NEUROPACE

2024 Annual Report

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

FORM 10-K

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

For the fiscal year ended December 31, 2024

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 001-40337

NEUROPACE

NEUROPACE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**22-3550230**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

455 N. Bernardo Avenue
Mountain View, CA 94043
(Address of principal executive offices and zip code)

(650) 237-2700
Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	NPCE	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2024 was approximately $135.5 million, based on the closing price of $7.56 for shares of the registrant's common stock as reported for such date by the Nasdaq Global Market. Shares of the registrant's common stock held by each executive officer, director and stockholders that the registrant has concluded are affiliates of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status does not reflect a determination that such persons are affiliates of the registrant for any other purpose.

As of February 28, 2025, the number of shares of the registrant's common stock outstanding was 32,560,130.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2025 Annual Meeting of Stockholders, or the Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Proxy Statement will be filed with Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, about us and our industry that involve substantial risks and uncertainties. All statements regarding results or events that may occur in the future contained in this report, including statements regarding our future results of operations and financial condition, as well as expectations of management for future operations, are forward-looking statements. In some cases, you can identity forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors and assumptions more thoroughly described in the section titled "Risk Factors" contained in Part I, Item 1A in this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These risks are not exhaustive. Moreover, we operate in a very competitive and rapidly changing environment. New risks factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

You should not rely on these forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K or to conform these statements to actual results or to changes in our expectations, whether as a result of any new information, future events, changed circumstances or otherwise. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expected future growth;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to accurately forecast demand for our products;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products, including pre-implant evaluations, implant procedures, and follow-up care;
- the performance of third parties in connection with the manufacturing and development of our products, including single-source suppliers;
- regulatory developments in the United States and in any foreign countries in which we may seek to do business;
- renewing our distribution agreement with DIXI Medical USA Corp., or DIXI Medical, or entering into a new agreement on acceptable terms;
- our ability to retain regulatory approval for our products or obtain regulatory approval for updates to our products, or new products or indications in the United States and in any foreign countries in which we may seek to do business;
- our research and development for existing products and new products, including our conduct of ongoing and future clinical trials for our existing products;

- our expectations with respect to our existing products and their ability to be used without modification in pediatric patients and in those with generalized epilepsy;
- our reliance on third-party suppliers for product components, some of which are single source suppliers;
- our ability to manufacture our products in conformity with FDA requirements and with regulatory requirements of any foreign countries in which we may seek to do business;
- our ability to predict product performance, including battery life of our RNS device;
- our expectations regarding the impact that our sales and marketing initiatives will have on our sales;
- our ability to retain or scale our organizational culture;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to attract and retain members of our board of directors, senior management, or operational personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act and as a smaller reporting company under the federal securities laws;
- our ability to develop and maintain our corporate infrastructure, including our ability to maintain an effective system of internal control;
- our expectations regarding the impact of public health crises and geopolitical tensions, such as the Russia-Ukraine war and ongoing conflicts in the Middle East, on our business, our industry and the economy;
- the impact of adverse economic conditions, including as a result of unfavorable global economic and political conditions, increased interest rates and inflation;
- our financial performance and capital requirements; and
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our products and technology, as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

You should read this Annual Report on Form 10-K as well as the documents that we reference in, and have filed as exhibits to, this report with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that such information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on them.

RISK FACTORS SUMMARY

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described in "Part I, Item 1A. Risk Factors" of this Annual Report on Form 10-K. Below is a summary of the principal factors and uncertainties that make investing in our common stock speculative or risky:

