for maintenance, repairs and installation. We provide a support hotline to respond to inquiries and technical questions that arise in all time zones.

International

We market our products in a few select markets outside the United States through independent distributors. In Japan, we have an exclusive distribution agreement with Teijin for the commercialization of our products. The current term of this distribution agreement expires March 31, 2027, subject to automatic renewal unless terminated by either party.

Competition

We have competitors that sell other forms of TMS therapy, including Brainsway, Apollo TMS, Magstim, MagVenture, CloudTMS and Nexstim, that compete directly with the NeuroStar Advanced Therapy System. We also face competition from pharmaceutical and other companies that develop products, such as antidepressant medications, for the treatment of neurohealth disorders.

For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors – Risks Related to Our Business and Industry.”

Intellectual Property

Our patent estate includes patents and applications with claims directed to our NeuroStar Advanced Therapy Systems and broader claims for potential future products and developments. On a worldwide basis, as of December 31, 2023, our patent estate included over 98 issued or allowed patents and 18 pending patent applications for our products and novel design methods, manufacturing processes, novel TMS devices and systems and future combination products that are mainly designed to treat psychiatric conditions or perform diagnostic procedures. In the United States, as of December 31, 2023, we owned or licensed 38 issued or

allowed patents and 10 pending patent applications that are directed to our TMS technology. Outside the United States, as of December 31, 2023, we owned or licensed 60 issued or allowed patents, 7 pending patent applications and 1 pending Patent Cooperation Treaty application.

These U.S. issued patents are expected to remain in effect until between 2024 and 2035. Non-U.S. patents are expected to remain in effect until between 2024 and 2035. In 2024, we expect that five U.S. patents will expire and 14 non -U.S. patents will expire. Our worldwide intellectual property portfolio includes multiple pending patent applications relating to methods and apparatuses for the treatment of psychiatric health conditions in Australia, Canada, the European Union, Japan and the United States. Our patents and patent applications mainly relate to iron core technology, including materials, manufacturing methods, geometries, applications, and open core technologies, TMS design patents, including coil position, motor threshold level determination, contact sensing, and articulation arm designs, patient comfort, TMS support technologies and pulse monitoring, and potential next generation technologies.

We own trade secrets relating to our technology, and we maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our trade secrets and know-how by entering into confidentiality agreements with third-parties, consultants and employees who have access to such trade secrets and know-how.

For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors—Risks Related to Intellectual Property.”

Raw Materials, Manufacturing and Supply

We manage all aspects of product supply through our operations team based in Malvern, Pennsylvania. We outsource the manufacturing of components and high-level assemblies, which are produced and tested to our specifications. We rely on third parties to acquire the raw materials and provide components used in existing products and we expect to continue to do so for future products.

We establish our relationships with our third-party manufacturers and suppliers through supplier contracts and purchase orders. In most cases, these supplier relationships may be terminated by either party upon short notice. As of December 31, 2023, we engaged with Gharieni Group GmbH to supply our chair, Molex Incorporated to supply our SenStar Components, and other companies to supply components of our chairs and treatment packs. We are continuing to transition our console manufacturing to Ascential Technologies (previous D&K), collaborating with them on optimizing the global supply chain.

Reimbursement, Payor Relations and Customer Support

Based on our estimates, over 65 major private insurers in the United States, including the top 25 largest private insurers and federal healthcare programs, have coverage policies for reimbursement of TMS, including NeuroStar Advanced Therapy System, representing over 300 million covered lives or about 95% of the total payor covered lives in the United States.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions.

FDA

Our products are subject to regulation as medical devices under the U.S. Federal Food, Drug, and Cosmetic Act, as amended (the “FDCA”), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event

reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA clearance or approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States. The marketing authorization process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or premarket approval ("PMA"). 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 efficacy. Class I includes devices with the lowest risk to the patient and are those for which safety and efficacy can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the quality systems regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and efficacy of the device. These special controls can include performance standards, post-market surveillance, patient registries, special labeling requirements, premarket data requirements, and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of 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. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, generally requiring approval of a PMA.

Our NeuroStar Advanced Therapy System is classified as a Class II medical device. We initially received marketing authorization of this device through the *de novo* classification process. Subsequently, we have cleared any changes made to our system through the 510(k) clearance process.

510(k) Marketing Clearance Pathway

To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. 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. The FDA's 510(k) clearance process usually takes from 30 to 90 days but may take significantly longer if the FDA requires additional information and places the submission on hold for up to an additional 180 days. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will issue a "substantially equivalent" letter, which serves as the 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 PMA requirements, or can request a risk-based classification determination for the device in accordance with

the “de novo” classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

Pre-Market Approval Process

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, clinical trials, manufacturing and labeling data to demonstrate to the FDA’s satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes 180 days, but may take longer if the FDA requests additional information and places the submission on hold for up to an additional 180 days. During this review period, the FDA may request additional information (e.g., clinical or non-clinical data) or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale, distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

De Novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified as Class III regardless of the level of risk they pose. 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 substantially equivalent 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 as 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, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, (the “FDASIA”), in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent to a predicate device. The FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. We were granted marketing authorization for our system using the *de novo* classification process after receiving a not substantially equivalent determination following the submission of a 510(k) premarket notification.

Clinical Trials

A clinical trial is typically required to support a PMA application or *de novo* classification and is sometimes required for a 510(k) pre-market notification, particularly in the case of changes to indications. Clinical trials

for significant risk devices generally require submission of an application for an Investigational Device Exemption ("IDE") to the FDA. 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 investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the study is deemed a non-significant risk and eligible for more abbreviated IDE requirements. Clinical trials may begin once the IDE application is approved by the FDA (or abbreviated IDE due to non-significant risk determination) as well as the appropriate institutional review boards at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

Changes to Marketed Devices

After a device receives 510(k) marketing clearance, or de novo classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will typically require a new 510(k) marketing clearance but may, depending on the modification, require a de novo classification or PMA. Depending on the scope of the change, a traditional, special, or abbreviated 510(k) application may be submitted. Compared to a traditional 510(k), a special 510(k) application may be used in special cases where: 1) the manufacturer makes a change to their own device; 2) performance data is unnecessary or well-established methods are available to evaluate the change; and 3) performance data necessary to demonstrate substantial equivalence can be presented in a summary or risk analysis format. In this case, the review time is shorter (approximately 30 days), compared to the review time of approximately 90 days for the traditional 510(k) pathway. Alternatively, the abbreviated 510(k) pathway may be used when the submission relies on FDA guidance documents, demonstration of compliance with special controls for the device type, and voluntary consensus standards. This pathway has a review time of approximately 90 days. The FDA requires each manufacturer to determine which pathway is most appropriate; however, in the event that the FDA disagrees with a manufacturer's determination, it may ask the manufacturer to convert its application to another type (e.g., if the FDA determines that it requires additional information about the performance testing beyond the summary data, it may ask the manufacturer to convert a special 510(k) to a traditional 510(k)).

Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file (a "LTF"). The LTF is documented in lieu of submitting a new 510(k) or PMA to obtain clearance or approval for every change and includes the rationale for why a submission was not filed. The changes contained in the LTFs are then summarized and included within the following 510(k) or PMA submission. The FDA will review these changes during the submission process or during an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Post-Market Regulation

After a device is cleared or approved for marketing, 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 and contract manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and, manufacturing, and distribution process;

- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;

- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

- medical device reporting 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 or serious adverse events, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls 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;

- complying with regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and efficacy data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements, such as ongoing safety/ malfunction surveillance and risk management. Our manufacturing processes 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. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. 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 voluntary or mandatory device corrections or removals.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we 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 delaying requests for 510(k) marketing clearance or PMAs of new products or modified products;

- withdrawing 510(k) clearances or PMAs that have already been authorized;

- refusal to authorize export or import approvals for our products; or

- criminal prosecution.

U.S. and Foreign Healthcare Laws and Compliance Requirements

Healthcare providers, physicians and third-party payors play a primary role in the recommendation, prescription and payment for medical treatments. A medical device manufacturer's arrangements with third-party payors, providers and patients may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect its business or the financial arrangements and relationships through which it markets, sells and distributes its products. Even if a medical device manufacturer does not control referrals of healthcare services or bill directly to Medicare, Medicaid, other federal healthcare programs, or other third-party payors, federal and state healthcare laws and regulations are applicable to its business. In addition, a portion of our business is subject to the Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), as a business associate of our covered entity customers. To provide our covered entity customers with services that involve the use or disclosure of protected health information ("PHI"), we are required to enter into business associate agreements. As a business associate, we are also directly liable for compliance with HIPAA. The laws that may affect a medical device manufacturer's ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim for reimbursement that includes items resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act ("FCA"). Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or a safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. The Social Security Act also has a provision that provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that such person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the

order or receipt of any item or service payable by a federal health care program. Private individuals, commonly known as "whistleblowers," can bring FCA qui tam actions on behalf of the government and themselves, and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $13,946 to $27,894 (beginning in 2024) per false or fraudulent claim or statement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial settlements under the FCA in connection with alleged off label promotion of their products and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government;

- the federal physician self-referral law ("Stark Law") prohibits, subject to exceptions, referring Medicare patients for "designated health services" (including "durable medical equipment and supplies" and "outpatient hospital services") ("DHS") to entities with which a referring physician (or immediate family member) maintains a "financial relationship." States (as required in order to maintain Medicaid funding) have further enacted similar prohibitions that apply to Medicaid, as well as other insurance programs, and which may be more restrictive than the Stark Law. Persons who attempt to circumvent these laws or submit (or cause others to submit) claims to payors in violation of these laws may be subject to significant civil and criminal penalties. As such, we are generally prohibited from billing for any services referred in violation of these laws. Importantly, we do not provide DHS and do not bill payors for DHS (or any other items or services). While we manufacture and sell equipment and supplies to our customers, we are not a Medicare supplier. Additionally, in instances in which we maintain contractual arrangements with physicians or hospitals, we have no reason to believe that we are engaged in assisting any person with circumventing these laws. Further, the services (specifically TMS) furnished (outside of a hospital context) by physician groups with whom we maintain contractual arrangements do not constitute DHS. Notably, however, the Stark Law is a strict liability statute and compliance is difficult to assure;

- HIPAA, among other things, established various criminal health care fraud laws, which impose criminal liability for 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 creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the applicable statute or specific intent to violate it or to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, which imposes privacy, security, transmission and breach reporting obligations with respect to individually identifiable health information upon "covered entities" subject to the law, including health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services on their behalf that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and

gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Patient Protection and Affordable Care Act ("PPACA"), which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicare Services,("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other professionals (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; state laws that require device manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and other federal and state laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts and data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the GDPR, which became effective in May 2018).

Because of the breadth of these laws and the narrowness of their statutory exceptions and regulatory safe harbors, it is possible that some of a medical device manufacturer's business activities could be subject to challenge under one or more of these laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If a medical device manufacturer's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, substantial monetary penalties, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect the ability of a medical device manufacturer to operate its business and the results of its operations.

United States Healthcare Reform

In the United States, a number of legislative and regulatory proposals have been considered or enacted to change the healthcare system in ways that could affect a medical device manufacturer's business. Among policy makers and governmental and private insurers in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. For example, in 2010, the PPACA was enacted, which include measures to significantly change the way health care is financed by both governmental and private insurers, and significantly impacts the medical device industry. Among other ways in which it may impact a medical device manufacturer's business, the PPACA:

- established a Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research;

- required manufacturers to report certain payments and other transfers of value pursuant to the Physician Payments Sunshine Act, described above;

- 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; and

- expanded the eligibility criteria for Medicaid programs and, originally, required certain employers to provide, and all individuals to obtain, health insurance.

Some of the provisions of the PPACA have yet to be implemented, and there were judicial and congressional challenges to certain aspects of the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Most recently, under President Biden, the Department of Justice dropped its support of two Supreme Court cases challenging PPACA in addition to a case before the U.S. Court of Appeals for the Fifth Circuit. On January 28, 2021, President Biden signed an executive order to expand access to PPACA coverage, stating that it is the "policy" of the Biden administration to protect and strengthen the PPACA and directing agencies to consider suspending, revising, or rescinding actions related to President Trump's executive orders that are inconsistent with this policy position. In the past, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. For example, in 2017 Congress effectively eliminated the individual mandate, which could result in adverse selection and decreased utilization of reimbursable healthcare services, such as those offered by healthcare providers via use of our products. Additionally, in 2019, Congress repealed a (repeatedly delayed) medical device excise tax previously passed under the PPACA. There is no way to know whether, and to what extent, if any, the PPACA will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, or other efforts to repeal and replace or, possibly, to restore the PPACA will impact the U.S. healthcare industry or our business.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing or manufacturer interactions with healthcare providers, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

It is likely that additional state and federal healthcare reform measures will 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 a medical device manufacturer's products or additional pricing pressure.

We cannot predict the impact that health care reform under the Biden administration will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, U.S. federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third-party payers are increasingly challenging the price, scrutinizing the medical necessity, and reviewing the cost-effectiveness of medical treatments. Any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

Japanese Regulation

In Japan, medical devices are regulated mainly under the Pharmaceutical and Medical Device Act. This act was implemented on November 25, 2014 and served as a revision to the original Pharmaceutical Affairs Law of 2005. Under this regulation, medical devices must be approved prior to importation and commercial sale by the Pharmaceutical Medical Device Agency ("PMDA") and Ministry of Health and Welfare ("MHLW"). The PMDA is the MHLW-created, quasi-independent agency that was established to review and approve pharmaceutics and medical devices for marketing in Japan. They are also responsible for Japan Good Manufacturing Practices audits, clinical studies oversight, and facility licensing. The approval process identifies a Marketing Authorization Holder ("MAH"), who is designated as the only authorized seller of products. Manufacturers of medical devices outside of Japan who do not operate through a Japanese entity are able to designate a MAH, known as a designated MAH ("D-MAH"), who will apply for product approval and take responsibility for the medical device within Japan. After receiving PMDA's recommendations for marketing approval, the MHLW will ultimately evaluate and approve those pharmaceutics and medical devices deemed to be safe and effective. As part of its approval process, the MHLW may require that the product be tested in Japanese laboratories. The approval process ranges in length between two and twelve months, depending on the submission type (e.g., Todokede – for Class I devices, Ninsho – for Class II and III devices, or Shonin for Class II through IV devices). Since the NeuroStar Advanced Therapy System is classified as a Class III under Japanese law, Neuronetics has followed the Shonin process for pre-market approval. After approval is received, the MHLW issues a Shonin approval to Neuronetics' D-MAH, thereby permitting such entity to import the device into Japan for sale. The MHLW is also responsible for creating policies, regulations, guidance documents, and laws, and governs safe use of medical products as well as for social insurance, reimbursement policies, and pricing.

After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance with labeling regulations, which prohibit promotion of devices for unapproved uses, and reporting regulations, which require reporting of product malfunctions, including serious injury or death caused by any approved device. Failure to comply with applicable regulatory requirements can result in enforcement action by the MHLW, which may include fines, injunctions, and civil penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of sales in Japan, or criminal prosecution.

European Union Regulation

Neuronetics has received European Conformity ("CE") certification under the European Union ("EU" or "E.U.") Medical Device Regulation ("MDR") (2017/745). This CE mark provides market authorization within the EU and European Economic Area ("EEA"). In the EU, a single regulatory approval process exists, in which a Notified Body assesses the conformity of the medical device intended to be marketed with the legal

requirements set forth in the EU MDR. To obtain a CE mark, medical devices and their accessories must meet minimum standards of performance, safety, and quality (i.e., the essential requirements), and then, according to their classification, comply with one or more of a selection of conformity assessment routes. After conformity is confirmed, the CE mark is affixed to the medical device itself or on its packaging, thus indicating its conformity status. The competent authorities of the EU countries separately regulate the clinical research for medical devices and the market surveillance of products once they are placed on the market.

Other International Regulation

Sales and marketing of medical devices outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. The global regulatory environment is increasingly stringent and unpredictable. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years, and other countries have expanded, or plan to expand, their existing regulations. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or obtain future approvals for our products. The time required to obtain appropriate marketing authorizations from other foreign authorities may be substantially longer or shorter than required for FDA approval. Some countries may not require any special registration process prior to importing and marketing the device. Whether or not we have obtained FDA approval, our NeuroStar Advanced Therapy System may be subject to different regulatory requirements in other jurisdictions. The foreign regulatory approval process includes all the risks associated with FDA regulation, as well as country-specific regulations.

Other Regulations

Import-export. Our international operations enable us to be subjected to laws regarding sanctioned countries, entities and persons, customs, and import-export. Among other things, these laws restrict, and in some cases can prevent, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in our business dealings with entities in and from foreign countries.

Data Privacy and Cybersecurity Laws and Regulations. As a business with a significant global footprint, compliance with evolving regulations and standards in data privacy and cybersecurity (relating to the confidentiality and security of our information technology systems, products such as medical devices, and other services provided by us) may result in increased costs, lower revenue, new complexities in compliance, new challenges for competition, and the threat of increased regulatory enforcement activity. Our business relies on the secure electronic transmission, storage and hosting of sensitive information, including personal information, financial information, intellectual property, and other sensitive information related to our customers and workforce.

For example, in the U.S. the collection, maintenance, protection, use, transmission, disclosure and disposal of certain personal information and the security of medical devices are regulated at the U.S. federal and state, and industry levels. U.S. federal and state laws protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by health care providers. In addition, the FDA has issued guidance advising manufacturers to take cybersecurity risks into account in product design for connected medical devices and systems, to assure that appropriate safeguards are in place to reduce the risk of unauthorized access or modification to medical devices that contain software and reduce the risk of introducing threats into hospital systems that are connected to such devices. The FDA also issued guidance on the post market management of cybersecurity in medical devices.

Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in these countries relating to the collection, storage, handling and transfer of personal data and, potentially, intellectual property continue to evolve with increasingly strict enforcement regimes.

Human Capital

Employees

As of December 31, 2023, we had 203 full time employees working collaboratively across our sales and customer support team, in research and development, including clinical, regulatory and certain quality functions, operations and in general and administrative. All of our employees are employed full time. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or represented by a labor union. We believe that our employee relations are strong.

We recruit employees with the skills and training relevant to functional responsibilities. We believe that cultural fit and energy are important considerations. We assess the likelihood that a particular candidate will contribute to the Company's overall goals, and beyond their specifically assigned tasks. We aim to provide market-based compensation and work to retain our employees for many years. During 2023, the Company continued to offer a two-day work from home policy to provide personal flexibility and support employees in managing family priorities.

Development

Developing employees contributes to growing our business. The Company has leadership development programs which bring a consistent approach to leadership development that all managers and directors are required to attend. The Company also provides learning opportunities for all employees to continue to progress their development and career at the Company.

Diversity, Inclusion and Belonging

A diverse and inclusive culture that provides fair and equitable opportunities helps the Company remain competitive, advance its innovation culture, and serve customers. The Company focuses on attracting and advancing top talent as well as advancing initiatives that enhance diversity, inclusion and belonging.

Compensation and Benefits

In addition to a professional work environment that promotes innovation and rewards performance, our total compensation for employees includes a variety of components that support sustainable employment and the ability to build a strong financial future, including competitive market-based pay, share-based compensation awards, and comprehensive benefits. In addition to earning a base salary, eligible employees are compensated for their contributions to the Company's goals with cash incentives and long-term equity-based incentives. The Company is committed to providing fair and equitable pay for employees. Eligible full-time employees also have access to medical, dental, and vision plans; savings and retirement plans; and other benefits.

Corporate Information

We were incorporated in Delaware in April of 2003. Our principal executive offices are located at 3222 Phoenixville Pike, Malvern, Pennsylvania 19355, and our telephone number is (610) 640-4202. Our website address is https://neurostar.com/neuronetics/. We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, which can be found at http://www.sec.gov. The information contained on, or accessible through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any information contained in, or that can be accessed through, our website as part of this Annual Report on Form 10-K.