- We currently rely on our RNS System, which can only be marketed in the United States for use in adults with drug-resistant focal epilepsy, as our primary source of revenue. If we fail to successfully market and sell our RNS System cost effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected;
- Our commercial success will continue to depend on attaining significant market acceptance of our products and increasing the number of patients treated. If we are unable to successfully achieve substantial market acceptance and drive adoption of our RNS System both within Level 4 comprehensive epilepsy centers and in the community, our sales, business, financial condition and results of operations would be harmed;
- We depend on a limited number of single-source suppliers and vendors in connection with the manufacture of our products, which makes us vulnerable to supply shortages and price fluctuations that could harm our business, financial condition, and results of operations;
- Our results of operations may be harmed if we are unable to accurately forecast customer demand for our products;
- We may be unable to compete successfully with other treatment options for drug-resistant focal epilepsy, which could harm our sales, business, financial condition and results of operations;
- If adequate reimbursement becomes unavailable for the procedures to implant our RNS System and for clinicians to provide ongoing care for patients treated with our RNS System, it could diminish our sales or affect our ability to sell our RNS System profitably;
- Use of our RNS System requires appropriate neurosurgeon training for implantation and epileptologist training for programming and ongoing patient care, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations;
- We may not be able to achieve or maintain satisfactory pricing and margins for our RNS System, which could harm our business and results of operations;
- We are seeking expanded FDA labeling for our RNS System to be able to treat patients with drug-resistant generalized epilepsy, as well as patients between the ages of 12 and 17 with drug-resistant focal epilepsy, but if we are unable to broaden the indications for our RNS System to include these patients, our growth potential could be harmed;
- Recent changes in staffing levels at FDA could create delays in its response to and review of our submissions for indication expansion, harming our growth potential and long range financial plans;
- Our operations are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations;
- Our actual or perceived failure to comply with data privacy and security laws and regulations could lead to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our data privacy and security practices, which may disrupt our business operations and harm our business and reputation, financial condition, results of operations and prospects and cause other adverse business consequences;
- If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained

is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products, our ability to continue to commercialize our RNS System, or our other products, may be harmed;

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it;
- We are party to an existing Term Loan Agreement, which contains restrictive covenants as well as financial maintenance covenants, and if we are unable to comply with these covenants then the lenders could declare an event of default and we may need to immediately repay the amounts due under the Term Loan Agreement;
- If our distribution agreement with DIXI Medical is not renewed or we fail to negotiate a new agreement, our overall revenue growth, financial condition and results of operations may be materially affected;
- Our actual operating results may differ significantly from any guidance provided;
- Our estimates of market opportunity and forecasts of market and revenue growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all;
- Our growth prospects may be harmed if we are unable to successfully use our unique data asset and analysis capabilities, internally or through collaborations, or if our expectations with respect to our ability to leverage our unique data asset prove to be incorrect;
- We may expand sales of our RNS System internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our RNS System internationally even if approved. A variety of risks associated with marketing our RNS System internationally could harm our growth potential; and
- Future legislation, potential changes in federal regulatory agency leadership, and new policies and priorities under the current Administration may adversely impact our company.

PART I

Item 1. Business.

Overview

We are a medical device company focused on transforming the lives of people living with epilepsy by reducing or eliminating the occurrence of debilitating seizures. Our novel and differentiated RNS System is the first and only commercially available, brain-responsive neuromodulation system that delivers personalized, real-time treatment at the seizure source. By continuously monitoring and analyzing the brain's electrical activity, recognizing patient-specific abnormal electrical patterns, and responding in real time with imperceptible electrical pulses to prevent seizures, our RNS System is programmed by clinicians to deliver the precise amount of therapy when and where it is needed and provides exceptional clinical outcomes with approximately three minutes of stimulation on average per day. Our RNS System is also the only commercially available device that records continuous brain activity data and allows clinicians to monitor patients not only in person, but also remotely, providing them the data they need to make more informed treatment decisions, thus optimizing patient care. We believe the therapeutic advantages of our RNS System, combined with the insights obtained from our extensive brain data set, offer a significant leap forward in epilepsy treatment. As of December 31, 2024, over 6,000 patients have received our RNS System. We believe our compelling body of long-term clinical data, demonstrating continuous improvement in outcomes over time, will support the continued adoption of our RNS System among the approximately 575,000 adults in the United States with drug-resistant focal epilepsy. We continue seeking indication expansion to, over time, cover the entire approximately 1.2 million drug-resistant epilepsy patients in the United States and may additionally seek to expand our operations to reach the approximately 16.5 million drug-resistant epilepsy patients globally.

Epilepsy is a devastating chronic disorder characterized by a tendency of the brain to produce sudden abnormal bursts of electrical energy that disrupt brain functions and cause seizures. The goal for treating epilepsy is to reduce the number and intensity of seizures that a patient experiences, without causing treatment-related side effects. While antiepileptic drugs are considered first-line treatment and are effective at controlling seizures in a large portion of the epilepsy population, approximately one-third of epilepsy patients are considered drug-resistant because they do not achieve complete seizure control or cannot tolerate the side effects of these drugs. According to the International League Against Epilepsy, or ILAE, drug-resistant epilepsy, or DRE, is defined as a patient failing to achieve sustained seizure freedom after trying two antiseizure medications. These drug-resistant epilepsy patients struggle with a variety of life-impacting challenges including psychological dysfunction, social stigmatization, reduced quality of life, and increased risk of mortality.

Epilepsy is further classified into two main categories– focal epilepsy and generalized epilepsy. Approximately 60% of epilepsy patients have focal epilepsy, which is characterized by electrical discharges that originate in a specific part of the brain. The remaining 40% of patients have generalized epilepsy, which is characterized by widespread electrical discharges that involve the entire brain at once. Our paradigm-shifting RNS System is currently indicated in the United States for use in adult epilepsy patients, meaning patients who are 18 years of age or older, with drug-resistant focal epilepsy, which we believe represents an approximately $27 billion total addressable market. While we are presently focused on this significant market opportunity, we have investigational device exemption, or IDE, approval for clinical trials to evaluate use of the RNS System to treat drug-resistant idiopathic generalized epilepsy, or IGE, and patients between ages 12 and 17 and we may later seek regulatory approval in markets outside the United States. We do not believe we will need to modify our RNS System for potential use in generalized epilepsy or in patients under the age of 18; however, we will need to complete clinical studies and obtain FDA approval prior to marketing the RNS System for these indications. We also believe that our RNS System may be effective in treating other brain disorders including depression, memory disorders, and post-traumatic stress disorder. We will need to conduct additional studies to determine if any modifications to the RNS System are necessary to address these other brain disorders and to obtain FDA approval for any new indications.

Our commercial efforts have historically been focused on growing adoption and utilization across Level 4 comprehensive epilepsy centers, or CECs, in the United States that facilitate appropriate care for drug-resistant epilepsy patients. In 2023, we received FDA approval of a Premarket Approval Supplement, or PMA-S, which updated the qualification criteria for centers and clinicians that may prescribe and implant the RNS System. This

supplemental approval allows us to expand our commercial efforts to target and be able to qualify the approximately 1,800 additional epileptologists outside of Level 4 CECs and the entire population of functional neurosurgeons, empowering them to provide the RNS System as a much-needed treatment option for their patients and expanding our current market opportunity to all 575,000 adults in the United States with drug-resistant focal epilepsy.

Our RNS System has an estimated average battery life of nearly 11 years, an increase from the previous model of the device. The sale of replacement neuromodulation devices provides a recurring revenue stream that is additive to the market opportunity for initial implants.

Resective or ablative surgery that removes or destroys brain tissue at the source of the seizure onset has historically been considered the best treatment option for drug-resistant focal epilepsy. However, resective or ablative surgery carries risk, including neurological risk, and only approximately half of resective or ablative surgery patients are seizure free two years after surgery. We estimate that only approximately 20% of drug-resistant focal epilepsy patients have a focus that is both safe to remove and likely to result in seizure control if removed, and are also willing to undergo the procedure. The ILAE guidelines state that DRE patients who may not appear to be appropriate candidates for resective or ablative epilepsy surgery should still be referred to a tertiary epilepsy center to evaluate other potential interventions.