Summary Risk Factors

An investment in shares of our common stock involves significant risks. See the “Risk Factors” section of this Annual Report on Form 10-K. These risks include, among others:

- We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.
- If insurance coverage is unavailable or reimbursement from third-party payors for treatments using our products significantly declines, psychiatrists may be reluctant to use our products.
- Our revenue has been concentrated among a small number of customers, and if we lose any of these customers and fail to replace them, or if any of these customers fail to perform their obligations to us, our revenue may decrease substantially.
- Our success depends upon patient satisfaction with the effectiveness of our NeuroStar Advanced Therapy System.
- We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected.
- The loss of certain members of our senior management or our inability to attract and retain highly skilled executives, salespeople, product development and other personnel could negatively impact our business.
- We rely on single-source suppliers for some components used in our NeuroStar Advanced Therapy System and on a single manufacturer for the assembly of our NeuroStar Advanced Therapy System, and we may be unable to find replacements or immediately transition to alternative parties for these components.
- We rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.
- If we are not able to obtain and enforce patent protection for our technologies, products, or product candidates, development and commercialization of our products and product candidates may be adversely affected.
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- Modifications to our products may require new 510(k) clearances, *de novo* classification or PMAs, and may require us to cease marketing or recall the modified products until clearances are obtained.
- Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.
- Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our

products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

- We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

- Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team as well as our field sales personnel in the United States and our independent third-party distributors outside of the United States. If our employees or our independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

- We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.

- The terms of our credit facility place restrictions on our operating and financial flexibility and could subject us to potential default. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

- If we experience significant disruptions in our information technology systems, our business may be adversely affected.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report on Form 10-K before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.

We have incurred net losses since inception, including net losses of $30.2 million and $37.2 million for the years ended December 31, 2023 and 2022, respectively. As a result of ongoing losses, as of December 31, 2023, we had an accumulated deficit of $376.1 million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, to obtain regulatory clearances or approvals for our products in additional countries and for additional indications, and to develop new products or add new features to our existing products. The net losses we incur may fluctuate significantly from quarter to quarter. We will need to generate significant additional revenues to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues.

We rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues, and we expect to generate substantially all of our revenues in the foreseeable future from sales of these and any related products and services. Because the market for TMS therapy is still developing and

contains a limited number of market participants, sales of our products could be negatively impacted by unfavorable market reactions to our or other TMS devices. If the use of our or other TMS therapies results in serious adverse events, or such products malfunction or are misused, patients and psychiatrists may attribute such negative events to TMS therapy generally, which may adversely affect market adoption of our products. Additionally, if patients undergoing treatment with a NeuroStar Advanced Therapy System perceive the benefits to be inadequate or adverse events too numerous or severe compared to the relevant rates of alternative TMS therapies or pharmaceutical options, it will be difficult to demonstrate the value of our NeuroStar Advanced Therapy System to patients and psychiatrists. As a result, demand for and the use of our NeuroStar Advanced Therapy System may decline or may not increase at the pace or to the levels we expect.

Our business and ability to meet obligations to our customers may be disrupted and our results of operations, financial condition, cash flows and liquidity may be adversely affected by a global pandemic or epidemic diseases.

Our operations and interactions with healthcare systems, providers and patients expose us to risks associated with public health crises, including epidemics and pandemics. The global impact of COVID-19, or other global pandemic including corresponding preventative and precautionary measures that we and other businesses, communities and governments may take to mitigate the spread of such disease, may lead to restrictions on, disruptions in, and other related impacts on business and personal activities, which may adversely impact our business and liquidity.

Throughout the year ended 2021 and into early 2022, we experienced a material impact to revenue particularly with regard to U.S. treatment session revenues as a result of the COVID-19 pandemic. Capital equipment sales and treatment session revenues may continue to be materially impacted by the pandemic as customers defer capital purchase decisions and delay new patient treatment starts. Further, during the COVID-19 pandemic, several countries placed significant restrictions on travel within their respective borders, leading to extended business closures in some instances.

The significance of the impact of a global pandemic on our operations depends on numerous evolving factors that we may not be able to accurately predict or effectively respond to, including, among others:

- the effect on global economic activity, financial markets and the resulting impact on our customer's businesses, their credit and liquidity, and their demand for our solutions and services, as well as their ability to pay;

- our ability to deliver and implement our solutions in a timely manner, including as a result of supply chain disruptions and related cost increases; and

- actions taken by U.S., foreign, state, and local governments, suppliers, and individuals in response to the outbreak (including the extent of travel restrictions and business closures).

If insurance coverage is unavailable or reimbursement from third-party payors for treatments using our products significantly declines, psychiatrists may be reluctant to use our products.

In the United States, sales of our products will depend, in part, on the extent to which the treatment sessions using our products are covered and reimbursed by third-party payors, including private insurers and government healthcare programs. Even if a third-party payor covers a particular treatment that uses our products, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase our products or ensure such purchase is profitable for the provider. Further, patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with

the treatment and may be unwilling to undergo such treatment in the absence of coverage and adequate reimbursement, or due to large annual deductibles associated with certain health insurance plans.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a treatment is neither experimental nor investigational, safe, effective, medically reasonable and necessary (which may include provision of treatment only in the absence of certain alternatives), appropriate for the specific patient, cost-effective, supported by peer-reviewed medical journals and/or included in clinical practice guidelines.

In the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, coverage, reimbursement and utilization guidelines for treatments may differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in-office treatment is made on a plan-by-plan basis. One payor's determination to provide coverage for a specific treatment does not assure that other payors will also provide coverage, and adequate reimbursement.

In addition, the federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third-party payors are increasingly challenging the price, scrutinizing the medical necessity and reviewing the cost-effectiveness of medical treatments.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets, including Japan, have government-managed healthcare systems that govern reimbursement for psychiatric treatments and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may not materialize or grow significantly.

The marketability of our products may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to adequately train psychiatrists and other treatment providers on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

There is a learning process involved for treatment providers to become proficient in the use of our products, which requires us to spend considerable time and resources for training. It is critical to the success of our commercialization efforts to train a sufficient number of psychiatrists and to provide them with adequate, ongoing instruction and training in the use of our products. This training process generally requires psychiatrists to review and study product materials, engage in multi-day, hands-on training sessions for up to four hours per day and participate in a multi-day observational period prior to treating patients independently. This training process may also take longer than expected or be more complicated than the psychiatrists or their personnel are comfortable with and may therefore affect our ability to increase sales. Convincing psychiatrists to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts.

Our revenue has been concentrated among a small number of customers, and if we lose any of these customers and fail to replace them, our revenue may decrease substantially.

A significant amount of our revenue is derived from a limited number of customers. Any material non-payment or non-performance by one of these customers, a significant downturn or deterioration in the business or financial condition of any of these customers, or any other event significantly negatively impacting a

contractual relationship with one of these customers could adversely affect our financial condition and results of operations.

Customers and their patients may be slow to adopt and use TMS therapies.

TMS therapy is an emerging treatment option for patients suffering from MDD. As a result, customer and patient awareness of TMS therapy as a treatment option for MDD, and experience with TMS therapies, is limited. Our success depends in large part on our ability to educate and train customers and patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our NeuroStar Advanced Therapy System. We have been engaging in an active marketing campaign to raise awareness of our NeuroStar Advanced Therapy System and its benefits among customers, but we cannot assure you that these efforts will be successful or that they will not prove to be cost-prohibitive. Some customers may also find the initial patient set up and the subsequent procedures for future treatment sessions to be difficult or complicated, or could be wary of the initial investment required for the purchase of the NeuroStar Advanced Therapy System, which may impact their decision to purchase or use the NeuroStar Advanced Therapy System as part of their practice. Similarly, customers may find it difficult to hire additional staff, allocate sufficient space or operationalize our NeuroStar Advanced Therapy System, which could slow its adoption.

In addition, customers may not derive sufficient cash flow from using the NeuroStar Advanced Therapy Systems due to their own practice economics or otherwise. Failure to achieve economic benefits from the purchase or use of the NeuroStar Advanced Therapy System would adversely affect our customers' purchase of treatment sessions. These factors could also reduce the number of procedures performed using our NeuroStar Advanced Therapy System, and if we do not facilitate the utilization of our products by our customers, our revenues and results of operations could be harmed.

Our success depends upon patient satisfaction with the effectiveness of our NeuroStar Advanced Therapy System.

In order to generate repeat and referral business, patients must be satisfied with the effectiveness of our NeuroStar Advanced Therapy System. Clinical studies demonstrate that, in order to be effective, our products must be used for a period of four to six weeks, and require a patient to return to a psychiatrist's office five days a week during that period in order to receive the recommended course of treatment. Since patients who achieve response or remission using our therapy will obtain these results gradually over this treatment period, their perception of their results may vary depending on their compliance with the prescribed treatment course.

We train our customers to select the appropriate patient candidates for treatment using the NeuroStar Advanced Therapy System, explain to their patients the time-period over which the results from a treatment course can be expected to occur, and measure the success of treatments using medical guidelines. However, our customers may not select appropriate patient candidates for NeuroStar Advanced Therapy System treatment, which may produce results that may not meet patients' expectations. In addition, the efficacy of treatment is dependent on proper patient set up at the initial treatment session and duplication of that set up at future treatment sessions. To the extent customers do not make the proper measurements for a specific patient or use the same procedures at each treatment session, it could result in variability of the treatment efficacy and results for the patient. If patients are not satisfied with the results of our NeuroStar Advanced Therapy System, our reputation and future sales will suffer.

We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected.

Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products or other market activities of current or new industry participants. Our ability to

compete successfully will depend on our ability to develop products that reach the market in a timely manner, to receive adequate coverage and reimbursement from third-party payors, and to successfully demonstrate to psychiatrists and patients the merits of our products compared to those of our competitors. If we are not successful in convincing others of the merits of our products, including in comparison to those of our competitors, or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales.

We have competitors that sell other forms of TMS therapy, including Brainsway, Magstim, MagVenture, CloudTMS and Nexstim, that compete directly with the NeuroStar Advanced Therapy System. Competing TMS therapy companies have developed and may develop additional treatments that can be administered for shorter time periods or for indications outside of MDD, or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from psychiatrists. We also face competition from pharmaceutical and other companies that develop competitive products, such as antidepressant medications. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize antidepressant medications or other treatments that are safer, more convenient or more effective than the NeuroStar Advanced Therapy System. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive.

In addition, our competitors may have more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent distributors outside the United States, both those presently working with us and those with whom we hope to work as we expand.

We may face difficulties encountered by companies in new and evolving markets.

In assessing our prospects, you must consider the risks and difficulties frequently encountered by companies in new and evolving markets. These risks include our ability to:

- manage rapidly changing and expanding operations;
- increase awareness of our brand and strengthen customer loyalty;
- successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and products in development;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;
- refrain from infringing on the intellectual property rights of others, and maintaining appropriate legal policies and procedures;
- expand our presence in existing and commence operations in new international markets; and
- attract, retain and motivate qualified personnel.

If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenues to achieve or sustain profitability.

Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team as well as our field sales personnel in the United States and our independent third-party distributors outside of the United States. If our employees or our independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

If we launch new products, expand our product offerings to new indications or increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees, and distributors with significant technical knowledge in various areas. Further, most of the salespersons we recently hired have technical expertise from other industries but no experience within our specific industry. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, new hires fail to successfully transition to our industry, or we experience high turnover in our sales force in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our products.

The loss of any member of our senior management or our inability to attract and retain highly skilled executives, salespeople, product development and other personnel could negatively impact our business.

Our success depends on the skills, experience and performance of the members of our senior management team. The individual and collective efforts of these employees will be important as we continue to develop our products and as we expand our commercial activities. We believe that it is challenging to identify individuals with the requisite skills to serve in many of our key positions, and the loss or incapacity of existing members of our executive management team could negatively impact our operations. We did not maintain key person life insurance on any of our employees in 2023 (other than our Chief Executive Officer, on whom we maintained a $1,000,000 key person life insurance policy) and do not expect to in the future. Our Chief Executive Officer's employment agreement does not guarantee our retention of our Chief Executive Officer for any period of time.

Our commercial, supply chain and research and development programs and operations depend on our ability to attract and retain highly skilled managers, salespeople and product development and customer training personnel. We may be unable to attract or retain qualified managers, salespeople or product development and customer training personnel in the future due to the competition for qualified personnel in the medical treatment and device fields, as well as other fields. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, supply chain and research and development programs. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

Our long-term growth depends on our ability to commercialize our approved products for current and future indications and to develop and commercialize additional products through our research and development efforts. If we fail to do so we may be unable to compete effectively.

In order to increase our future revenues, we must successfully enhance our existing product offerings and introduce new products in response to changing customer demands and competitive pressures and technologies. Our industry is characterized by intense competition, including from lower-cost competitors, rapid technological changes, new product introductions and enhancements and evolving industry standards. We also face competition from pharmaceutical companies, including large pharmaceutical companies with

greater capital. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our technology, including in new markets that develop as a result of technological, pharmaceutical and scientific advances, while improving the performance and cost-effectiveness of our products. New pharmaceutical products, technologies, techniques or other products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as psychiatrist practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully further commercialize or develop or obtain regulatory clearances or approvals to market new products or our existing products for additional indications. Future products, even if cleared, might not be accepted by psychiatrists or the third-party payors who reimburse for the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous additional factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- demonstrate the benefits associated with the use or our products when compared to the products and devices of our competitors;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearances or approvals for new products or indications or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Nevertheless, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions.

We rely on single-source suppliers for some components used in our NeuroStar Advanced Therapy System and on a single manufacturer for the assembly of our NeuroStar Advanced Therapy System, and we may be unable to find replacements or immediately transition to alternative parties for these components.

We rely on single-source suppliers for some components used in our NeuroStar Advanced Therapy System, and we do not have long-term supply contracts with these suppliers. Furthermore, we rely on a single manufacturer for the assembly of the mobile console and patient positioning system used in our NeuroStar Advanced Therapy System. For us to be successful, our suppliers and contract manufacturer must be able to

provide us with components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers have generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including our lack of long-term agreements with those suppliers, our relative importance as a customer of those suppliers, or, as applicable, their ability to produce the components for or provide assembly services to manufacture our NeuroStar Advanced Therapy System. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components or manufactured products, if we cannot obtain an acceptable substitute.

Any transition to a new supplier or contract manufacturer could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our NeuroStar Advanced Therapy System or could require that we modify its design. If we are required to change our contract manufacturer, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar non-U.S. regulatory authorization may be necessary before we implement the change, which could cause a substantial delay. We cannot assure you that we will be able to identify and engage alternative suppliers or contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturer could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for our NeuroStar Advanced Therapy System in a timely and cost-effective manner. During 2023, we transitioned to a new contract manufacturer for our console in a planned process.

We may be unable to achieve or manage our anticipated growth effectively, which could make it difficult to execute our business strategy.

We have a relatively short history of operating as a commercial company and our growth rate may be volatile. For example for 2023, 2022 and 2021 our growth rate was 9%, 18% and 12% respectively. We intend to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality, or delivery timelines, of our products or customer service or satisfy customer demand if our business grows too rapidly. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, and our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, training and education personnel, billing, accounting reporting and general process improvements and expand our internal quality assurance program, among other things. Because our products require us to devote significant resources to training our customers on the use, and educating our customers on the benefits, of our products, we will be required to expand these personnel as we increase our sales efforts. We may not successfully implement these increases in scale or the expansion of our personnel, which could harm our business.

We rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.

We rely on a network of third-party distributors to market and distribute our products in international markets. We currently sell our products in five countries outside of the United States and plan to market and sell our

products through our exclusive distribution agreement in Japan once we attain reimbursement approval. We are assessing the opportunity to continue expanding into other international markets. We may face significant challenges and risks in managing a geographically dispersed distribution network. We have limited ability to control any third-party distributors. Our distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing, sales, education and training efforts that we believe enable the products to develop, achieve or sustain market acceptance. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. In addition, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent that distributor from helping competitors solicit business from our existing customers, which could further adversely affect our sales. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party distributors become unsatisfactory, we may experience delays in meeting our customers' demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose potential customers.

We face risks associated with our international business.

We currently market and sell our products outside of the United States, including in Japan, and plan to market and sell our products through our exclusive distribution agreement in Japan. Once we attain satisfactory reimbursement approval, we expect that sales of our NeuroStar Advanced Therapy System in Japan will increase.

The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. We expect our international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations, to the extent we establish non-U.S. operations;
- attaining reimbursement under differing and multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties in determining and creating the proper sales pathway in new, international markets;
- compliance with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, (the "FCPA"), and anti-money laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;

- tariffs and trade barriers, export regulations, sanctions and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;

- potential adverse tax consequences, including imposition of limitations on or increases of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;

- imposition of differing labor laws and standards;

- armed conflicts or economic, political, health (including pandemic diseases) or social instability in foreign countries and regions;

- fluctuations in foreign currency exchange rates;

- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action;

- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; and

- conducting post-market surveillance on product performance.

We are assessing the opportunity to expand into other international markets. However, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory hurdles to overcome, and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business.

Our employees, consultants, distributors and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors and other commercial partners may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, distributors and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. These risks may be more pronounced, and we may find that the processes and policies we have implemented are not effective at preventing misconduct. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. Whether or not we are successful in defending against such

actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We rely in part on third parties to conduct our clinical trials. If these third parties fail to perform their duties on time or as expected, we may not be able to obtain regulatory approval for additional indications that we may seek for the NeuroStar Advanced Therapy System.

Our clinical trials are managed by our own staff and personnel, but we rely in part upon certain third parties, including clinical trial sites, medical institutions, clinical research organizations, ("CROs"), and private practices, for, among other things, site monitoring, statistical work and electronic data capture in our clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocols, and legal, regulatory and scientific standards, including current good clinical practices, ("CGCPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials. If we or any such third parties fail to comply with applicable CGCPs, the clinical data generated in such trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a marketing application for any particular indication. In addition, if such third parties do not devote sufficient time and resources to our clinical trials or otherwise carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they assist in obtaining is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates in a specified indication.

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for the treatment of MDD. Our treatments are designed for patients who suffer from significant neurohealth disorders, and these patients are more likely to experience significant adverse health outcomes, which could increase the risk of product liability lawsuits. Furthermore, if psychiatrists are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenues;
- the inability to commercialize new products or product candidates; and

- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

Our insurance policies protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, cybersecurity liability, employee benefits liability, property, umbrella, workers' compensation, products and clinical trial liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on the products we supply for one year from the date of delivery. There can be no assurance that we will not face increased claims in the future. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior as is required by U.S. laws and by our corporate policies. We are subject to the risk that we, our U.S. employees or any future employees or consultants located in other jurisdictions or any third parties such as our distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

We will face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. We have implemented company policies relating to compliance with the FCPA and similar laws. However, such policies may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-

compliance, including the ability to terminate the agreement, our distributors may not comply with U.S. laws, including the FCPA.

Any violation of the FCPA or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including for our TrakStar system and accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing upgrades to our information technology systems, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to provide customers with data on patient outcomes, track the usage of our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to access patient data or use our products for treatments. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. Currently we carry business interruption coverage to mitigate any potential losses, but we cannot be certain that such potential losses will not exceed our policy limits.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

Security and privacy breaches may expose us to liability and harm our reputation and business.

As part of our business we receive and process information about our customers, partners and their patients, including PHI, and we may store or contract with third parties to store our customers' data, including PHI. PHI, a subset of individually identifiable information, is regulated at the federal level by HIPAA, as amended by HITECH, and by various laws at the state level, as more fully described below. We are required to safeguard PHI in accordance with HIPAA and, as a business associate, we are also directly liable for compliance with HIPAA.