There are currently two other neuromodulation devices, Vagus Nerve Stimulation, or VNS, and Deep Brain Stimulation, or DBS, that are also approved to address the approximately 80% of drug-resistant focal epilepsy patients who are not ideal candidates for resective or ablative surgery. However, we believe the technology attributes of these devices limit their utility in practice. Both VNS and DBS devices stimulate an anatomical target that is not specific to where seizures start and use the same treatment paradigm for all patients, regularly stimulating the vagus nerve in the case of VNS or one specific location deep in the brain in the case of DBS, using a non-varying schedule in an attempt to prevent seizures. These devices stimulate for multiple hours per day, increasing the occurrence of stimulation-related side effects such as memory impairment, depression, sleep disruption, and vocal disturbances. Additionally, neither of these devices record the brain electrical data known as intracranial electroencephalograms, or iEEGs, that we believe are important to physicians in helping guide the therapy decisions that improve patient results over time. We believe there is a significant unmet need for a personalized, targeted therapy that collects brain data and improves outcomes over time without causing stimulation-related side effects or presenting the neurocognitive risks that are associated with resective or ablative surgery.

We developed our RNS System to address the individualized nature of drug-resistant epilepsy and deliver a safe and effective therapy for focal onset seizures anywhere in the brain. Unlike other neuromodulation devices, our RNS System continuously monitors and analyzes the brain's electrical activity, recognizes patient-specific abnormal patterns, and delivers treatment at the seizure source when needed, providing significant, sustained, and improving reductions in seizure frequency, including, in some cases, eliminating seizures, without stimulation-related side effects at therapeutic settings. As such, we believe our RNS System is superior in tolerability and efficacy to other neuromodulation approaches, gathering insights from individual patients' brain activity which help clinicians in making better treatment decisions and optimizing patient care. In addition, the non-destructive, reversible nature of the implant procedure makes it an attractive option for drug-resistant focal epilepsy patients, the majority of whom are not candidates for, or are unwilling to undergo, resective or ablative surgery.

The key efficacy and safety benefits of our RNS System are demonstrated by four multi-center FDA approved prospective clinical studies that collectively include approximately 600 patients with up to nine years of follow-up, as well as multiple retrospective studies reporting real-world outcomes. Evidence generated from patients enrolled in our initial clinical studies demonstrated a 44% median reduction in seizure frequency at one year that improved to a 75% median reduction at nine years, with enduring improvements in quality of life and cognition. Importantly, the more recent real-world results from a post-approval retrospective study published in 2020 showed a median seizure frequency reduction of 67% at one year ($p<0.05$), which is consistent with the interim one year results of our ongoing prospective post-approval study, which we refer to herein as the Post-Approval Study, increasing to 82% at three or more years, demonstrating the utility of our unique brain data set in driving improvements in therapy effectiveness across patient cohorts over time – the patients not only start at a higher median seizure frequency reduction rate, but that rate continues to improve. Over the 3,400 patient implant years reported in our prospective studies, our RNS System has been shown to be well tolerated without any adverse stimulation-related side effects at

therapeutic settings. We believe our extensive and growing body of clinical data is being used to improve patient outcomes, which we believe will support increased adoption.

We received Pre-Market Approval, or PMA, from the FDA for our RNS System in late 2013 and began the commercial rollout of our RNS System in early 2014. We have historically marketed our RNS System in the United States through a direct sales organization primarily to the epileptologists and neurosurgeons who respectively prescribe and implant neuromodulation devices in the approximately 200 Level 4 CECs in the United States. We have established a significant account base at these CECs. Given the concentrated and underpenetrated nature of our target market, we believe there is a significant opportunity to efficiently drive higher adoption and utilization within these centers, grow our account base, and expand our referral pathways to increase the number of drug-resistant patients referred to Level 4 CECs. Additionally, as a result of the approval of a PMA-S in 2023, we are now able to expand our commercial efforts to the approximately 1,800 additional epileptologists as well as the remaining functional neurosurgeons practicing outside of Level 4 CECs. We initiated a pilot program to begin our outreach to these clinicians in 2024 and have commenced program expansion that will continue through 2025. We plan to address this opportunity in a targeted manner with incremental expansion of our sales force.

The implant procedure for our RNS System and the ongoing patient treatment provided by clinicians, including monitoring and programming, are reimbursed under well-established physician and hospital codes. In addition, we believe that our RNS System is currently the only neuromodulation system for epilepsy with reimbursement available for periodic in-person or remote review of brain activity data. Given the relatively young average age of our patient population, our payor mix has historically been more heavily weighted towards commercial payors. As of December 31, 2024, commercial payors have written positive coverage policies that address over 200 million covered lives in the United States. Medicare and Medicaid also routinely provide coverage for implantation of our RNS System and follow-up care. Based on our experience, less than 1% of potential RNS System patients have been unable to undergo an implant procedure with our RNS System due to lack of payor coverage. We believe the established, differentiated, and favorable reimbursement paradigm for our RNS System will continue to support its broad commercial adoption.

Our near-term research, development, and clinical efforts are focused on continuing to improve therapy effectiveness, enhance the patient and provider experience, and expand the population of patients that can be treated with our RNS System. Our near-term product development pipeline includes enhanced offerings that leverage our extensive brain activity database and our advanced data analysis, machine learning and artificial intelligence, or AI, capabilities. We are also pursuing studies to support label expansion for our RNS System in additional epilepsy populations.

In February 2025, we received approximately $69.8 million in net proceeds from the sale of 7,475,000 shares of our common stock, including 975,000 shares from the exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share. We used $49.5 million of the net proceeds from the offering to repurchase all of the shares held by our significant stockholder, KCK Ltd. We intend to use the remaining net proceeds from the offering for general corporate purposes, which may include clinical trial and other research and development expenses, selling, general and administrative expenses, debt reduction and working capital.

Our Growth Strategies

We expect that the near-term growth of our business will be primarily driven by new patients being treated with our RNS System. We believe the following strategies will contribute to growth in initial patient implants and advance our mission to dramatically improve clinical outcomes and quality of life for patients living with epilepsy and other disabling brain disorders:

- ***Drive adoption and utilization of our RNS System within Level 4 CECs***. Our commercial efforts have primarily been focused on the Level 4 CECs where drug-resistant focal epilepsy patients are actively seeking treatment. In 2024 there were approximately 200 Level 4 CECs in the United States. We estimate that there are approximately 1,200 epileptologists affiliated with these centers, approximately five to seven per center on average. We believe the remaining epileptologists in our existing accounts who are not currently prescribing the RNS System represent a significant potential opportunity to drive efficient growth.

Our partnership with DIXI Medical further enhances our ability to drive adoption and utilization by giving our representatives access to epilepsy monitoring units in Level 4 CECs, generating earlier opportunities to provide education and awareness about the RNS System.

- ***Expand RNS System access outside of Level 4 CECs, in the community***. Our sales team has begun to target epileptologists and functional neurosurgeons practicing outside of Level 4 CECs to expand access to RNS therapy, both in the community and through referral of patients to Level 4 CECs. As we expand our footprint, we plan to continue to drive increased adoption and utilization of our RNS System within new and existing accounts by (i) growing the number of epileptologists recommending our system within each customer account, (ii) increasing utilization of our system by prescribers, and (iii) expanding our referral pathways to increase the number of patients with drug-resistant epilepsy that are referred to CECs for the care that they need. We believe that with incremental additional resources, our focused commercial organization will be able to grow adoption and utilization both at Level 4 CECs and in the community. Our goal is to establish our RNS System as a standard treatment for drug-resistant focal epilepsy patients by engaging in targeted, efficient sales and education efforts to expand our footprint.