The security measures we have implemented relating to our NeuroStar Advanced Therapy System and TrakStar database, specifically, and our operations, generally, may not prevent security breaches that could

harm our business. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or breach of our systems and the data and PHI we store and process. Our security measures have been and may in the future be breached as a result of actions by third parties or employee error or malfeasance. A party who is able to circumvent our security measures or exploit inadequacies in our security measures, could, among other things, misappropriate proprietary information, including information about our customers and their patients, cause the loss or disclosure of some or all of this information, cause interruptions in our or our customers' operations or expose our customers to computer viruses or other disruptions or vulnerabilities. Any compromise of our systems or the data we store or process could implicate reporting requirements under HIPAA, result in a loss of confidence in the security of our software, damage our reputation, disrupt our business, lead to legal liability and adversely affect our results of operations. Moreover, a compromise of our systems could remain undetected for an extended period of time, exacerbating the impact of that compromise. Actual or perceived vulnerabilities may lead to claims against us by our customers, their patients or other third parties, including the federal and state governments. While our customer agreements typically contain provisions that seek to limit our liability, there is no assurance these provisions will be enforceable and effective under applicable law. In addition, the cost and operational consequences of implementing further data protection measures could be significant.

Employment litigation and unfavorable publicity could negatively affect our future business.

Employees may, from time to time, bring lawsuits against us or make public claims about us regarding injury, creating a hostile workplace, discrimination, wage and hour, sexual harassment and other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Companies that have faced employment or harassment related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their sales. If we were to face any employment related claims or allegations, our business could be negatively affected.

The 2017 comprehensive tax reform law could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation, (Pub. L. 115-97), commonly referred to as the Tax Cuts and Jobs Act of 2017, (the "TCJA"), which significantly revised the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contained significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the TCJA. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to

state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

A major earthquake, fire or other disaster, such as a major flood, seasonal storms, global pandemic (such as COVID-19), or terrorist attack affecting our facilities, or those of our third-party manufacturers or suppliers, could significantly disrupt our or their operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our third-party manufacturers or suppliers' damaged manufacturing facilities. These delays could be lengthy and costly. If any of our manufacturers', suppliers' or customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our or their facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak a pandemic (such as COVID-19) could have a negative effect on our operations.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, distributors and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;

- potential loss of key employees of the acquired businesses; and

- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock or other equity-linked securities as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States, ("U.S. GAAP"), are subject to interpretation by the Financial Accounting Standards Board, ("FASB"), or SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results and could affect the reporting of transactions completed before the announcement of a change.

Refer to "Note 4. Recent Accounting Pronouncements" in our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Our sales volumes and our results of operations may fluctuate over the course of the year.

We have experienced and may continue to experience meaningful variability in our sales and gross profit among fiscal quarters. In the first quarter, our results can be impacted by the resetting of annual U.S. patient healthcare insurance plan deductibles, which may cause delays in patients seeking NeuroStar Advanced Therapy System treatments. Historically, we have seen a sequential decline in third quarter revenues, which we believe is attributable to summer vacation plans of psychiatrists and patients. In addition, the fourth quarter has consistently been a strong revenue quarter on a sequential basis primarily due to U.S. psychiatrists' historical timing for capital expenditures and patients' needs to exhaust remaining balances in flexible spending accounts.

Additional factors that we expect may contribute to variability in our sales and gross profit over the course of the year include:

- the growth or decline of our installed system base;

- the unpredictability of future sales by our international distributors, including through our exclusive distributor in Japan;

- the demand for, and pricing of, our products and the products of our competitors;

- the timing of or failure to obtain regulatory clearances or approvals for other products, indications or treatments; or

- the costs, benefits and timing of new product introductions.

Risks Related to Intellectual Property

If we are not able to obtain and enforce patent protection for our technologies, products, or product candidates, development and commercialization of our products and product candidates may be adversely affected.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We have applied, and we intend to continue applying, for patents covering aspects of our technologies that we deem appropriate. However, the patent process is expensive and time consuming, and we may not be able to apply for patents on certain aspects of our current or future products and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

We cannot offer any assurances about which, if any, of our patent applications will issue or whether any of our issued patents will be found invalid and unenforceable or will be threatened by third parties. Any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. We also cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect and provide exclusivity for our products, any additional features we develop for our products or any new products. Other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop. Since patent applications in the US and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our technologies, products, or product candidates. Furthermore, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office, (the “USPTO”), to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013.

The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Proceedings challenging our patents, which may continue for a protracted period of time, could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for alternative and possibly more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages;

- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;

- we may develop or in-license additional proprietary technologies that are patentable;

- the patents of others will not have an adverse effect on our business;

- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we will develop additional proprietary technologies or products that are separately patentable; or

- our commercial activities or products will not infringe upon the patents of others.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business.

Our inability to effectively protect our proprietary technologies could harm our competitive position.

Although our competitors have utilized and are expected to continue utilizing technologies similar to ours, our success will depend upon our ability to protect and continue to develop proprietary technologies and products and to defend any advantages afforded to us relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and thereby erode any competitive advantages we may have. For example, patents for our core technology will begin to expire in the United States in 2024, and our patents outside of the United States are expected to remain in effect until between 2024 and 2035. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We have agreements with our employees and selected consultants that obligate them to assign their inventions to us. If the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, including by refusing or being unavailable to sign assignments, oaths, declarations or other documents, we may not have adequate remedies for any such breach or violation, and we could lose our rights in inventions through such breaches or violations. Furthermore, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the US, the natural expiration of a utility patent is generally 20 years after its first effective filing date. The natural expiration of a design patent is generally 14 years after the grant of the design patent for design patent applications filed before May 13, 2014, and the natural expiration of a design patent is generally 15 years after the grant of the design patent for design patent applications that are filed on or after May 13, 2015. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, or product candidates are obtained, once the patent life has expired, we may be open to competition. Patents covering some of our core

technology have expired or will expire within the next five years. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products, and product candidates, our business and results of operations will be adversely affected.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

Significant litigation regarding patent rights occurs in our industry. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation.

We may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such

as review, reexamination, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, regardless of the merit of the claims, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, including enhanced damages if we are found to have willfully infringed or misappropriated such rights;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights

of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

In addition, we generally indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect through non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending

intellectual property rights in certain foreign jurisdictions. These challenges can be caused by the absence or inconsistency of the application of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop infringement of our foreign patents, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products, and product candidates. While we will endeavor to try to protect our technologies, products, and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property, including studies we commission or reports on the efficacy of our products. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Our patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations. There are a number of recent changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the United States has enacted and is currently implementing the America Invents Act of 2011, a wide-ranging patent reform legislation. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. As an example, the first to file provisions, which became effective March 2013, mean that the party that is first to file in the United States generally is awarded the patent rights, regardless of who invented first. This could have a negative impact on some of our IP and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, 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 would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the US in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we in-license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we fail to comply with our obligations under license or technology agreements with third parties, we may be required to pay damages and we could lose license rights that are critical to our business.

We license certain intellectual property, and in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various payment obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor could cause us to lose valuable rights, and could prevent us from distributing our products, or inhibit our ability to commercialize future products. Our business could suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive. Our trademarks or trade names may be determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the

USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA, FTC, and their foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

We may not receive the necessary regulatory clearances or approvals to market our future products or other proposed indications for our products in the future, and failure to timely obtain necessary clearances or approvals for such future products or indications would adversely affect our ability to grow our business.

An element of our strategy is to continue to upgrade our products, add new enhancements and features and expand clearance or approval of our current products to include new indications. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a premarket approval application (PMA) from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial

equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. Our ability to successfully obtain clearance for any new indications will be dependent on us submitting data as to the successful completion of clinical trials evidencing safety and efficacy. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification request, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510(k) submissions. We initially received marketing authorization of our device through the *de novo* classification process, and we have made changes to our system through subsequent 510(k) clearances. Competitors may seek 510(k) clearance of similar products with similar indications and use our de novo classification as a predicate device in their submission. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and the manufacturing process or facilities we use may not meet applicable requirements. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex, lengthy, and burdensome application than a 510(k) submission. To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases, such studies may be requested for a 510(k) as well. We may not be able to meet the requirements to obtain 510(k) clearance or PMA (or a de novo classification request), in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended uses of our products as a condition to a 510(k) clearance or PMA. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approval of new products we develop, any limitations imposed by the FDA on new product use or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition, and results of operations.

Even if granted, a 510(k) clearance, *de novo* classification, or PMA imposes substantial restrictions on how our devices may be marketed or sold, and the FDA continues to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation (QSR). In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export restrictions. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, recalls, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying requests for 510(k) marketing clearance or PMA of new products or modified products; withdrawing 510(k) marketing clearances or PMAs that have already been granted; refusing to provide Certificates for Foreign Government; refusing to grant export approval for our products; or pursuing criminal prosecution. Any of these sanctions could impair our ability to produce or commercialize our products in a cost-effective and timely manner in

order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other regulatory compliance costs or take other actions that may have a negative impact on our sales and our ability to generate profits.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad, especially with a new administration that may have different policy priorities than the previous one.

In order to sell our products in member countries of the European Economic Area, or (EEA) or in countries that also rely on the CE Mark outside the EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC), and with the Medical Device Regulation (Regulation 2017/745). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

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. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our surgical systems, which would prevent us from selling them within the EEA and may have an impact on our marketing authorization in other countries.

We or our distributors will also need to obtain or retain regulatory approval in other foreign jurisdictions in which we plan to or currently do market and sell our products, and we or they may not obtain such approvals as necessary to commercialize our products in those territories. Regulatory marketing authorizations in these foreign jurisdictions typically require device testing, conformance to classification requirements, pre-market requests to authorize commercialization, and in some cases inspections.

Modifications to our products may require new 510(k) clearances. de novo classification, or PMAs, and may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Any modification to a 510(k)-cleared product that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance

or de novo classification, or, possibly, approval of a PMA. Modifications to products that have been approved through the PMA process generally require premarket FDA approval. Similarly, certain modifications made to products cleared through a 510(k) or authorized through the de novo classification process may require a new 510(k) clearance. Each of the PMA, de novo classification, and the 510(k) clearance processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials.

Despite the time, effort, and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory authorizations could harm our business. Furthermore, even if we are granted regulatory authorizations, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

Any modifications to our existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming, and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA requires every manufacturer to make this modification determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances were not required. We may make similar modifications or add additional enhancements or features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, *de novo* classifications, or PMAs for modifications to our previously authorized products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation (QSR) which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved devices in the United States. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. Foreign regulatory authorities also impose manufacturing quality requirements, which may differ from the FDA requirements, with which we must comply.

We or our third-party suppliers and manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or foreign jurisdiction requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenues and increased costs.

If treatment guidelines for the clinical conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.

If treatment guidelines for the clinical conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign the applicable product and seek new clearances or approvals from the FDA. Our existing 510(k) and *de novo* clearances from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could suffer.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies, particularly if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our product has been authorized for marketing by the FDA for a specific indication. We train our commercial organization and distributors inside and outside the United States to not promote our products for uses outside of the FDA-cleared indications for use, known as "off-label uses." However, we cannot guarantee that all of our employees, representatives, and agents will abide by our marketing policies.

If the FDA or any foreign regulatory body determines that our promotional materials, training, or other marketing activities constitute promotion of an off-label or unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violations that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as laws prohibiting false claims for reimbursement.

Moreover, even if we, and all our employees, contractors, and agents, market our products in compliance with applicable FDA regulations, such regulations do not apply to the practice of medicine, and we cannot prevent a physician from prescribing and/or using our products off-label when, in the physician's independent professional medical judgment, he or she deems it appropriate. Similarly, we cannot prevent patients from using our products off-label. There may be increased risk of injury to patients if physicians attempt to prescribe, or patients attempt to use, our products off-label. Furthermore, the use of our products for indications other than those authorized by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. There are similar risks if our products are used off-label with respect to non-U.S. regulatory approvals.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report or Safety Alert to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

Any adverse event involving our products could result in voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as exposing us to private litigation, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA and/or the permission to affix the CE Mark does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers, patients and third-party payors are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government in addition to the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim for reimbursement that includes items resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (“FCA”). Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or a safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe

harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. The Social Security Act also has a provision that provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that such person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service payable by a federal health care program. Private individuals commonly known as "whistleblowers," can bring FCA qui tam actions on behalf of the government and themselves, and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $13,946 to $27,894 (beginning in 2024) per false or fraudulent claim or statement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial settlements under the FCA in connection with alleged off label promotion of their products, and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government;

- the federal physician self-referral law ("Stark Law") prohibits, subject to exceptions, referring Medicare patients for "designated health services" (including "durable medical equipment and supplies" and "outpatient hospital services") ("DHS") to entities with which a referring physician (or immediate family member) maintains a "financial relationship." States (as required in order to maintain Medicaid funding) have further enacted similar prohibitions that apply to Medicaid, as well as other insurance programs, and which may be more restrictive than the Stark Law. Persons who attempt to circumvent these laws or submit (or cause others to submit) claims to payors in violation of these laws may be subject to significant civil and criminal penalties. As such, we are generally prohibited from billing for any services referred in violation of these laws. Importantly, we do not provide DHS and do not bill payors for DHS (or any other items or services). While we manufacture and sell equipment and supplies to our customers, we are not a Medicare supplier. Additionally, in instances in which we maintain contractual arrangements with physicians or hospitals, we have no reason to believe that we are engaged in assisting any person with circumventing these laws. Further, the services (specifically TMS) furnished (outside of a hospital context) by physician groups with whom we maintain contractual arrangements do not constitute DHS. Notably, however, the Stark Law is a strict liability statute and compliance is difficult to assure;

- HIPAA among other things established various criminal health care fraud laws, which impose criminal liability for 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 creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false,

fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the applicable statute or specific intent to violate it or to have committed a violation;

- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security, transmission and breach reporting obligations with respect to individually identifiable health information upon "covered entities" subject to the law, including health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services on their behalf that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act" created under the PPACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicare Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) other professionals (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; state laws that require device manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and other federal and state laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts and data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the GDPR, which became effective in May 2018).

These laws and regulations, among other impacts, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with psychiatrists, other healthcare provides, or other potential purchasers of our products. We have also entered into consulting agreements with physicians, which are subject to these laws. Further, while we do not submit claims to any payor and our customers make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

From time to time, Congress drafts legislation that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, revisions, or reinterpretations of existing regulations may impose additional costs, lengthen review times of any future products, or make it more difficult to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future.

For example, in March 2010, the PPACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- required manufacturers to report certain payments and other transfers of value pursuant to the Physician Payments Sunshine Act, described above;

- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, psychiatrists and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

- expands the eligibility criteria for Medicaid programs and, originally, required certain employers to provide, and all individuals to obtain, health insurance.

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.

Our employees, distributors, and other third parties may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, distributors, and other third parties may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or

negligent conduct or other unauthorized activities that violate, regardless of intent, regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale, promotion and labeling of medical devices or arrangements with healthcare providers, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, patient steering and other abusive practices, as described herein. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer or patient incentive programs, and other business, investment or compensation arrangements. It is not always possible to identify and deter misconduct by our employees, distributors, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Efforts to ensure that the activities of these parties will comply with applicable healthcare laws and regulations involve substantial costs. These risks may exceed those which we have identified, and the processes and policies we have implemented may not be sufficient to prevent misconduct. Noncompliance may result in the imposition of significant fines or other sanctions, including civil, criminal and administrative penalties, monetary damages, fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to Our Capital Structure

We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.

If our available cash balances, potential future borrowing capacity, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of the risks described in this Annual Report on Form 10-K, we may seek to sell common or preferred equity or debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. Our present and future funding requirements will depend on many other factors, including:

- our ability to achieve revenue growth and improve operating margins;
- our ability to comply with financial and other restrictive covenants in our credit facility, which, among other things, requires us to maintain specified financial covenants;
- our ability to improve or maintain coverage and reimbursement arrangements with domestic third-party and government payors;
- our rate of progress in establishing coverage and reimbursement arrangements from international commercial third-party and government payors, particularly in Japan;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and maintaining or improving our sales to our current customers;

- the cost of research and development activities, including research and development relating to additional indications;

- the effect of competing technological and market developments;

- costs related to international expansion; and

- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- expand our sales and marketing efforts to increase market adoption of our products and address competitive developments;

- fund development and marketing efforts of any future products or additional features to then-current products;

- acquire, license or invest in new technologies;

- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products

- acquire or invest in complementary businesses or assets; and

- finance capital expenditures and general and administrative expenses.

Additional capital may not be available to us at such times or in the amounts we need. Even if capital is available, it might be available only on unfavorable terms. Any issuance of additional equity or equity-linked securities could be dilutive to our existing stockholders, and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock, including the shares of common stock sold in this offering. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt, pay dividends, repurchase our stock, make investments and engage in merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish or license some rights to our technologies or products, on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

The terms of our credit facility place restrictions on our operating and financial flexibility and could subject us to potential default. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On September 29, 2023, the Company entered into a fifth amendment (the “Solar Fifth Amendment”) to the Loan and Security Agreement dated March 2, 2020 with SLR Investment Corp.(formerly known as Solar Capital Ltd.) (“Solar”), as collateral agent, and the lenders as defined in the agreement, that is secured by a lien covering substantially all of our assets (as amended, the “Solar Facility”). The credit facility contains customary covenants and events of default applicable to us. The affirmative covenants include, among others, a covenant that requires us to achieve agreed amounts of trailing twelve month net product revenue (“net product revenue covenant”), measured monthly through the term of the credit facility. The negative covenants include, among others, restrictions on us transferring collateral, changing businesses, engaging in

mergers or acquisitions, incurring additional indebtedness and encumbering collateral. If we default under the credit facility, Solar may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Solar's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Solar could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the credit facility, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by Solar of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

In certain months of 2023 and 2021, we did not achieve the required revenue under the net product revenue covenant and we obtained waivers from Solar to cure the non-compliance of the net product revenue covenant. We cannot provide any assurance that our lender would provide us with a waiver should we not be in compliance in the future. A failure to maintain compliance along with our lender not agreeing to a waiver for the non-compliance would cause the outstanding borrowings to be in default and payable on demand which would have a material adverse effect on us and our ability to continue as a going concern.

Our ability to comply with financial covenant tests can be affected by events beyond our control, including economic, financial and industry conditions. If market or other economic conditions deteriorate, our ability to comply with these covenants may be impaired. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our existing or future debt and meet our other obligations. If we do not have enough money to service our existing or future debt, we may be required to refinance all or part of our existing or future debt, sell assets, borrow more money or raise equity. We may not be able to refinance our existing or future debt, sell assets, borrow more money or raise equity on terms acceptable to us, if at all.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2023, we had federal and state net operating loss carryforwards of $338.0 million and $217.1 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2024. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not done an analysis to determine whether or not ownership changes have occurred since inception and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Ownership of Our Common Stock

The price of our common stock has been and may continue to be volatile.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- the actual or anticipated fluctuations in our financial condition and operating results;

- the actual or anticipated changes in our growth rate;
- the commercial success and market acceptance of our products;
- the success of our competitors in developing or commercializing products;
- media exposure of our products or of those of others in our industry;
- our ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the addition or departure of key personnel;
- product liability claims;
- general prevailing economic, industry and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors;
- business disruptions caused by earthquakes, fires, pandemic diseases (such as from coronavirus), or other natural disasters;
- disputes or other developments concerning our intellectual property or other proprietary rights, including litigation;
- the FDA or other U.S. or foreign regulatory actions affecting us or the healthcare or medical device industry;
- healthcare reform measures in the United States;
- third-party payor developments in the United States and other countries;
- sales of our common stock by our directors, officers, or stockholders;
- the timing and amount of our investments in the growth of our business;
- inability to obtain additional funding;
- future sales or issuances of equity or debt securities by us;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; and
- the issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for companies like ours in particular, have from time to time experienced extreme volatility that has been often unrelated to the operating performance of the company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenues or earnings forecasts that we may provide.

Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline.

If our stockholders or option holders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline.

Shares of common stock that are either subject to outstanding options, or are outstanding but subject to vesting or reserved for future issuance under our 2018 Equity Incentive Plan (the "2018 Plan"), will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act. We have also filed a registration statement permitting certain shares of common stock issued under our 2003 Stock Incentive Plan, or the 2003 Plan, and shares of common stock issued pursuant to the 2018 Plan or our 2018 Employee Stock Purchase Plan (the "2018 ESPP"), to be freely resold by plan participants in the public market, subject to applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. Both the 2018 Plan and the 2018 ESPP contain provisions for the annual increase of the number of shares reserved for issuance under such plans, which shares we also intend to register. If the shares we may issue from time to time under the 2003 Plan, the 2018 Plan or the 2018 ESPP are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline.

Certain shares of common stock are entitled to rights with respect to registration under the Securities Act. Such registration would result in these shares becoming fully tradable without restriction under the Securities Act when the applicable registration statement is declared effective. Sales of such shares could cause the price of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and are able to exert control over matters subject to stockholder approval.

As of February 29, 2024, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially owned approximately 10% of our outstanding common stock. Accordingly, these stockholders have a material influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, mergers, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Provisions of our amended and restated charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our 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;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue blank-check preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, other than an action or suit to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General

Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not intend to do so in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth and development of our business. In addition, the terms of our credit agreements contain, and the terms of any future credit agreements we may enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, to some extent, on the research and reports that securities or industry analysts publish about us and our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

General Risk Factors

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

While we currently qualify as a smaller reporting company under SEC regulations, we cannot be certain whether taking advantage of the reduced disclosure requirements applicable to these companies will not make our common stock less attractive to investors. Once we lose smaller reporting company status, the costs and demands placed upon our management are expected to increase.

The SEC's rules permit smaller reporting companies to take advantage of certain exemptions from various reporting requirements applicable to other public companies. As long as we qualify as a smaller reporting

company, based on our public float, and report less than $100 million in annual revenues in a fiscal year we are permitted, and we intend to, omit the auditor's attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act.

Our status as an emerging growth company expired as of December 31, 2023. While we expect to remain a smaller reporting company and non-accelerated filer, we now face increased disclosure requirements as a non-emerging growth company, such as stockholder advisory votes on executive compensation ("say-on-pay"). Until such time that we lose smaller reporting company status, it is unclear if investors will find our common stock less attractive because we may rely on certain disclosure exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and could cause our stock price to decline.

As a result of the loss of our emerging growth company status, we expect the costs and demands placed upon our management to increase, as we now have to comply with additional disclosure and accounting requirements. In addition, even if we remain a smaller reporting company, if our public float exceeds $75 million and we report $100 million or more in annual revenues in a fiscal year, we will become subject to the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring an independent registered public accounting firm to provide an attestation report on the effectiveness of our internal control over financial reporting, making the public reporting process more costly.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and the value of our common stock.

As a public company, we are required under the Sarbanes-Oxley Act to maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and regulations, and that information required to be disclosed in reports under the Exchange Act, is communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Any failure to maintain effective controls could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will be required to include in periodic reports we file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on the Nasdaq Global Market.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting due to our status as a smaller reporting company ("SRC").

Pursuant to the Exchange Act Continuous Disclosure Accommodations, the auditor attestation requirement of section 404(b) of the Sarbanes Oxley Act of 2002 is not required by SRCs, with public common equity float between $75 million and $700 million and annual revenues of less than $100 million.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We regularly assess risks from cybersecurity threats; monitor our information systems for potential vulnerabilities; and test those systems pursuant to our cybersecurity policies, processes, and practices, which are integrated into our overall risk management program. To protect our information systems from cybersecurity threats, we use various industry standard security tools that are designed to help identify, escalate, investigate, resolve, and recover from security incidents in a timely manner. Given the prevalence of social engineering attacks, we have implemented a two-pronged approach of training and security mitigations: educating users about how to detect a potential attack (phishing, malware, etc.) and security tools, which can decrease the likelihood of occurrence through multi-factor authentication, endpoint detection and response and other tools focused on locking down cyber threats. A team of industry experts comprised of representatives from our Information Technology department and support functions, along with outside experts assesses risks based on probability and potential impact to key business systems and processes. Risks that are considered high are incorporated into our overall risk management program. A mitigation plan is developed for each identified high risk, with progress reported to the Executive Leadership Team and Audit Committee and tracked as part of our overall risk management program overseen by the Audit Committee of our board of directors. These mitigations target implementing automated tools for detection and prevention wherever possible, supplemented by training and process controls as needed. Recurring maintenance, reporting and awareness tasks are conducted and documented within our Service Management Software and Security tools for record keeping and trending.

We collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes through various penetration testing and best practice reviews. These include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary. We are aware that cybersecurity is a continually changing landscape and as a result, the engagement with these experts helps us evaluate our risk-based processes with respect to the trends.

Cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected our Company, including our business strategy, results of operations, or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents of which we are aware are reasonably likely to materially affect our Company. Refer to the risk factor captioned “Security and privacy breaches may expose us to liability and harm our reputation and business ” in Part I, Item 1A. “Risk Factors” for additional description of cybersecurity risks and potential related impacts on our Company.

Governance

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks, directly and through its committees. The Audit Committee of the board oversees our risk management program, which focuses on the most significant risks we face in the short-, intermediate-, and long-term timeframe. Audit Committee meetings include discussions of emerging industry-wide trends in cybersecurity risks along with specific risk areas our company has greater risks throughout the year, including, among

others, those relating to cybersecurity threats. These reports come from the Head of IT to include our enterprise risk profile on a quarterly basis. The Audit Committee reviews our cybersecurity risk profile with management on a periodic basis using key performance and/or risk indicators. These key performance indicators are industry-standard metrics and measurements designed to assess the effectiveness of our cybersecurity program in the prevention, detection, mitigation, and remediation of cybersecurity incidents.

We take a risk-based approach to cybersecurity and have implemented cybersecurity policies throughout our operations that are designed to address cybersecurity threats and incidents. The Company's Head of IT is responsible for the establishment and maintenance of our cybersecurity program, as well as the assessment and management of cybersecurity risks. The current Head of IT has over 20 years of experience in information security and possesses the requisite education, skills and experience expected of an individual assigned to these duties. In addition to individual skills, the Head of IT has partnered with several third-party Cybersecurity experts to identify new areas of risk and the latest trends in security tools and methods.

Item 2. Properties.

We occupy an approximately 42,500 square foot facility in Malvern, Pennsylvania, under a lease that ends in February 2028, for our corporate headquarters, which includes office and warehouse space. We have an option to extend the lease for an additional five-year term. We also occupy an approximately 9,600 square foot facility in Charlotte, North Carolina, under a lease that ends in 2027, which is being used as a training facility for our NeuroStar Advanced Therapy Systems. We have an option to extend the lease for an additional one-year term. We believe that our existing facilities are adequate to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

The Company is subject from time to time to various claims and legal actions arising during the ordinary course of its business. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition, or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "STIM" since June 28, 2018. Prior to that time, there was no public market for our common stock. The shares of our common stock sold in our IPO on June 27, 2018 were priced at $17.00 per share. The shares of our common stock sold in our secondary public offering and sale of our common stock on February 2, 2021 were priced at $15.50 per share.

Holders of Record

As of February 29, 2024, there were approximately 54 holders of record of our common stock, solely based upon the count our transfer agent provided to us as of that date.

Sales of Unregistered Securities

None.

Equity Compensation Plans

The following table details information regarding our existing equity compensation plans as of December 31, 2023:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (in thousands) (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities reflected in Column (a) (in thousands) (c)
Equity compensation plans approved by security holders	1,270	$ 3.90	2,028
Equity compensation plans not approved by security holders	—	—	(1) 285
Total	1,270	$ 3.90	2,313

(1) This number includes 284.9 thousand shares available for issuance under the 2020 Inducement Incentive Plan as of December 31, 2023.

See "Item 15. Exhibits and Financial Statement Schedules — Notes to Financial Statements — Note 13. Stockholders' Equity, Note 15. Share-Based Compensation and Note 16. Employee Benefit Plans" for additional information on compensation plans under which equity securities of the registrant are authorized for issuance without the approval of stockholders.

Issuer Purchases of Equity Securities

None

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the ''Risk Factors'' section of this Annual Report on Form 10-K for a discussion of important factors that could cause our 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 commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from neurohealth disorders. Our first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses TMS to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the FDA to treat adult patients with MDD that have failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. NeuroStar Advanced Therapy System is safe, clinically effective, reproducible and precise and we believe is supported by the largest clinical data set of any competing TMS system. We believe we are the market leader in TMS therapy based on the estimated 169,068 global patients treated with over 6.1 million of our treatment sessions through December 31, 2023. We generated revenues of $71.3 million and $65.2 million for the years ended December 31, 2023 and 2022, respectively.

We designed the NeuroStar Advanced Therapy System as a non-invasive therapeutic alternative to treat patients who suffer from MDD and to address many of the key limitations of existing treatment options. We generate revenues from initial capital sales of our systems, sales of our recurring treatment sessions and from service and repair and extended warranty contracts. We derive the majority of our revenues from recurring treatment sessions. For the year ended December 31, 2023, revenues from sales of our treatment sessions and NeuroStar Advanced Therapy Systems represented 73% and 24% of our U.S. revenues, respectively. For the year ended December 31, 2022, revenues from sales of our treatment sessions and NeuroStar Advanced Therapy Systems represented 71% and 26% of our U.S. revenues, respectively.

We currently sell our NeuroStar Advanced Therapy System and recurring treatment sessions in the United States through our sales and customer support team. Our sales force targets an estimated 53,000 psychiatrists across 26,000 practices. We expect to continue to expand our direct sales and customer support team to further penetrate the market by demonstrating the benefits of our NeuroStar Advanced Therapy System to psychiatrists and their MDD patients. Some of our customers have and may purchase more than one NeuroStar Advanced Therapy System. Based on our commercial data, we believe psychiatrists can recoup their initial capital investment in our system by providing a standard course of treatment to approximately 12 patients. We believe psychiatrists can generate approximately $8,500 of average revenue per patient for a standard course of treatment, which may provide meaningful incremental income to their

practices. We have a diverse customer base of psychiatrists in group psychiatric practices in the United States. For the years ended December 31, 2023, 2022 and 2021 one customer accounted for 15%, 17% and 20% respectively, of the Company's revenue. Patients are reimbursed by federal healthcare programs and the vast majority of commercial payors in the United States for treatment sessions utilizing our NeuroStar Advanced Therapy System.

We market our products in a few select markets outside the United States through independent distributors. International revenues represented 3% of our total revenues for the years ended December 31, 2023 and 2022, respectively. In October 2017, we entered into an exclusive distribution agreement with Teijin, for the distribution of our NeuroStar Advanced Therapy Systems and treatment sessions to customers who will treat patients with MDD in Japan. We received regulatory approval for our system in Japan in September 2017. We obtained reimbursement coverage for NeuroStar Advanced Therapy System in Japan, which went into effect on June 1, 2019 and covers patients who are treated in the largest inpatient and outpatient psychiatric facilities in Japan. We expect our international revenues to be consistent as a percentage of our total revenue.

Our research and development efforts are focused on the following: hardware and software product developments and enhancements of our NeuroStar Advanced Therapy System and clinical development relating to additional indications. We outsource the manufacture of components of our NeuroStar Advanced Therapy Systems that are produced to our specifications, and individual components are either shipped directly from our third-party contract manufacturers to our customers or consolidated into pallets at our Malvern, Pennsylvania facility prior to shipment. Final installation of these systems occurs at the customer site.

Our total revenues increased by $6.1 million, or 9%, from $65.2 million for the year ended December 31, 2022 to $71.3 million for the year ended December 31, 2023. For the year ended December 31, 2023, our U.S. revenues were $69.3 million, compared to $63.4 million for the year ended December 31, 2022, which represented an increase of 9% period over period. As of December 31, 2023, we had an accumulated deficit of $376.1 million.

Components of Our Results of Operations

Revenues

To date, we have generated revenues primarily from the capital portion of our business and related sales and rentals of the NeuroStar Advanced Therapy System and the recurring revenues from our sale of treatment sessions in the United States.

NeuroStar Advanced Therapy System Revenues. NeuroStar Advanced Therapy System revenues consist primarily of sales or rentals of a capital component, including equipment upgrades to the initial sale of the system. NeuroStar Advanced Therapy Systems can be purchased outright or on a rent-to-own basis by certain customers.

Treatment Session Revenues. Treatment session revenues primarily include sales of NeuroStar Treatment Sessions and SenStar treatment links. The NeuroStar Treatment Sessions are access codes that are delivered electronically in the United States. The SenStar treatment links are disposable units containing single-use access codes that are sold and used outside the United States. Access codes are purchased separately by our customers, primarily on an as-needed basis, and are required by the NeuroStar Advanced Therapy System in order to deliver treatment sessions.

Other Revenues. Other revenues are derived primarily from service and repair extended warranty contracts with our existing customers.

We refer you to the section titled “Critical Accounting Policies and Use of Estimates—Revenue Recognition” appearing elsewhere in this Annual Report on Form 10-K for additional information regarding how we account for revenues.

Sales in the United States represented 97% of our total revenues for the years ending December 31, 2023 and 2022, respectively, and have been generated by our direct sales force. Outside the United States, our sales are made through local third-party distributors. International revenues were 3% for the years ended December 31, 2023 and 2022, respectively. We expect that both our United States and international revenues will increase in the near term as we continue to expand active customer sites utilizing our NeuroStar Advanced Therapy Systems and increase the related patient utilization in the United States, as well as grow our presence in Japan. We expect our revenues to be positively impacted to the extent our direct sales force is successful in increasing the rate of adoption and utilization of treatment with TMS Therapy as an alternative to other MDD treatments.

Cost of Revenues and Gross Margin

Cost of revenues primarily consists of the costs of components and products purchased from our third-party contract manufacturers of our NeuroStar Advanced Therapy Systems as well as the cost of treatment packs for individual treatment sessions. We use third-party contract manufacturing partners to produce the components for and assemble the completed NeuroStar Advanced Therapy Systems. Cost of revenues also includes costs related to personnel, royalties, warranty, shipping, amortization of capitalized software and our operations and field service departments. We expect our cost of revenues to decrease as our product mix changes and we realize efficiencies with our new contract manufacturer.

Our gross profit is calculated by subtracting our cost of revenues from our revenues. We calculate our gross margin as our gross profit divided by our revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily product sales mix, pricing and third-party contract manufacturing costs. Our gross margins on revenues from sales of NeuroStar Advanced Therapy Systems are lower than our gross margins on revenues from sales of treatment sessions and, as a result, the sales mix between NeuroStar Advanced Therapy Systems and treatment sessions can affect the gross margin in any reporting period.

Sales and marketing Expenses

Sales and marketing expenses consist of market research and commercial activities related to the sale of our NeuroStar Advanced Therapy Systems and treatment sessions and salaries and related benefits, sales commissions and share-based compensation for employees focused on these efforts. Other significant sales and marketing costs include conferences and trade shows, promotional and marketing activities, including direct and online marketing, practice support programs, primarily digital media campaigns, travel and training expenses.

We anticipate that our sales and marketing expenses will remain materially consistent during 2024 compared to 2023 expenses, with the exception of the planned growth in our co-op marketing program.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, including salaries and related benefits, share-based compensation and travel expenses, for employees in executive, finance, information technology, legal and human resource functions. General and administrative expenses also include the cost of insurance, outside legal fees, accounting and other consulting services, audit fees from our independent registered public accounting firm, board of directors’ fees and other administrative costs, such as corporate facility costs, including rent, utilities, depreciation and maintenance not otherwise included in cost of revenues.

We anticipate that our general and administrative expenses will remain relatively consistent during 2024 compared to our 2023 expenses.

Research and Development Expenses

Research and development expenses consist primarily of personnel expenses, including salaries and related benefits and share-based compensation for employees in clinical development, product development, regulatory and quality assurance functions, as well as expenses associated with outsourced professional scientific development services and costs of investigative sites and consultants that conduct our preclinical and clinical development programs. We typically use our employee, consultant and infrastructure resources across our research and development programs.

We plan to incur research and development expenses for the near future as we expect to continue our development of TMS Therapy for the treatment of additional patient populations and new indications related to neurohealth disorders, as well as for various hardware and software development projects. As a result, we expect our research and development expenses to increase during 2024 compared to our 2023 expenses.

Interest Expense

Interest expense consists of cash interest payable under our credit facility and non-cash interest attributable to the accrual of final payment fees and the amortization of deferred financing costs related to our indebtedness.

Other Income, Net

Other income, net consists primarily of interest income earned on our money market account balances and notes receivable.

Results of Operations

Comparison of the Years ended December 31, 2023 and 2022

	Years ended December 31,		Increase / (Decrease)	
	2023	2022	Dollars	Percentage
	(in thousands, except percentages)			
Revenues	$ 71,348	$ 65,206	$ 6,142	9 %
Cost of revenues	19,643	15,483	4,160	27 %
Gross Profit	51,705	49,723	1,982	4 %
Gross Margin	*72.5 %*	*76.3 %*		
Operating expenses:				
Sales and marketing	47,318	49,982	(2,664)	(5)%
General and administrative	25,426	25,516	(90)	(0)%
Research and development	9,515	9,336	179	2 %
Total operating expenses	82,259	84,834	(2,575)	(3)%
Loss from Operations	(30,554)	(35,111)	4,557	13 %
Other (income) expense:				
Interest expense	5,424	4,251	1,173	28 %
Other income, net	(5,789)	(2,203)	(3,586)	(163)%
Net Loss	$ (30,189)	$ (37,159)	$ 6,970	19 %

Revenues by Geography
Years ended December 31,

	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
United States	$ 69,336	97 %	$ 63,406	97 %
International	2,012	3 %	1,800	3 %
Total revenues	$ 71,348	100 %	$ 65,206	100 %

U.S. Revenues by Product Category
Years ended December 31,

	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 16,460	24 %	$ 16,575	26 %
Treatment sessions	50,896	73 %	45,077	71 %
Other	1,980	3 %	1,754	4 %
Total U.S. revenues	$ 69,336	100 %	$ 63,406	100 %

United States NeuroStar Advanced Therapy System
Revenues by Type
Years ended December 31,

	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar capital	$ 15,805	96 %	$ 15,792	95 %
Operating lease	162	1 %	222	1 %
Other	493	3 %	561	3 %
Total United States NeuroStar Advanced Therapy System revenues	16,460	100 %	$ 16,575	100 %

Revenues

Total revenues increased by $6.1 million, or 9%, from $65.2 million for the year ended December 31, 2022 to $71.3 million for the year ended December 31, 2023. For the period ended December 31, 2023, U.S. revenue increased by 9% and international revenue increased by 12% over the comparative prior year period. The U.S. revenue growth was primarily due to an increase in Treatment sessions revenues in connection with the growth of active customer sites and utilization.

Revenues in the United States increased by $5.9 million, or 9%, from $63.4 million for the year ended December 31, 2022 to $69.3 million for the year ended December 31, 2023. NeuroStar Advanced Therapy System revenue in the United States for year ended December 31, 2023 was $16.5 million which was in line with revenue at December 31, 2022 at $16.6 million. NeuroStar capital sales consisted of 204 units in NeuroStar Advanced Therapy Systems for the year ended December 31, 2023 compared to 213 units for the year ended December 31, 2022. The Company expects to recognize future recurring treatment session revenue related to the sale of 204 NeuroStar Advanced Therapy systems for the year ended December 31, 2023.

Treatment sessions revenues represented 73% and 71% of total revenues in the United States for the years ended December 31, 2023 and 2022, respectively, and increased by 13% from $45.1 million for the year ended December 31, 2022 to $50.9 million for the year ended December 31, 2023. The increase in U.S. treatment session revenue was primarily the result of an increase of 218,244 treatment sessions sold from 572,587 units for the year ended December 31, 2022 to 791,023 for the year ended December 31, 2023. We

believe the increase in overall volume of treatment session revenue between these two periods was primarily due to the growth in active customer sites of 44 from 1,101 as of December 31, 2022 to 1,145 as of December 31, 2023 and increase in overall utilization. Due to the time it takes for the customer sites to become fully operational, treatment session revenue will lag in the growth of our active customer sites.

Cost of Revenues and Gross Margin

Cost of revenues increased by $4.2 million, or 27%, from $15.5 million for the year ended December 31, 2022 to $19.6 million for the year ended December 31, 2023. This increase was primarily due to the recording of a $1.9 million inventory impairment for specialized component parts secured for discontinued NeuroStar Advanced Therapy Systems for which costs exceed net realizable value. Also capitalized software and the corresponding amortization expense increased by $1.3 million associated with the latest product release. One-time expense relating to our transition to a new contract manufacturer amounted to $0.7 million. Gross margin was 72.5% for the year ended December 31, 2023 compared to 76.3% for the year ended December 31, 2022. The decrease in gross margin was driven by the one-time inventory impairment, the higher operational costs related to our transition to a new third-party contract manufacturing partner and software amortization expense from the latest product release.

Sales and marketing Expenses

Sales and marketing expenses decreased by $2.7 million, or 5%, from $50.0 million for the year ended December 31, 2022 to $47.3 million for the year ended December 31, 2023. The decrease was primarily driven by the discontinuation of a sales compensation program in 2023. Neuronetics offered a retention program to sales personnel in 2022 and did not continue the program in 2023, resulting in a decrease in sales personnel expense. The decrease was partially offset by an increase in marketing program spend, specifically the growth in the co-op marketing initiative.

General and Administrative Expenses

General and administrative expenses remained relatively consistent at $25.4 million for the year ended December 31, 2023 compared with $25.5 million for the year ended December 31, 2022.

Research and Development Expenses

Research and development expenses remained relatively consistent at $9.5 million for the year ended December 31, 2023 compared with $9.3 million for the year ended December 31, 2022

Interest Expense

Interest expense increased by $1.2 million, or 28%, from $4.2 million for the year ended December 31, 2022 to $5.4 million for the year ended December 31, 2023 due to interest rates and debt balance increases.

Other Income, Net

Other income, net increased by $3.5 million from $2.2 million for the year ended December 31, 2022 to $5.8 million for the year ended December 31, 2023, primarily as a result of the Employee Retention Credit (the “ERC”) of $2.9 million, increased interest income earned on the Company’s money market accounts and increase in notes receivable interest.

Comparison of the Years ended December 31, 2022 and 2021

The information required within this section is incorporated by reference to the information set forth in the section titled “Comparison of the Years ended December 31, 2022 and 2021” in “Management’s Discussion

and Analysis of our Financial Condition and Results of Operations" in our 2022 Annual Report on Form 10-K filed on March 7, 2023.

Liquidity and Capital Resources

Overview

As of December 31, 2023, we had cash and cash equivalents of $59.7 million and an accumulated deficit of $376.1 million, compared to cash and cash equivalents of $70.3 million and an accumulated deficit of $345.9 million as of December 31, 2022. We incurred negative cash flows from operating activities of $32.0 million and $30.7 million for the years ended December 31, 2023 and 2022, respectively. We have incurred operating losses since our inception, and we anticipate that our operating losses will continue in the near term as we seek to expand our sales and marketing initiatives to support our growth in existing and new markets, invest funds in additional research and development activities and utilize cash for other corporate purposes. Our primary sources of capital to date have been from our IPO, private placements of our convertible preferred securities, borrowings under our credit facility, sales of our products and a secondary public offering of our common stock. As of December 31, 2023, we had $60.0 million of borrowings outstanding under our credit facility, which has a final maturity in March 2028. Management believes that the Company's cash and cash equivalents as of December 31, 2023 and anticipated revenues from sales of its products are sufficient to fund the Company's operations for at least 12 months.

If our cash and cash equivalents and anticipated revenues from sales or our products are insufficient to satisfy our liquidity requirements, we may seek to sell additional common or preferred equity or debt securities or enter into a new credit facility or another form of third-party funding or seek other debt financing. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all. It is also possible that we may allocate significant amounts of capital towards products or technologies for which market demand is lower than expected and, as a result, abandon such efforts. If we are unable to maintain our current financing or obtain adequate additional financing when we require it, or if we obtain financing on terms which are not favorable to us, or if we expend capital on products or technologies that are unsuccessful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may be required to delay the development, commercialization and marketing of our products.

Our current and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve operating margins;
- compliance with the terms and conditions, including covenants, set forth in our credit facility;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our ability to improve or maintain coverage and reimbursement arrangements with domestic third-party and government payors, particularly in Japan;
- our rate of progress in establishing coverage and reimbursement arrangements from international commercial third-party and government payors;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and maintaining or improving our sales to our current customers;

- the cost of research and development activities, including research and development relating to additional indications of neurohealth disorders;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

The Company's material cash requirements include the following contractual and other obligations.

Debt

In March 2020, the Company entered into the Solar Facility. As of December 31, 2023, the Company had $60.0 million of borrowings outstanding under the Solar Facility, which has a final maturity in March 2028. The interest rate on borrowings under the credit facility is variable and resets monthly. The Company will commence principal payments on the facility starting April 2026 with total borrowings of $60.0 million due at maturity. In addition, the Company will make a final payment fee of $1.9 million at maturity. Future interest payments related to the facility total $22.0 million, including $6.7 million due within the next twelve months as of December 31, 2023.

On March 7, 2024, the Company entered into a sixth amendment (the "Solar Sixth Amendment") to the Solar Facility.

Under the Solar Sixth Amendment, Solar (i) waived the specified events with respect to the Company's non-compliance with the required revenue under the net product revenue covenant and (ii) amended the financial covenants to reflect current projections.

The foregoing summary of the Solar Sixth Amendment does not purport to be complete and is qualified in its entirety by reference to the Solar Sixth Amendment, a copy of which is filed as Exhibit 10.9 hereto and incorporated herein by reference.

Leases

The Company has lease arrangements for equipment and certain facilities, including corporate headquarters and our warehouse in Malvern, Pennsylvania and a training facility in Charlotte, North Carolina. As of December 31, 2023, the Company had fixed lease payment obligations of $3.7 million, including $0.9 million due within the next twelve months.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2023, 2022, and 2021:

	December 31,		
	2023	2022	2021
Net Cash Used in Operating Activities	$ (32,038)	$ (30,739)	$ (27,983)
Net Cash (Used in) Provided by Investing Activities	(1,322)	6,731	(9,839)
Net Cash Provided by Financing Activities	22,697	207	83,006
Net (Decrease) in Cash and Cash Equivalents	$ (10,663)	$ (23,801)	$ 45,184

Net Cash Used in Operating Activities

Net cash used in operating activities for 2023 was $32.0 million, consisting primarily of a net loss of $30.2 million and an increase in net operating assets of $14.1 million, partially offset by non-cash charges of $12.3 million. The increase in net operating assets was primarily due to increases in accounts receivable and prepaid commission expense, and decreases in accrued compensation. Non-cash charges consisted of depreciation and amortization, inventory impairment, non-cash interest expense, share-based compensation, and the cost of rental units purchased by customers.

Net cash used in operating activities for 2022 was $30.7 million, consisting primarily of a net loss of $37.2 million and an increase in net operating assets of $4.8 million, partially offset by non-cash charges of $11.2 million. The increase in net operating assets was primarily due to increases in accounts receivable, inventory and prepaid commission expense, which were offset by increases in accounts payable and accrued expenses as a result of timing and accrued 2022 compensation and commissions as of December 31, 2022. Non-cash charges consisted of depreciation and amortization, non-cash interest expense, share-based compensation, and the cost of rental units purchased by customers.

Net cash used in operating activities for 2021 was $28.0 million, consisting primarily of a net loss of $31.2 million and an increase in net operating assets of $6.6 million, partially offset by non-cash charges of $9.8 million. The increase in net operating assets was primarily due to increases in accounts receivable, inventory and prepaid commission expense, which were offset by increases in accounts payable and accrued expenses as a result of timing and accrued 2021 compensation and commissions as of December 31, 2021. Non-cash charges consisted of depreciation and amortization, non-cash interest expense, share-based compensation, and the cost of rental units purchased by customers.

Net Cash (Used in) Provided by Investing Activities

Net cash (used in) provided by investing activities for the years ended December 31, 2023, 2022 and 2021 was $(1.3) million, $6.7 million and $(9.8) million, respectively. Net cash used in investing activities for the year ended December 31, 2023 was due to payments received on our promissory notes offset partially by purchases of property and equipment and capitalized software costs. Net cash provided by investing activities for the year ended December 31, 2022 was attributable to repayment of a promissory note and purchases of property and equipment and capitalized software costs. Net cash used in investing activities for the year ended December 31, 2021 was attributable to issuance of our promissory note and purchase of property and equipment and capitalized software costs.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $22.7 million attributable primarily to additional debt net of final payment and amendment fee paid in connection with the two amendments of the Solar Facility in 2023.

Net cash provided by financing activities for the year ended December 31, 2022 was $0.2 million attributable primarily to proceeds related to stock option exercises.

Net cash provided by financing activities for the year ended December 31, 2021 was $83.0 million and primarily consisted of additional proceeds from our secondary public offering and sale of our common stock on February 2, 2021 and cash proceeds related to stock option exercises.

Indebtedness

Refer to “Note 12. Debt” in our audited financial statements and related notes thereto appearing elsewhere in this Annual Report on Form 10-K for information regarding our current Solar Facility.

Solar Credit Facility

The following table sets forth by year our required future principal payments under the term loan portion of the Solar Facility (as discussed in “Note 12. Debt”) (in thousands):

Year:	Principal Payments
2024	$ —
2025	—
2026	22,500
2027	30,000
2028	7,500
Total principal payments	$ 60,000

Common Stock Offering

On February 2, 2021, we closed a secondary public offering of our common stock in which we issued and sold 5,566,000 shares of our common stock, which included shares pursuant to an option granted to underwriters to purchase additional shares, at a public offering price of $15.50 per share. We received net proceeds of approximately $80.6 million after deducting underwriting discounts, commissions and estimated offering expenses. The Company intends to use the net proceeds of the offering for general corporate purposes, including working capital, research and development, marketing and evaluating new clinical indications.

Critical Accounting Policies and Use of Estimates

The preparation of our financial statements in accordance with U.S. GAAP and the rules and regulations of the SEC requires us to make estimates and assumptions, based on judgments considered reasonable, which 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. We base our estimates and assumptions on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although we believe our estimates and assumptions are reasonable when made, they are based upon information available to us at the time they are made. We evaluate our estimates and assumptions on an ongoing basis and, if necessary, make adjustments. Due to the risks and uncertainties involved in our business and evolving market conditions and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

We define our critical accounting policies as those accounting policies that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments. While our significant accounting policies are more fully described in “Note 3. Summary of Significant Accounting Policies” in our audited financial statements and related notes thereto appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies.

Revenue Recognition

We account for revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. Under ASC 606, we recognize revenue when control of the promised good or service is transferred to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those good or services. Accordingly, we determine revenue recognition by applying the following steps:

- identification of the contract, or contracts, with a customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;
- allocation of the transaction price to the performance obligations in the contract; and
- recognition of revenue when, or as, we satisfy a performance obligation.

We primarily earn revenues from the sale of NeuroStar Advanced Therapy Systems, consumable use treatment sessions, and accessory products. A contract's transaction price is allocated to each performance obligation and recognized as revenue when, or as, the performance obligation is satisfied, which generally is the point in time when the product is shipped or control is transferred. We sell to end users in the United States and to third-party distributors outside the United States and do not provide return rights. Sales to distributors outside the United States are made in U.S. dollars.

Revenue attributable to the NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis are accounted for either (1) as operating leases and revenue is recognized on a straight-line basis over the term of the lease; or (2) as a sales-type lease and revenue is recognized upon installation.

Our NeuroStar Advanced Therapy System sales in the United States typically have a post-sale training obligation. This obligation is fulfilled after product shipment, and we defer recognizing revenue until training occurs. We defer the fair value attributable to the post shipment training and recognize such revenue when the obligation is fulfilled. We base the fair value of the training using stand-alone service rates. Our sales to our third-party distributors outside the United States do not have these post-sale obligations.

In addition, we provide a one-year warranty for systems sold in the United States. Terms of product warranty differ amongst our third-party distributors outside the United States, but are generally one year. We provide for the estimated cost to repair or replace products under any warranty at the time of sale. We also offer our customers in the United States annual service contracts. Revenue from the sale of annual service contracts is recognized on a straight-line basis over the period of the applicable contract. We also earn revenue from customers from services outside of their warranty term or annual service contracts. Such service revenue is recognized as the services are provided.

Recent Accounting Pronouncements

We refer you to "Note 4. Recent Accounting Pronouncements" in our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our cash is held in an insured cash sweep account at a large financial institution, which manages our risk by limiting the amount of cash in any one financial institution up to $250,000. These balances are insured by the Federal Deposit Insurance Corporation ("FDIC"), which provides an insurance coverage limit of $250,000 per

depositor, per FDIC-insured bank, per ownership category. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with limited credit risk to us.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents and accounts receivable. We limit our credit risk associated with cash equivalents by placing investments in highly-rated money market funds. We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers.

As discussed in “Note 12. Debt” in our audited financial statements and related notes thereto appearing elsewhere in of this Annual Report on Form 10-K, our credit facility bears interest which resets monthly and is equal to the greater of (a) 3.95% or (b) Daily Simple Secured Overnight Financing Rate (“SOFR”) for a term of one month, plus 5.65%. As a result, a 1% increase in interest would result in approximately $0.6 million in additional interest expense.

Inflationary factors, such as increases in our cost of revenues and operating expenses, may adversely affect our operating results. Although we do not believe inflation has had a material impact on our financial condition, results of operations or cash flows to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenues if our selling prices of our products do not increase as much or more than our costs increase.

We do not currently have any exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Item 8. Financial Statements and Supplementary Data.

The financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K and incorporated by reference herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2023 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2023 at the reasonable assurance level.

This Annual Report on Form 10-K does not include an attestation report of internal control over financial reporting from our independent registered public accounting firm due to our status as a smaller reporting company.

Changes in Internal Control over Financial Reporting

During the fourth quarter ended December 31, 2023, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in the information set forth in the sections titled "Proposal 1 - Election of Directors," "Information Regarding the Board of Directors and Corporate Governance" and "Executive Officers of the Company" contained in "Delinquent Section 16(a) Reports" in our 2024 Proxy Statement.

Item 11. Executive Compensation.

The information required by this item will be included in information set forth in the section titled "Executive Compensation" in our 2024 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation" in our 2024 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in information set forth in the section titled "Transactions with Related Persons" and "Information regarding the Board of Directors and Corporate Governance" in our 2024 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in information set forth in the section titled "Principal Accountant Fees and Services" contained in "Proposal 2 – Ratification of Selection of Independent Registered Public Accounting Firm" in our 2024 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes listed in the Index to Financial Statements beginning on page F-1.

(b) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Exhibit Index

Exhibit Number	Description of Exhibit
3.1	Ninth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed July 6, 2018)
3.2	Certificate of Amendment to the Registrant's Ninth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Form 8-K filed May 30, 2019)
3.3	Fourth Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed December 29, 2022)
3.4	Certificate of Designations of Series A Junior Participating Preferred Stock of Neuronetics, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed April 8, 2020)
3.5	Certificate of Elimination of Series A Junior Participating Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed April 9, 2021)
4.1	Specimen Stock Certificate evidencing shares of common stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K filed on March 3, 2020)
10.1◊	Distribution Agreement, by and between the Registrant and Teijin Pharma Limited, dated October 12, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.2◊	Amendment No. 1 to Distribution Agreement, by and between the Registrant and Teijin Pharma Limited, dated May 31, 2019 (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed August 6, 2019)
10.3	Form of Indemnification Agreement between the Registrant and its non-employee directors and officers (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.4	Loan and Security Agreement by and between Solar Capital Ltd., the lenders identified therein and the Registrant, dated March 2, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 3, 2020)
10.5	Second Amendment to Loan and Security Agreement, by and among Solar Capital Ltd., as collateral agent, the lenders listed on the signature pages thereto, and the Registrant, dated December 2, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 8, 2020)
10.6	Third Amendment to Loan and Security Agreement, by and among SLR Investment Corp. (formerly known as Solar Capital Ltd.), as collateral agent, the lenders listed on the signature pages thereto, and the Registrant, dated February 15, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 22, 2022)

10.7	Fourth Amendment to Loan and Security Agreement, dated March 29, 2023, by and among SLR Investment Corp. (formerly known as Solar Capital Ltd.), as collateral agent, the lenders listed on the signature pages thereto, and Neuronetics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 4, 2023).
10.8	Fifth Amendment to Loan and Security Agreement, dated September 29, 2023, by and among SLR Investment Corp. (formerly known as Solar Capital Ltd.), as collateral agent, the lenders listed on the signature pages thereto, and Neuronetics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 3, 2023).
10.9*◊	Sixth Amendment to Loan and Security Agreement, dated March 7, 2024, by and among SLR Investment Corp. (formerly known as Solar Capital Ltd.), as collateral agent, the lenders listed on the signature pages thereto, and Neuronetics, Inc.
10.10+	Amended and Restated 2003 Stock Incentive Plan of the Registrant, as amended (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.11+	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on November 6, 2018)
10.12+	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on November 6, 2018)
10.13	Neuronetics, Inc. 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-8 (File No. 333-252233) filed January 19, 2021)
10.14	Lease Agreement by and between Exeter 3222 Phoenixville, L.P., and the Registrant, dated January 3, 2013 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-225307))
10.15	First Amendment dated March 22, 2019 to Lease Agreement by and between Exeter 3222 Phoenixville, L.P., and the Registrant, dated January 3, 2013 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-225307))
10.16+	Form of Non-Qualified Stock Option Agreement for the Amended and Restated 2003 Stock Incentive Plan, as amended, of the Registrant (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.17+	Form of Incentive Stock Option Agreement for the Amended and Restated 2003 Stock Incentive Plan, as amended, of the Registrant (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.18+	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.19+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.20+	Form of Severance Agreement (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.21+	Form of Restrictive Covenant and Invention Assignment Agreement (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.22*+	Form of Restrictive Covenant and Severance Agreement
10.23	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.24+	Employment Offer Letter Agreement between the Registrant and Stephen Furlong dated July 1, 2019 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed July 2, 2019)
10.25+	Employment Agreement, dated July 14, 2020, by and between the Registrant and Keith J. Sullivan, dated July 14, 2020, (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 17, 2020)
10.26*+	Amended and Restated Employment Agreement, dated November 2, 2023 by and between the Registrant and Keith J. Sullivan
10.27*+	Amended and Restated Restrictive Covenant and Severance Agreement dated November 2, 2023 by and between the Registrant and Keith J. Sullivan

10.28*+◊	Employment Offer Letter Agreement dated November 25, 2019 by and between the Registrant and Andrew Macan
10.29+	Form of Neuronetics, Inc. Performance Restricted Stock Unit Grant Notice and Award Agreement under Nasdaq Listing Rule 5635(c)(4) (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.30+	Form of Neuronetics, Inc. Performance Restricted Stock Unit Grant Notice and Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.31+	Form of Neuronetics, Inc. Restricted Stock Unit Grant Notice and Award Agreement under Nasdaq Listing Rule 5635(c)(4) (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.32+	Form of Neuronetics, Inc. Stock Option Grant Notice and Agreement (Nonstatutory Stock Option) under Nasdaq Listing Rule 5635(c)(4) (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.33+	Performance Restricted Stock Unit Grant Notice and Award Agreement, dated July 14, 2020, by and between the Registrant and Keith J. Sullivan (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.34+	Restricted Stock Unit Grant Notice and Award Agreement, dated July 14, 2020, by and between the Registrant and Keith J. Sullivan (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.35+	Stock Option Grant Notice and Agreement (Nonstatutory Stock Option), dated July 14, 2020, by and between the Registrant and Keith J. Sullivan (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546) filed on August 4, 2020)
10.36+	Neuronetics, Inc. 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-8 (File No. 333-252233) filed January 19, 2020)
10.37+	Form of Neuronetics, Inc. Performance Restricted Stock Unit Grant Notice and Award Agreement under the 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-8 (File No. 333-252233) filed January 19, 2020)
10.38+	Form of Neuronetics, Inc. Restricted Stock Unit Grant Notice and Award Agreement under the 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-8 (File No. 333-252233) filed January 19, 2020)
10.39+	Form of Neuronetics, Inc. Stock Option Grant Notice and Agreement (Nonstatutory Stock Option) under the 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-8 (File No. 333-252233) filed January 19, 2020)
10.40+	Secured Promissory Note, by and between Check Five LLC d/b/a Success TMS and the Registrant, dated September 29, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed October 5, 2021)
10.41	Secured Promissory Note, by and between Check Five LLC d/b/a Success TMS and the Registrant, dated September 29, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed October 5, 2021)
10.42	Subordination Agreement, by and between ZW Partners, LLC and the Registrant, dated April 29, 2022 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 5, 2022)
23.1*	Consent of KPMG LLP, independent registered public accounting firm
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
97.1*	Clawback Policy
101*	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, were formatted in Inline XBRL (Extensible Business Reporting Language): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Changes in Stockholders' Equity, (iv) Statements of Cash Flows, and (v) Notes to Financial Statements. The instance document does

not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

104* Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* Filed herewith

\+ Indicates management contract or compensatory plan.

◊ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The Company will furnish copies of any such information to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

Not applicable.

NEURONETICS, INC.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Neuronetics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Neuronetics, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Sufficiency of audit evidence obtained over revenue

As discussed in Note 3 to the financial statements, the Company recorded $71.3 million of revenue for the year ended December 31, 2023. The majority of the Company's revenue contracts are comprised of the following performance obligations: (1) NeuroStar Advanced Therapy Systems (the System), (2) NeuroStar Treatment Sessions, (3) separately priced extended warranties and when-and-if-available upgrade rights, and

(4) system clinical and reimbursement training. The Company also offers certain customers the option to lease the System. Additionally, the Company has an exclusive distribution agreement with a foreign entity. We identified the evaluation of the sufficiency of audit evidence obtained over revenue as a critical audit matter. Evaluating the sufficiency of audit evidence obtained required subjective auditor judgment due to the number of revenue streams involved in the process. This included determining the revenue streams over which procedures were performed and evaluating the nature and extent of evidence obtained over each revenue stream.

The following are the primary procedures we performed to address this critical audit matter. We applied auditor judgment to determine the nature and extent of procedures to be performed over revenue, including the determination of the revenue streams over which procedures were to be performed. For certain revenue streams, we evaluated the design and implementation of certain internal controls over the Company's revenue process. For each revenue stream for which procedures were performed, we assessed the recorded revenue by selecting a sample of revenue transactions and comparing the amounts recognized for consistency with relevant underlying documentation, including payment received, delivery confirmation, and/or external confirmation. We evaluated the sufficiency of audit evidence obtained over revenue by assessing the results of the procedures performed, including the appropriateness of the nature and extent of such evidence.

/s/ KPMG LLP

We have served as the Company's auditor since 2003.

Philadelphia, Pennsylvania
March 7, 2024

NEURONETICS, INC.
Balance Sheets
(In thousands, except per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 59,677	$ 70,340
Accounts receivable, net	15,782	13,591
Inventory	8,093	8,899
Current portion of net investments in sales-type leases	905	1,538
Current portion of prepaid commission expense	2,514	1,997
Current portion of notes receivable	2,056	230
Prepaid expenses and other current assets	4,766	2,174
Total current assets	93,793	98,769
Property and equipment, net	2,009	1,991
Operating lease right-of-use assets	2,773	3,327
Net investments in sales-type leases	661	1,222
Prepaid commission expense	8,370	7,568
Long-term notes receivable	3,795	362
Other assets	4,430	3,645
Total assets	$ 115,831	$ 116,884
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,752	$ 2,433
Accrued expenses	12,595	14,837
Deferred revenue	1,620	1,980
Current portion of operating lease liabilities	845	824
Current portion of long-term debt, net	—	13,125
Total current liabilities	19,812	33,199
Long-term debt, net	59,283	22,829
Deferred revenue	200	829
Operating lease liabilities	2,346	2,967
Total liabilities	81,641	59,824
Commitments and contingencies (Note 18)	—	—
Stockholders' equity:		
Preferred stock, $0.01 par value: 10,000 shares authorized; no shares issued or outstanding on December 31, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value: 200,000 shares authorized; 29,092 and 27,268 shares issued and outstanding on December 31, 2023 and December 31, 2022, respectively	291	273
Additional paid-in capital	409,980	402,679
Accumulated deficit	(376,081)	(345,892)
Total Stockholders' equity	34,190	57,060
Total liabilities and Stockholders' equity	$ 115,831	$ 116,884

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.
Statements of Operations
(In thousands, except per share data)

	Years ended December 31,		
	2023	2022	2021
Revenues	$ 71,348	$ 65,206	$ 55,312
Cost of revenues	19,643	15,483	11,653
Gross profit	51,705	49,723	43,659
Operating expenses:			
Sales and marketing	47,318	49,982	37,746
General and administrative	25,426	25,516	25,554
Research and development	9,515	9,336	7,923
Total operating expenses	82,259	84,834	71,223
Loss from operations	(30,554)	(35,111)	(27,564)
Other (income) expense:			
Interest expense	5,424	4,251	4,019
Other income, net	(5,789)	(2,203)	(390)
Net loss	$ (30,189)	$ (37,159)	$ (31,193)
Net loss per share of common stock outstanding, basic and diluted	$ (1.05)	$ (1.38)	$ (1.22)
Weighted-average common shares outstanding, basic and diluted	28,658	26,900	25,479

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.
Statements of Changes in Stockholders' Equity
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	19,114	$ 191	$ 302,842	$ (277,540)	$ 25,493
Share-based awards and options exercises	1,715	17	2,418	—	2,435
Issuance of common stock, net of issuance costs of $401	5,566	56	80,515	—	80,571
Share-based compensation expense	—	—	7,869	—	7,869
Net loss	—	—	—	(31,193)	(31,193)
Balance at December 31, 2021	26,395	264	393,644	(308,733)	85,175
Share-based awards and options exercises	873	9	289	—	298
Share-based compensation expense	—	—	8,746	—	8,746
Net loss	—	—	—	(37,159)	(37,159)
Balance at December 31, 2022	27,268	273	402,679	(345,892)	57,060
Share-based awards and options exercises	1,824	18	(18)	—	—
Share-based compensation expense	—	—	7,319	—	7,319
Net loss	—	—	—	(30,189)	(30,189)
Balance at December 31, 2023	29,092	$ 291	$ 409,980	$ (376,081)	$ 34,190

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.
Statements of Cash Flows
(In thousands)

	Years ended December 31,		
	2023	**2022**	**2021**
Cash flows from Operating activities:			
Net loss	$ (30,189)	$ (37,159)	$ (31,193)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,006	1,648	1,060
Allowance for credit losses	390	341	763
Inventory impairment	1,905	—	—
Share-based compensation	7,319	8,746	7,869
Non-cash interest expense	634	709	715
Cost of rental units purchased by customers	—	92	203
Changes in certain assets and liabilities:			
Accounts receivable, net	(8,831)	(6,658)	(3,817)
Inventory	(1,098)	(2,587)	(3,444)
Net investments in sales-type leases	1,193	1,114	324
Prepaid commission expense	(1,319)	(1,243)	(1,926)
Prepaid expenses and other assets	(2,845)	786	62
Accounts payable	2,029	(1,968)	276
Accrued expenses	(2,243)	6,604	910
Deferred revenue	(989)	(1,164)	215
Net Cash used in Operating activities	(32,038)	(30,739)	(27,983)
Cash flows from Investing activities:			
Purchases of property and equipment and capitalized software	(2,369)	(3,269)	(2,353)
Repayment (issuance) of notes receivable	1,047	10,000	(7,486)
Net Cash (used in) provided by Investing activities	(1,322)	6,731	(9,839)
Cash flows from Financing activities:			
Payments of debt issuance costs	(1,104)	(91)	—
Proceeds from issuance of long-term debt	25,000	—	—
Repayment of long-term debt	(1,200)	—	—
Proceeds from the issuance of common stock	—	—	80,972
Payments of common stock offering issuance cost	—	—	(401)
Proceeds from exercises of stock options	1	298	2,435
Net Cash provided by Financing activities	22,697	207	83,006
Net (decrease) increase in Cash and Cash equivalents	(10,663)	(23,801)	45,184
Cash and Cash equivalents, Beginning of Period	70,340	94,141	48,957
Cash and Cash equivalents, End of Period	$ 59,677	$ 70,340	$ 94,141
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 4,790	$ 3,543	$ 3,304
Transfer of inventory to property and equipment	$ 210	$ 250	$ 601
Supplemental disclosure of non-cash investing and financing activities:			
Purchases of property and equipment and capitalized software in accounts payable and accrued expenses	$ 239	$ 103	$ 273
Reduction of accounts receivable in current and long-term notes receivable	$ 6,468	$ 432	$ 2,514

The accompanying notes are an integral part of these financial statements.

1. DESCRIPTION OF BUSINESS

Neuronetics, Inc. (the "Company") is a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from neurohealth disorders. The Company's first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, ("TMS"), to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system was cleared in 2008 by the FDA to treat adult patients with MDD who have failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. The NeuroStar Advanced Therapy System is also available in other parts of the world, including Japan, where it is listed under Japan's national health insurance. The Company intends to continue to pursue development of its NeuroStar Advanced Therapy System for additional indications.

Liquidity

As of December 31, 2023, the Company had cash and cash equivalents of $59.7 million and an accumulated deficit of $376.1 million. The Company incurred negative cash flows from operating activities of $32.0 million, $30.7 million and $28.0 million for the years ended December 31, 2023, 2022 and 2021, respectively. The Company has incurred operating losses since its inception, and management anticipates that its operating losses will continue in the near term as the Company continues to invest in sales and marketing and product development activities. The Company's primary sources of capital to date have been from its initial public offering ("IPO"), private placements of its convertible preferred securities, borrowings under its credit facility, proceeds from its secondary public offering of common stock, and revenues from sales of its products. As of December 31, 2023, the Company had $60.0 million of borrowings outstanding under its credit facility, which matures in March 2028. Management believes that the Company's cash and cash equivalents as of December 31, 2023 and anticipated revenues from sales of our products are sufficient to fund the Company's operations for at least the next 12 months from the issuance of these financial statements.

2. BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Updates ("ASUs"), promulgated by the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP and the rules and regulations of the SEC, requires the use of estimates and assumptions, based on judgments considered reasonable, which 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. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although management believes its estimates and assumptions are reasonable when made, they are based upon information available at the time they are made. Management evaluates the estimates and assumptions on an ongoing basis and, if necessary, makes adjustments. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2023 and 2022, cash equivalents consisted of money market funds.

Concentrations of Credit Risk

The Company's cash is held on deposit in demand accounts at large financial institutions in amounts in excess of the FDIC insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category.

Financial instruments that potentially subject the Company to concentrations of credit risk principally consist of cash equivalents and accounts receivable. The Company limits its credit risk associated with cash equivalents by placing investments in highly-rated money market funds. The Company limits its credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but it does not require collateral to secure amounts owed by its customers.

Allowance for Credit Losses

The Company adopted ASC Topic 326, *Financial Instruments-Credit losses* on January 1, 2023, see note 6 Accounts Receivable for further discussion. The Company monitors accounts receivable and long-term notes receivable and estimates the allowance for lifetime expected credit losses. Estimates of expected credit losses are based on historical collection experience and other factors, including those related to current market conditions and events.

Leases

The Company accounts for leases in accordance with ASC Topic 842, *Leases* ("Topic 842"). The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys to the customer the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the customer has the right to control the use of the identified asset.

The Company leases warehouse, office space, a training facility and office equipment pursuant to net operating leases. Operating leases where the Company is the lessor are included in revenue on the Statements of Operations.

From time to time the Company enters into sales-type lease arrangements that include a lessee obligation to purchase the leased equipment at the end of the lease term, automatic transfer of ownership of the leased equipment at the end of the lease, a lessee purchase option reasonably certain to be exercised, or provides for minimum lease payments with a present value equal to or exceeding substantially all of the fair value of the underlying leased equipment at the date of lease inception. Sales-type leases where the Company is the lessor are included in revenue on the Statements of Operations.

Operating leases where the Company is the lessee are included in operating lease right-of-use assets and operating lease liabilities on the Balance Sheets. The lease liabilities are initially measured at the present value of the unpaid lease payments at the lease commencement date.

The Company uses the following inputs in its lease calculations under Topic 842: (1) the discount rate the Company uses to discount the unpaid lease payments to present value, (2) lease term, and (3) lease payments.

(1) Topic 842 requires a lessor to discount its unpaid lease payments using the interest rate implicit in the lease and a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As the rate implicit in the Company's lease is not readily determinable, the Company uses the incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate for a lease is the rate of interest the Company would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. The Company uses the implicit rate when readily determinable.

(2) The lease term for all leases includes the noncancelable period of the lease plus any additional periods covered by either a lessee option to extend (or not to terminate) the lease that the lessee is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor.

(3) Lease payments included in the measurement of the lease asset or liability comprise the following: fixed payments (including in-substance fixed payments), and the exercise price of a lessee option to purchase the underlying asset if the lessee is reasonably certain to exercise.

For operating leases where the Company is the lessor, the Company continues recognizing the underlying asset and depreciating it over its estimated useful life. Lease income from lessees is recognized on a straight-line basis over the terms of the relevant lease agreement in revenue. Operating leases for equipment with fixed rentals and step rentals are recognized on a straight-line basis over the term of the lease, assuming no renewals, in revenue. Revenue is not recognized when collection is not reasonably assured. When collectability is not reasonably assured, the customer is placed on non-accrual status and revenue is recognized when cash payments are received.

The lease asset for sales-type leases is initially measured as the total net investment in the lease, which comprises the initial amount of the lease receivable plus the deferred initial direct costs.

The lease asset for sales-type leases is subsequently measured throughout the lease term at the carrying amount of the net investment in the lease which is increased by interest income and reduced by lease payments collected. The lease payments are segregated into principal and interest components similar to a loan. Equipment leasing revenues are recognized on an effective interest method over the lease term. The principal component of the lease payment is reflected as a reduction to the net investment in the lease.

For operating leases where the Company is the lessee, the right-of-use ("ROU"), asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. The ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Lease assets for sales-type leases where the Company is the lessor and ROU assets for operating leases where the Company is the lessee are periodically reduced by impairment losses. The Company uses the loans impairment guidance in ASC Subtopic 330-10, Receivables, and the long-lived assets impairment guidance in ASC Subtopic 360-10, Property, Plant, and Equipment – Overall, to determine whether a lease asset or a ROU asset, respectively, is impaired, and if so, the amount of the impairment loss to recognize. For the years ended December 31, 2023 and 2022 the Company did not recognize any impairment losses. The

Company recognized $0.1 million in impairment losses which is included within sales and marketing expense on the Statement of Operations for the year ended December 31, 2021.

The Company monitors for events or changes in circumstances that require a reassessment of its leases. When a reassessment results in the remeasurement of a lease liability, a corresponding adjustment is made to the carrying amount of the corresponding ROU asset unless doing so would reduce the carrying amount of the ROU asset to an amount less than zero. In that case, the amount of the adjustment that would result in a negative ROU asset balance is recorded in profit or loss.

The Company has elected not to recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. The Company recognizes the lease payments associated with the short-term leases as an expense on a straight-line basis over the lease term. Variable lease payments associated with these leases are recognized and presented in the same manner as for all other leases. The Company has elected to exclude sales and other similar taxes from lease payments in arrangements where the Company is a lessor.

Inventory

Inventory is stated at the lower of cost and net realizable value, with cost being determined on a first in, first out basis. The Company's inventory is primarily comprised of finished goods and work-in-process. For the year ended December 31, 2023, the Company recorded a $1.9 million inventory impairment within cost of revenue on the Statements of Operations for a specialized component part secured for discontinued NeuroStar Advanced Therapy Systems to which such cost exceeds net realizable value.

Property and Equipment and Capitalized Software

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Depreciation and amortization are recognized using the straight-line method based on the estimated useful lives of the related assets. The Company uses an estimated useful life of three years for computers and software, five years for laboratory, auto and office equipment, six years for devices in the rental agreement program and the lesser of five years or the remaining life of the underlying facility lease for leasehold improvements.

Software development costs relating to assets to be sold in the normal course of business are included in research and development and are expensed as incurred until technological feasibility is established. After technological feasibility is established, software development costs are capitalized. The Company uses an estimated useful life of two years for capitalized software and amortizes these costs beginning at the product release.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Impairment testing requires management to estimate the future net undiscounted cash flows of an asset using assumptions believed to be reasonable. Actual cash flows may differ from the estimates used in the impairment testing. If such assets are considered to be impaired, the Company recognizes an impairment loss when and to the extent that the estimated fair value of an asset is less than its carrying value. The Company has not recorded any impairment of its long-lived assets for the years ended December 31, 2023, 2022 and 2021.

Notes Receivable

Notes receivable are reported on the Company's Balance Sheet at amortized cost basis. The Company recognizes interest income within other income, net within the Statements of Operations.

Notes receivables are periodically reviewed to determine whether a note receivable is impaired, and if so, the amount of the impairment loss to recognize. For the years ended December 31, 2023 and 2022, there were no impairment charges. For the year ended December 31, 2021, the Company recognized $0.1 million in impairment charges which is included within sales and marketing expense on the Statements of Operations.

Deferred Debt Issuance Costs

The Company capitalizes direct costs incurred to obtain debt financing and amortizes these costs to interest expense over the term of the debt using the effective interest method. These costs are recorded as a debt discount and are netted against the related debt on the Company's Balance Sheets.

Revenue Recognition

ASC Topic 606, *Revenue from Contracts with Customers* ("Topic 606") is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Sales and usage-based taxes are excluded from revenues.

Contract Formation

The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement.

Performance Obligations

The unit of account for Topic 606 is the performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer or a series of distinct goods or services that are substantially the same and have the same pattern of transfer. A contract's transaction price is allocated to each performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The majority of the Company's contracts are comprised of the following performance obligations:

(1) The NeuroStar TMS Therapy System (the "System") which includes a chair, an electromagnet coil, a monitoring console and accessories. The various components are inputs that function together to deliver a combined output and together form one performance obligation (a NeuroStar Advanced Therapy System). Revenues from the sale of the System are satisfied at the point-in-time when shipped from our premises.

(2) NeuroStar Treatment Session (the "Treatment Session") is a single use consumable that is delivered via an encrypted activation code and is required in order for a clinician to perform TMS therapy. Revenues from the sale of the Treatment Sessions are satisfied at the point-in-time when delivered to the customer. The Company determined that sales of Treatment Sessions are not part of the enforceable rights and obligations of the System sales, except when sold with System sales.

(3) Separately priced extended warranties and when-and-if-available upgrade rights are considered service-type warranties. Warranty services are considered stand-ready obligations satisfied over-time and recognized using a straight-line time-based measurement toward completion.

(4) The System clinical and reimbursement training enable the clinician to provide patient treatment. The trainings are not required in order to operate the System but are required in order to receive a certification from the Company and accordingly are not essential to the functionality of other

performance obligations. Training services are recognized at a point-in-time when training is complete, typically simultaneous to or near the time of delivery of the System.

In addition, the Company has determined that there are various perfunctory deliverables such as installation of the System, the technical support hotline and marketing materials which the Company does not separately recognize as revenue nor does the Company accrue the estimated cost of providing these goods and services because they are not material. The Company provides a one-year warranty on all new System sales which were determined to be assurance-type warranties and thus not considered a separate performance obligation. The Company accrues the cost of providing these warranties.

There is no right of return or refund for any of the Company's products or services and the Company has elected to treat shipping and handling as a fulfillment activity and expenses the costs as incurred.

Sales Type Lease

The System is typically purchased but the Company does offer certain customers the option to lease instead. The Company accounts for these leases are typically accounted for as a sales-type lease which results in the derecognition of the underlying asset, the recognition of profit or loss on the sale, and the recognition of an investment in sales-type lease. The investment is periodically increased for interest earned and reduced as lease payments are received.

Distribution Agreement

The Company has an exclusive distribution agreement that began in October 2017 with a foreign entity for a period of 7 ½ years with two 2 year renewal options. As consideration for the right to be the sole distributor of the Company's products and use of the Company's intellectual property in the foreign territory, the distributor is required to make certain fixed milestone payments upon contract execution and regulatory approval. In addition, the distributor is required to make variable milestone payments depending upon regulatory reimbursement rates. Furthermore, the distributor is required to make certain minimum purchases based upon sales history and forecasts subject to a ceiling and floor. The Company assessed the potential performance obligations in this contract and concluded that the contract contained the following performance obligations:

- Exclusive distribution and intellectual property license
- NeuroStar TMS Therapy System
- NeuroStar Treatment Session

The distribution agreement contains pricing for the Company's products and services. The contractual purchase prices were determined to be at the standalone selling prices based on the expected sales volumes of this customer type and thus the Company concluded that this agreement did not contain a separate performance obligation for the material right to discounted Systems and Treatments Sessions. The Company allocated the transaction price through a combination of the cost plus a margin approach and the residual method. For the System and Treatment Sessions the Company maximized the use of observable inputs by beginning with average historical contractual selling prices and adjusting on a consistent and rational basis for pricing trends, the customer type and expected sales volumes and the Company's changing cost and margins. Since it was determined that the contractual selling prices for the Company's products and services in the distribution agreement were at the standalone selling prices, the residual consideration which is made up of the fixed and variable milestone payments was allocated to the exclusive distribution and intellectual property license. The exclusive distribution and intellectual property rights were determined to be symbolic IP and thus recognized over time. The System and Treatment Sessions were determined to be performance obligations recognized at a point-in-time when delivered to the distributor.

Contract Estimates

Accounting for the Company's contracts involves the use of significant judgments and estimates including determining the separate performance obligations, allocating the transaction price to the different performance obligations and determining the method to measure the entity's performance toward satisfaction of performance obligations that most faithfully depicts when control is transferred to the customer. The Company allocates the contract's transaction price to each performance obligation using the Company's best estimate of the standalone selling price for each distinct good or service in the contract. The Company maximizes the use of observable inputs by beginning with average historical contractual selling prices and adjusting as necessary and on a consistent and rational basis for other inputs such as pricing trends, customer types, volumes and changing cost and margins.

Contract Balances

Payment terms typically require payment upon shipment of the System and additional payments as access codes are delivered, which can span several years after the System is first delivered and installed. The timing of revenue recognition compared to billings and cash collections typically results in accounts receivable. However, sometimes customer advances and deposits might be required for certain customers and are recorded as contract liabilities. Changes in the contract asset and liability balances during the years ended December 31, 2023 and 2022 were not materially impacted by any other factors.

As of December 31, 2023, the Company expects to recognize approximately the following percentages of deferred revenue by year:

Year:	Revenue Recognition
2024	85 %
2025	13 %
2026	2 %
2027	— %
2028	— %
Total	100 %

Revenue recognized for the years ended December 31, 2023 and 2022 that was included in the contract liability balance at the beginning of the year was $2.0 million and $2.5 million, respectively, and primarily represented revenue earned from separately priced extended warranties, rent-to-own revenue, milestone revenue, and clinical training.

Customers

Significant customers are those which represent more than 10% of the Company's total revenue. For the years ended December 31, 2023, 2022 and 2021, one customer accounted for 15%, 17% and 20%, respectively, of the Company's revenue.

Accounts receivable outstanding related to the customer was $1.9 million and $5.2 million as of December 31, 2023 and 2022, respectively.

Notes receivable outstanding related to the customer was $5.2 million and $0 million as of December 31, 2023 and 2022, respectively.

Geographical Information

The following geographic data includes revenue generated from the Company's third-party distributors. The Company's revenue was generated in the following geographic regions and by product line for the periods indicated (in thousands):

	Revenues by Geography Year ended December 31,			
	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
U.S.	$ 69,336	97 %	$ 63,406	97 %
International	2,012	3 %	1,800	3 %
Total revenues	$ 71,348	100 %	$ 65,206	100 %

	U.S. Revenues by Product Category Year ended December 31,			
	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 16,460	24 %	$ 16,575	26 %
Treatment sessions	50,896	73 %	45,077	71 %
Other	1,980	3 %	1,754	3 %
Total U.S. revenues	$ 69,336	100 %	$ 63,406	100 %

	International Revenues by Product Category Year ended December 31,			
	2023		2022	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 629	31 %	$ 811	45 %
Treatment sessions	754	38 %	354	20 %
Other	629	31 %	635	35 %
Total International revenues	$ 2,012	100 %	$ 1,800	100 %

	Revenues by Geography Year ended December 31,			
	2022		2021	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
United States	$ 63,406	97 %	$ 53,447	97 %
International	1,800	3 %	1,865	3 %
Total revenues	$ 65,206	100 %	$ 55,312	100 %

	U.S. Revenues by Product Category Year ended December 31,			
	2022		2021	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 16,575	26 %	$ 9,760	18 %
Treatment sessions	45,077	71 %	41,933	78 %
Other	1,754	3 %	1,754	4 %
Total U.S. revenues	$ 63,406	100 %	$ 53,447	100 %

	International Revenues by Product Category Year ended December 31,			
	2022		2021	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 811	45 %	$ 1,108	59 %
Treatment sessions	354	20 %	264	14 %
Other	635	35 %	493	27 %
Total International revenues	$ 1,800	100 %	$ 1,865	100 %

Research and Development Expenses

Research and development activities are expensed as incurred. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Share-based Compensation

The Company recognizes the grant-date fair value of share-based awards issued as compensation as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The fair value of restricted stock units is estimated at the time of grant, based on the grant date fair value of the Company's common stock. The fair value of performance restricted stock units ("PRSUs") is estimated at the time of grant and is determined using a risk neutral Monte Carlo simulation valuation model, which requires the use of inputs and assumptions such as the fair value of the underlying common stock, risk free interest rate, and expected volatility. The PRSUs generally vest based on appreciation of the Company's common stock to a certain price as determined by the Company's board of directors measured using a trailing 30-day "volume-weighted" average price of a share of the Company's common stock. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying common stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company accrues interest and related penalties are classified as income tax expense in the Statements of Operations. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

4. RECENT ACCOUNTING PRONOUNCEMENTS

New Accounting Standards Not Yet Adopted by the Company

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires public companies to disclose for each reportable segment the significant expense categories and amounts for such expenses. ASU 2023-07 is effective for annual periods beginning December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. This ASU will be effective for our annual period ended December 31, 2024. The Company is currently evaluating the guidance to determine the impact on its disclosures.

In December 2023, the FASB issued *ASU 2023-09, Improvements to Income Tax Disclosures ("ASU 2023-09")*, which requires public business entities to disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. ASU 2023-09 is effective for annual periods beginning after December 15, 2023. This ASU will be effective for our annual period ended December 31, 2024. The Company is currently evaluating the impacts of ASU 2023-09 on its disclosures.

Other than the items noted above, there have been no new accounting pronouncements not yet effective or adopted in the current year that we believe have a material impact, or potential material impact, to our financial statements.

5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash equivalents, accounts receivable, prepaid and other current assets, and accounts payable on the Company's Balance Sheets approximated their fair values as of December 31, 2023 and 2022 due to their short-term nature. The carrying values of the Company's current credit facility approximated its fair value as of December 31, 2023 and 2022 due to its variable interest rate. The carrying value of the Company's notes receivable approximated its fair value as of December 31, 2023 and 2022 due to its variable interest rate.

Certain of the Company's financial instruments are measured at fair value using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1: Inputs are quoted prices for identical instruments in active markets.

Level 2: Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3: Inputs are unobservable and reflect the Company's own assumptions, based on the best information available, including the Company's own data.

The following tables set forth the carrying amounts and fair values of the Company's financial instruments as December 31, 2023 and 2022 (in thousands):

	December 31, 2023				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices In Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds (cash equivalents)	$ 27,507	$ 27,507	$ 27,507	$ —	$ —

	December 31, 2022				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices In Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds (cash equivalents)	$ 68,002	$ 68,002	$ 68,002	$ —	$ —

6. ACCOUNTS RECEIVABLE

The following table presents the composition of accounts receivable, net as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Gross accounts receivable - trade	$ 16,577	$ 15,239
Less: Allowances for credit losses	(795)	(1,648)
Accounts receivable, net	$ 15,782	$ 13,591

The following table presents a rollforward of the allowance for credit losses (in thousands):

	Balance at Beginning of Period	Bad Debt Expense Recognized	Write-offs of Uncollectible Balances	Balance at End of Period
Year ended December 31, 2021	$ (1,012)	(763)	313	$ (1,462)
Year ended December 31, 2022	$ (1,462)	(341)	155	$ (1,648)
Year ended December 31, 2023	$ (1,648)	(390)	1,243	$ (795)

7. PROPERTY AND EQUIPMENT AND CAPITALIZED SOFTWARE

The following table presents the composition of property and equipment, net as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 702	$ 462
Office equipment	495	508
Auto	23	—
Computer equipment and software	1,082	1,758
Manufacturing equipment	551	343
Leasehold improvements	1,436	1,435
Rental equipment	542	542
Property and equipment, gross	4,831	5,048
Less: Accumulated depreciation	(2,822)	(3,057)
Property and equipment, net	$ 2,009	$ 1,991

As of December 31, 2023 and 2022, the Company had capitalized software costs, net of $4.2 million and $3.6 million, respectively, which are included in other assets on the Balance Sheets. During the year ended December 31, 2023, the Company disposed of $0.9 million of fully depreciated property and equipment.

Depreciation and amortization expense was $2.0 million, $1.6 million, and $1.1 million for the years ended December 31, 2023, 2022 and 2021, respectively.

8. NOTES RECEIVABLE

Greenbrook TMS Inc.

On March 31, 2023, the Company entered into a Secured Promissory Note and Guaranty Agreement (the "Promissory Note") with TMS Neurohealth Centers Inc. (the "Maker") and Greenbrook TMS Inc. and its subsidiaries, excluding the Maker (the "Guarantors"), in the principal amount of $6.0 million for a period of four years.

The Promissory Note will bear interest at a rate equal to the sum of (a) the floating interest rate of daily secured overnight financing rate as administered by the Federal Reserve Bank of New York on its website ("SOFR") plus (b) 7.65%.

Pursuant to the terms of the Promissory Note, in the event of an event of default thereunder, the Maker will be required to issue common share purchase warrants to the Company equal to (i) 200% of the unpaid amount of any delinquent amount or payment due and payable under the Promissory Note, together with all outstanding and unpaid accrued interest, fees, charges and costs, divided by (ii) the exercise price of the warrants, which will represent a 20% discount to the 30-day volume-weighted average closing price of Greenbrook TMS Inc.'s common shares traded on the Nasdaq Stock Market ("Nasdaq") prior to the date of issuance (subject to any limitations that may be required by Nasdaq).

Under the Promissory Note and related loan documents, the Maker and the Guarantors have granted to the Company a security interest in substantially all of the Maker's and the Guarantors' assets and the Guarantors have guaranteed the Maker's obligations under the Promissory Note. The Company's security interest pursuant to the Promissory Note and related loan documents ranks pari passu with the Maker's senior lender, Madryn Fund Administration, LLC, and is subject to an intercreditor agreement.

Success TMS

On September 29, 2021, the Company entered into an exclusive, five-year master sales agreement with Check Five, LLC d/b/a Success TMS ("Success TMS"). In connection with the Commercial Agreement, the Company agreed to loan Success TMS the principal amount of $10.0 million for a period of five years pursuant to a secured promissory note (the "Note").

On July 14, 2022, Success TMS repaid in full the Note with a cash payment of $10.5 million, which included all outstanding principal, prepayment premium and accrued but unpaid interest. The repayment extinguished the Note in its entirety and terminated the Subordination Agreement entered into by the Company.

Interest income recognized by the Company related to notes receivable was $0.6 million, $1.0 million and $0.2 million for the years ended December 31, 2023, 2022 and 2021, respectively, and is included within other income, net on the Statements of Operations.

9. LEASES

Lessee:

The Company has operating leases for its corporate headquarters, a training facility and office equipment, including copiers. The Company leases an approximately 32,000 square foot facility in Malvern, Pennsylvania for its corporate headquarters, which includes office and warehouse space. In the first quarter of 2019, the Company signed a lease modification for its Malvern facility that extended the lease through February 2028 and included approximately 10,000 square foot of additional premises. The Company has an option to extend the lease on its combined 42,000 square foot facility for an additional five-year term; however, the Company has determined it is not reasonably certain to exercise the option at this time after assessing contract, asset, entity and market conditions present upon lease commencement.

The Company leases an approximately 9,600 square foot facility in Charlotte, North Carolina as a training facility for its NeuroStar Advanced Therapy Systems. The lease ends in September 2027. The Company has an option to extend the lease on its training facility for an additional one-year term; however, the Company has determined it is not reasonably certain to exercise the option at this time after assessing contract, asset, entity and market conditions present upon lease commencement.

Operating lease rent expense was $0.8 million, $0.8 million, and $0.7 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, the weighted-average remaining lease term of operating leases was 4.1 years and the weighted-average discount rate was 7.2%.

The following table presents the supplemental cash flow information as a lessee related to leases for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,077	$ 892
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ —

The following table sets forth by year the required future payments of operating lease liabilities as of December 31, 2023 (in thousands):

	Year ended December 31, 2023
2024	$ 876
2025	898
2026	921
2027	882
2028	116
Total lease payments	3,693
Less imputed interest	(503)
Present value of operating lease liabilities	$ 3,190

Lessor sales-type leases:

Certain costumers have purchased NeuroStar Advanced Therapy Systems on a rent-to-own basis. The lease term is three or four years with a customer option to purchase the NeuroStar Advanced Therapy System at the end of the lease or automatic transfer of ownership of the NeuroStar Advanced Therapy System at the end of the lease.

The following table sets forth the profit recognized on sales-type leases (in thousands):

	Year ended December 31,	
	2023	2022
Profit recognized at commencement, net	$ 129	$ 478
Interest income	—	—
Total sales-type lease income	$ 129	$ 478

The following table sets forth a maturity analysis of the undiscounted lease receivables related to sales-type leases as of December 31, 2023 (in thousands):

	December 31, 2023
2024	$ 915
2025	442
2026	118
2027	91
Total sales-type lease receivables	$ 1,566

As of December 31, 2023 and 2022, the carrying amount of the lease receivables is $1.6 million and $2.8 million, respectively. The Company does not have any unguaranteed residual assets.

Lessor operating leases:

NeuroStar Advanced Therapy Systems sold on a rent-to-own basis prior to January 1, 2019 are accounted for as operating leases. NeuroStar Advanced Therapy Systems sold subsequent to January 1, 2019 for which collection is not probable are also accounted for as operating leases. For the years ended December 31, 2023, 2022 and 2021, the Company recognized operating lease income of $0.2 million, $0.2 million and $0.3 million, respectively.

The Company maintained rental equipment, net of $0.3 million and $0.5 million, as of December 31, 2023 and 2022, respectively, which are included in Property and equipment, net on the Balance Sheets. Rental

equipment depreciation expense was $0.09 million, $0.10 million and $0.05 million for the years ended December 31, 2023, 2022 and 2021, respectively.

10. PREPAID COMMISSION EXPENSE

The Company pays a commission on both NeuroStar Advanced Therapy System sales and Treatment Session sales. Since the commission paid for NeuroStar Advanced Therapy System sales is not commensurate with the commission paid for Treatment Sessions, the Company capitalizes commission expense associated with NeuroStar Advanced Therapy System commissions paid that is incremental to specifically anticipated future Treatment Session orders. In developing this estimate, the Company considered its historical Treatment Session sales and customer retention rates, as well as technology development life cycles and other industry factors. These costs are periodically reviewed for impairment.

NeuroStar Advanced Therapy System commissions are deferred and amortized on a straight-line basis over a seven year period equal to the average customer term, which the Company deems to be the expected period of benefit for these costs.

On the Company's Balance Sheets, the current portion of capitalized contract costs is represented by the current portion of prepaid commission expense, while the long-term portion is included in prepaid commission expense. Amortization expense was $2.3 million and $1.8 million for the years ended December 31, 2023 and December 31, 2022, respectively, and presented within sales and marketing in the Statements of Operations.

11. ACCRUED EXPENSES

The following table presents the composition of accrued expenses as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Compensation and related benefits	$ 8,003	$ 11,201
Consulting and professional fees	488	761
Research and development expenses	260	678
Sales and marketing expenses	1,760	410
Warranty	213	328
Sales and other taxes payable	818	659
Other	1,053	800
Accrued expenses	$ 12,595	$ 14,837

12. DEBT

The following table presents the composition of debt as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Outstanding principal	$ 60,000	$ 35,000
Accrued final payment fees	1,856	1,925
Less debt discounts	(2,573)	(971)
Total debt, net	59,283	35,954
Less current portion	—	(13,125)
Long-term debt, net	$ 59,283	$ 22,829

For the year ended December 31, 2023, the Company recognized interest expense of $5.4 million, of which $4.8 million was cash and $0.6 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees.

For the year ended December 31, 2022, the Company recognized interest expense of $4.3 million, of which $3.6 million was cash and $0.7 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees.

For the year ended December 31, 2021, the Company recognized interest expense of $4.0 million, of which $3.3 million was cash and $0.7 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees.

Solar Credit Facility

Solar Facility Fourth and Fifth Amendments

On September 29, 2023, the Company entered into the Solar Fifth Amendment. The Solar Fifth Amendment allowed the Company to draw on the $22.5 million Term C Loan portion of the Solar Facility and revise the required testing levels of the net product revenue and minimum liquidity covenants for certain testing periods. On October 3, 2023, the Company borrowed an aggregate amount of $22.5 million under the Term C Loan portion of the Solar Facility.

On March 29, 2023, the Company entered into a fourth amendment (the “Solar Fourth Amendment”) to Solar Facility.

The Solar Fourth Amendment increased the borrowings by $2.5 million, extended the interest only period from March 2023 to March 2026 and extended the maturity date from February 2025 to March 2028. In addition the amendment changed the basis of the interest expense from LIBOR to SOFR.

The Solar Facility is $60.0 million and consists of three tranches of term loans, a “Term A Loan” in an aggregate amount of $35.0 million, a “Term B Loan” in an aggregate amount of $2.5 million, and a “Term C Facility” (collectively with the Term A Loan and Term B Loan, the “Loans”) in an aggregate principal amount equal to $22.5 million. The Term A Loan was fully drawn prior to the effectiveness of the Solar Fourth Amendment. On March 29, 2023, the Company borrowed an amount of $2.5 million under the Term B Loan.

On October 3, 2023, the Company borrowed an amount of $22.5 million under the Term C Facility (the “Term C Funding Date”). The maturity date of the Loans is March 29, 2028. Prior to the effectiveness of the Solar Fourth Amendment, the maturity date of the Term A Loan was February 28, 2025.

The Loans accrue interest from the date of borrowing through the date of repayment at a floating per annum rate of interest, which resets monthly and is equal to the greater of 5.65% plus (a) 3.95% or (b) daily simple SOFR for a term of one month. Only interest is required to be paid on the Loans until March 1, 2026. Prior to the effectiveness of the Solar Fourth Amendment, the interest only period with respect to the Term A Loan expired on March 1, 2023. Commencing April 1, 2026, the Company will be required to make monthly payments of principal and interest on the Loans.

In addition to the principal and interest payments due under the Solar Facility, the Company is required to pay a final payment fee to Solar upon the earlier of prepayment, acceleration or the maturity date of the Loans equal to 4.95% of the principal amount of the term loans actually funded. If the Company prepays the Loans prior to their respective scheduled maturities, the Company will also be required to pay prepayment fees to Solar equal to 3% of the principal amount of such term loan then-prepaid if prepaid on or before the first anniversary of the Term C Funding Date, 2% of the principal amount of such term loan then-prepaid if prepaid

after the first anniversary and on or before the second anniversary of the Term C Funding Date, or 1% of the principal amount of such term loan then-prepaid if prepaid after the second anniversary of the Term C Funding Date.

The Company is also required to pay Solar an exit fee upon the occurrence of (a) any liquidation, dissolution or winding up of the Company, (b) any transaction that results in a person obtaining control over the Company, (c) the Company achieving $100 million in trailing twelve-month net product revenue or (d) the Company achieving $125 million in trailing twelve-month net product revenue. The exit fee for liquidation, dissolution, winding up or change of control of the Company is equal to 2% of the principal amount of the term loans actually funded. The exit fee for achieving either $100 million or $125 million in trailing twelve-month net product revenue is equal to 1% of the principal amount of the term loans actually funded or, if both net product revenue milestones are achieved, 2% of the principal amount of the term loans actually funded. The exit fee is capped at 2% of the principal amount of the term loans actually funded.

On December 31, 2023, January 31, 2024 and February 29, 2024, the Company was not in compliance with its minimum net product revenue covenant under the Solar Facility. Subsequently, the Company was granted a waiver from Solar for the covenant violations that occurred. The amount of borrowings affected by this non compliance was $60 million, see “Note 22. Subsequent Event” for further discussion on the waiver.

The following table sets forth by year our required future principal payments under the term loan portion of the Solar Facility:

Year:	Principal Payments
2024	$ —
2025	—
2026	22,500
2027	30,000
2028	7,500
Total principal payments	$ 60,000

13. STOCKHOLDERS’ EQUITY

Common Stock Offering

On February 2, 2021, the Company closed on their secondary public offering and sale (the “Offering”) of their common stock in which the Company issued and sold 5,566,000 shares of our common stock, which included shares pursuant to an option granted to underwriters to purchase additional shares, at a public offering price of $15.50 per share. The Company received net proceeds of $80.6 million after deducting underwriting discounts, commissions and offering expenses.

Common Stock

The Company’s amended and restated certificate of incorporation as of December 31, 2020 authorized the issuance of 200.0 million shares of common stock, $0.01 par value per share, of which 29.1 million were issued and outstanding as of December 31, 2023.

The following table summarizes the total number of shares of the Company's common stock issued and reserved for issuance as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Shares of common stock issued	29,092	27,268
Shares of common stock reserved for issuance for:		
Common stock warrants outstanding	41	61
Stock options outstanding	1,270	1,301
Restricted stock units outstanding	3,360	3,901
Shares available for grant under stock incentive plans	978	1,140
Shares available for sale under employee stock purchase plan	1,335	1,063
Total shares of common stock issued and reserved for issuance	36,076	34,734

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Holders of common stock are entitled to receive any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. The Company has never paid, and for the foreseeable future does not expect to pay, a dividend on its common stock.

Common Stock Warrants

The following table summarizes the Company's outstanding common stock warrants as of December 31, 2023 and 2022 (in thousands):

December 31, 2023 Warrants Outstanding (in thousands)	Exercise Price	Expiration Date
20	$ 9.73	Mar-2024
21	$ 9.73	Dec-2024
41		

December 31, 2022 Warrants Outstanding (in thousands)	Exercise Price	Expiration Date
20	$ 9.73	Aug-2023
20	$ 9.73	Mar-2024
21	$ 9.73	Dec-2024
61		

14. LOSS PER SHARE

The Company's basic loss per common share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. The Company's restricted stock awards (non-vested shares) are issued and outstanding at the time of grant but are excluded from the Company's computation of weighted-average shares outstanding in the determination of basic loss per share until vesting occurs.

A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted loss per common share are the same. If in the future the Company achieves profitability, the denominator of a diluted earnings per common share calculation will include both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options, non-vested restricted stock awards and non-vested performance restricted stock units using the treasury stock method, along with the effect, if any, from the potential conversion of outstanding securities, such as convertible preferred stock.

The following potentially dilutive securities outstanding as of December 31, 2023, 2022 and 2021 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	December 31,		
	2023	2022	2021
Stock options	1,270	1,301	1,499
Non-vested PRSUs	395	395	395
Non-vested restricted stock units	2,965	3,506	1,729
Common stock warrants	41	61	75

15. SHARE-BASED COMPENSATION

The amount of share-based compensation expense recognized by the Company by location in its Statements of Operations for the years ended December 31, 2023, 2022 and 2021 is as follows (in thousands):

	Years ended December 31,		
	2023	2022	2021
Cost of revenues	$ 140	$ 130	$ 79
Sales and marketing	2,330	4,286	2,096
General and administrative	4,172	3,868	5,496
Research and development	677	462	198
Total	$ 7,319	$ 8,746	$ 7,869

2018 Equity Incentive Plan

In June 2018, the Company adopted the 2018 Plan, which authorized the issuance of up to 1.4 million shares, subject to an annual 4% increase based on the number of shares of common stock outstanding, in the form of restricted stock, stock appreciation rights and stock options to the Company's directors, employees and consultants. The amount and terms of grants are determined by the Company's board of directors. All stock options granted to date have had exercise prices equal to the fair value, as determined by the closing price as reported by the Nasdaq Global Market, of the underlying common stock on the date of grant. The contractual term of stock options is up to 10 years, and stock options are exercisable in cash or as otherwise determined by the board of directors. Generally, stock options vest 25% upon the first anniversary of the date of grant and the remainder ratably monthly thereafter for 36 months. Restricted stock units generally vest ratably in three equal installments on the first, second and third anniversaries of the grant date. PRSUs generally vest based on appreciation of the Company's common stock to a certain price as determined by the Company's board of directors measured using a trailing 30-day volume weighted average price of a share of the Company's common stock. The fair value of the PRSU awards are determined using a risk neutral Monte Carlo simulation valuation model. As of December 31, 2023, there were 0.7 million shares available for future issuance under the 2018 Plan.

2020 Inducement Incentive Plan

In December 2020, the Company adopted the 2020 Inducement Incentive Plan, which authorized the issuance of up to 0.4 million shares in the form of stock options, stock appreciation rights, restricted stock

awards, restricted stock unit awards, performance stock awards and other stock awards to eligible employees who satisfy the standards for inducement grants under Nasdaq global market rules. In March 2022, the Company's board of directors approved an additional 0.5 million shares for issuance under the plan. An individual who previously served as an employee or director of the Company is not eligible to receive awards under this plan. The amount and terms of grants are determined by the Company's board of directors. As of December 31, 2023, there were 0.3 million shares available for future issuance under the 2020 Inducement Incentive Plan.

Stock Options

The following table summarizes the Company's stock option activity for the years ended December 31, 2023, 2022 and 2021:

	Number of Shares under Option (in thousands)	Weighted-average Exercise Price per Option	Weighted-average Remaining Contractual Life (in years)	Aggregate average Intrinsic Value (in thousands)
Outstanding at December 31, 2020	2,365	$ 4.62		
Granted	—	$ —		
Exercised	(698)	$ 4.01		
Forfeited	(168)	$ 14.32		
Outstanding at December 31, 2021	1,499	$ 4.01		
Granted	—	$ —		
Exercised	(168)	$ 1.77		
Forfeited	(30)	$ 13.81		
Outstanding at December 31, 2022	1,301	$ 4.07		
Granted	—	$ —		
Exercised	(1)	$ 1.63		
Forfeited	(30)	$ 11.67		
Outstanding at December 31, 2023	1,270	$ 3.90	6.0	$ 862
Exercisable at December 31, 2023	1,123	$ 4.15	6.0	$ 728
Vested and expected to vest at December 31, 2023	1,270	$ 3.90	6.0	$ 862

The Company recognized share-based compensation expense related to stock options of $0.4 million, $0.7 million and $0.8 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, there was $0.1 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 0.5 years. The total intrinsic value of stock options exercised during the years ended December 31, 2023, 2022 and 2021 was $0.0 million, $0.2 million, and $8.2 million, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock unit and performance restricted stock unit activity for the years ended December 31, 2023, 2022 and 2021:

	Non-vested Restricted Stock Units (in thousands)	Weighted-average Grant-date Fair Value	Non-vested PRSUs (in thousands)	Weighted-average Grant-date Fair Value
Non-vested at December 31, 2020	1,860	$ 3.58	500	$ 1.71
Granted	1,008	$ 11.51	145	$ 15.59
Vested	(780)	$ 3.63	(250)	$ 1.77
Forfeited	(359)	$ 7.86	—	$ —
Non-vested at December 31, 2021	1,729	$ 7.29	395	$ 6.77
Granted	2,902	$ 3.36	—	$ —
Vested	(705)	$ 7.32	—	$ —
Forfeited	(420)	$ 5.35	—	$ —
Non-vested at December 31, 2022	3,506	$ 4.29	395	$ 6.77
Granted	1,674	$ 4.68	—	$ —
Vested	(1,823)	$ 4.32	—	$ —
Forfeited	(392)	$ 5.50	—	$ —
Non-vested at December 31, 2023	2,965	$ 4.37	395	$ 6.77

The Company recognized share-based compensation expense related to restricted stock units and performance restricted stock units of $6.9 million, $8.1 million, and $7.1 million during the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, there was $7.7 million of unrecognized compensation cost related to non-vested restricted stock units and performance restricted stock units that the Company expects to recognize over a weighted-average period of 1.7 years. The total fair value at the vesting date of restricted stock units and performance restricted stock units vested during the years ended December 31, 2023, 2022 and 2021 was $8.6 million, $2.5 million, and $14.1 million, respectively.

The Company did not grant performance restricted stock units during the years ended December 31, 2023 and 2022. For the year ended December 31, 2021, the grant-date fair value of the performance restricted stock units was estimated at the time of grant using the following inputs and assumptions in the Monte Carlo simulation valuation model:

	2021
Closing price of common stock	$ 15.92
Risk-free interest rate	1.15 %
Expected volatility	99.7 %

16. EMPLOYEE BENEFIT PLANS

Defined Contribution Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its employees. Employees are eligible to participate on the first of the month following their date of hire. Under the 401(k) plan, participating employees may defer up to 100% of their pre-tax salary but not more than statutory limits. As of December 31, 2023, the Company contributes 3% of employee salary to the participant's defined contribution plan, which vests immediately. Employee contributions also vest immediately.

2018 Employee Stock Purchase Plan

In July 2018, the Company adopted the 2018 Employee Stock Purchase Plan ("2018 ESPP") with an initial 0.2 million share reserve, subject to automatic annual increases on January 1st of each year for a period of up to ten years, as defined in the plan document. The purpose of the 2018 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2018 ESPP provides the opportunity to purchase the Company's common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. As of December 31, 2023, the Company had not yet approved any offering under the plan and 1.3 million shares were reserved for issuance.

17. INCOME TAXES

The Company's loss before income taxes was $30.2 million, $37.2 million, $31.2 million for the years ended December 31, 2023, 2022, and 2021, respectively, and was generated entirely in the United States. The Company did not record current or deferred income tax expense or benefit during the years ended December 31, 2023, 2022, and 2021.

A reconciliation of the statutory United States federal income tax rate to the Company's effective tax rate is as follows:

	Tax Year ended December 31,		
	2023	2022	2021
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State and local taxes, net of federal benefit	4.2 %	(0.9)%	5.5 %
Nondeductible expenses	0.5 %	(2.3)%	10.6 %
Research and development credits	(0.3)%	— %	— %
Tax rate change and true-up	0.8 %	(1.5)%	0.8 %
Net operating loss	(0.6)%	—	—
Change in valuation allowance	(25.6)%	(16.3)%	(37.9)%
Effective income tax rate	— %	— %	— %

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 82,179	$ 76,013
Research and development credits	2,923	3,008
Share-based compensation	2,538	2,273
Accruals	1,161	1,379
Interest expense	4,451	3,807
Lease liability	782	929
Capitalized start-up costs	—	215
Capitalized R&D costs	3,790	2,165
Other temporary differences	1,032	1,000
Gross deferred tax assets	98,856	90,789
Less: Valuation allowance	(94,473)	(86,733)
Total deferred tax assets	$ 4,383	$ 4,056
Deferred tax liabilities:		
Capitalized software	$ (1,038)	$ (894)
Right-of-use asset	(679)	(816)
Prepaid commission	(2,666)	(2,346)
Gross deferred tax liabilities	(4,383)	(4,056)
Net deferred taxes	$ —	$ —

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. The Company believes that it is more likely than not that the Company's deferred income tax asset associated with its net operating losses will not be realized in the immediate future. As such, there is a full valuation allowance against the net deferred tax assets as of December 31, 2023 and 2022. The valuation allowance increased by $7.7 million and $6.1 million during the years ended December 31, 2023 and 2022, respectively, due primarily to the generation of net operating losses and the federal tax rate reduction during the periods. The changes in the valuation allowance were as follows (in thousands):

	Year ended December 31,	
	2023	2022
Balance at the beginning of the year	$ 86,733	$ 80,663
Amounts charged to expense	7,739	6,070
Balance at the end of the year	$ 94,472	$ 86,733

The following table summarizes carryforwards of federal net operating losses and tax credits as of December 31, 2023 (in thousands):

	Amount	Expiration Beginning in
Federal net operating losses	$ 338,027	2024
State net operating losses	$ 217,071	2024
Research and development credits	$ 2,923	2024

Under the Tax Reform Act of 1986 (the "Act"), the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating

loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2023, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's Statements of Operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2022 remain subject to examination by the taxing jurisdictions.

18. COMMITMENTS AND CONTINGENCIES

Executive Employment Agreements

The Company has entered into an employment agreement and offer letters with certain key executives, providing for compensation and severance in certain circumstances, as defined in the agreements.

On November 2, 2023, the Company's board of directors directed the Company to: (A) amend its employment agreement with Keith J. Sullivan, the Company's President and Chief Executive Officer, to: (i) extend, from 18 months to 24 months, the duration of Mr. Sullivan's severance benefits if the Company terminates Mr. Sullivan's employment without cause, or if Mr. Sullivan resigns for good reason, within 12 months of a change in control; and (ii) reflect Mr. Sullivan's current annual base salary, as approved by the Company's board of directors via unanimous written consent on February 8, 2023, in lieu of the outdated annual base salary as reflected in such employment agreement prior to such amendment; and (B) take any other actions necessary to effectuate such amendments, which may include an amendment to any ancillary agreements by and between Mr. Sullivan and the Company regarding any such severance benefits.

Legal Matters

The Company is subject from time to time to various claims and legal actions arising during the ordinary course of its business. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition or cash flows.

19. DISTRIBUTION AGREEMENT WITH TEIJIN PHARMA LIMITED

In October 2017, the Company entered into a distribution agreement with Teijin for the exclusive distribution of its NeuroStar Advanced Therapy System to customers who will treat patients with MDD in Japan. Under the distribution agreement, Teijin is generally restricted from selling competing products in Japan. The distribution agreement provides that the Company will have primary responsibility for obtaining reimbursement approval for use of NeuroStar Advanced Therapy System for the treatment of MDD in Japan, and Teijin will promote the sales of NeuroStar Advanced Therapy System for treatment of MDD in Japan. The Company has agreed to provide sales and technical support training to Teijin for its NeuroStar Advanced Therapy Systems. Teijin is required to purchase minimum dollar values of NeuroStar Advanced Therapy Systems and treatment sessions from the Company.

In 2017, under the distribution agreement with Teijin, the Company received an upfront payment of $0.75 million and a milestone payment of $2.0 million following the Japanese Ministry of Health, Labour and Welfare's, or JMHLW, approval of marketing the NeuroStar Advanced Therapy System for the treatment of

MDD in Japan. In the second quarter of 2019, under the distribution agreement with Teijin, the Company earned a second milestone payment of $0.7 million, following Japan's Central Social Insurance Medical Council (Chuikyo) approval of the recommendation by JMHLW's expert review panel to provide reimbursement for NeuroStar Advanced Therapy for the treatment of MDD in adults. The reimbursement went into effect on June 1, 2019 and covers patients who are treated in the largest inpatient and outpatient psychiatric facilities in Japan at the rate of JPY12,000 per treatment session. These upfront and subsequent milestone payments have been deferred and are being recognized as revenue over term of the agreement.

In May 2019, the Company and Teijin entered into an amendment to the distribution agreement, which among other things finalized transfer prices, forecasting and minimum purchases, and made certain clarifications to the agreement.

The distribution agreement is scheduled to expire on March 31, 2027, subject to earlier termination if the Company or Teijin breach the agreement, Teijin fails to maintain distributor-level permits and approvals, Teijin fails to purchase from the Company specified dollar values of its sales forecasts, reimbursement for treatment of MDD using the NeuroStar Advanced Therapy System is not obtained from JMHLW by specified dates or such reimbursement is below specified minimums, Teijin reasonably believes that it is not commercially reasonable to continue distributing the NeuroStar Advanced Therapy System in Japan or bankruptcy related events occur. The term of the distribution agreement will be automatically extended for two years unless either party gives the other party at least two years' prior written of notice of non-renewal, except that the Company cannot decline to renew the agreement if Teijin has purchased 100% of its sales forecasts over the term of the agreement.

20. SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company currently operates in one business segment as it is managed and operated as one business. A single management team that reports to the chief operating decision maker comprehensively manages the entire business. The Company does not operate any material separate lines of business or separate business entities with respect to its products or product development.

21. GOVERNMENT ASSISTANCE

Employee Retention Credit

The Coronavirus Aid, Relief and Economic Security Act provided an Employee Retention Credit (the "ERC"), which was a refundable tax credit related to certain payroll taxes. The Company applied the grant model and determined that the criteria for recognition of the ERC was met during the year ended December 31, 2023 based on the Company's determination of eligibility and filing of the ERC claim. As of December 31, 2023, the $2.9 million ERC receivable is reported within prepaid expenses and other current assets on the Company's Balance Sheet. The credit is reported within other income, net in the Company's Statement of Operation for the year ended December 31, 2023.

22. SUBSEQUENT EVENTS

As disclosed in "Note 12. Debt", the Company was not in compliance with its minimum net product revenue covenant for certain periods, including January 31, 2024 and February 29, 2024 under the Solar Facility. On March 7, 2024, the Company entered into the Solar Sixth Amendment.

Under the Solar Sixth Amendment, Solar (i) waived the specified events with respect to the Company's non-compliance with the required revenue under the net product revenue covenant and (ii) revised the required testing levels of the net product revenue and minimum liquidity covenants for certain future testing periods.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEURONETICS, INC.

By: /s/ Keith J. Sullivan
Keith J. Sullivan
President, Chief Executive Officer and Director
Date: March 7, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Keith J. Sullivan **Keith J. Sullivan**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2024
/s/ Stephen Furlong **Stephen Furlong**	Executive VP, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 7, 2024
/s/ Robert Cascella Robert Cascella	Director	March 7, 2024
/s/ John Bakewell **John Bakewell**	Director	March 7, 2024
/s/ Sheryl Conley **Sheryl Conley**	Director	March 7, 2024
/s/ Megan Rosengarten **Megan Rosengarten**	Director	March 7, 2024
/s/ Wilfred Jaeger, M.D. **Wilfred Jaeger, M.D.**	Director	March 7, 2024
/s/ Glenn Muir **Glenn Muir**	Director	March 7, 2024
/s/ Joseph H. Capper **Joseph H. Capper**	Director	March 7, 2024