- ***Broaden indications for our RNS System to include patients with generalized epilepsy and patients under age 18.*** Of the 50,000 drug-resistant epilepsy patients that present at Level 4 CECs in the United States annually, we estimate that approximately 48%, or 24,000, are adults with drug-resistant focal epilepsy who are currently candidates for our RNS System. The remaining patients include approximately 40%, or 20,000 patients with drug-resistant generalized epilepsy and approximately 12%, or 6,000 patients under the age of 18 with drug-resistant focal epilepsy. Supported by a growing body of evidence published in peer-reviewed journals, we believe that our current RNS System may be able to effectively treat these expanded patient populations, and we are pursuing clinical studies to support label expansion for these indications. In March 2024, we finished implanting patients in our clinical trial to evaluate RNS System use in the generalized epilepsy population. We do not believe we will need to modify our RNS System for potential use in patients under the age of 18 or in generalized epilepsy; however, we will need to complete our clinical studies and obtain FDA approval prior to marketing the RNS System for these indications.

- ***Continue building and using our unique data asset and our monitoring and analysis capabilities.*** Our RNS System is the only commercially available closed-loop system that is not only able to deliver therapy, but also continuously monitors, analyzes and records brain activity. As we continue to derive insights from AI-driven analyses of our unique and extensive brain data set to further improve the effectiveness of RNS therapy, we believe our data and analyses also have the potential to support more efficient development of other epilepsy therapies through collaborations with third parties. In November 2023, we entered into a collaboration agreement with Rapport Therapeutics, Inc., or Rapport, a clinical-stage biotechnology company, to leverage our RNS System's unique biomarker monitoring and data analysis capabilities. The collaboration evaluates biomarker changes in currently implanted RNS System patients that have enrolled in Rapport's clinical trial of its product candidate. Pursuant to this agreement, we provide information to Rapport that will help evaluate the impact of their product candidate on certain biomarkers of patients with focal onset seizures. We may enter into similar collaborations with other companies.

- ***Expand into international markets***. We estimate that the global drug-resistant epilepsy market includes approximately 16.5 million patients, of which the United States represents approximately 1.2 million patients. While we are presently focused on addressing the significant domestic market opportunity, we believe our RNS System offers an attractive value proposition for patients, providers, and payors in the large potential market outside of the United States and may additionally seek to expand our operations to reach the approximately 16.5 million drug-resistant epilepsy patients globally. While our RNS System is not yet approved for sale outside the United States, other than limited case-by-case approvals pursuant to a special program in Canada, if we determine to expand internationally, we will plan to pursue regulatory approvals and reimbursement with a priority on markets in which we see significant potential opportunity.

- ***Pursue additional indications outside of epilepsy***. We believe our versatile, closed-loop, brain-responsive neuromodulation platform has potential applications in other brain disorders including depression, memory disorders, and post-traumatic stress disorder. For each of these conditions, we are collaborating with

academic investigators in early IDE feasibility studies using our RNS System in patients. In the future, depending on the outcome of these studies, we may seek regulatory approval to commercialize our technology for these or other indications. We will need to conduct additional studies to determine if any modifications to the RNS System are necessary and to obtain FDA approval prior to marketing the RNS System for any new indications.

Our RNS System

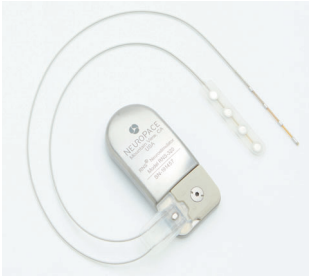
Our RNS System, which is a compilation of several of our products, is a paradigm-shifting approach to treating epilepsy that combines the power of continuous iEEG monitoring with responsive neuromodulation. With our RNS System, we offer a personalized treatment option that delivers a safe and effective therapy for focal onset seizures originating anywhere in the brain. We believe our RNS System is superior in tolerability and efficacy to other neuromodulation approaches and provides clinicians with actionable insights based on their patients' brain activity, facilitating better treatment decisions and optimizing patient care.

Overview

Our RNS System includes our RNS neurostimulator, our cortical strip leads and depth leads, and our Patient Remote Monitor, as well as other implantable and non-implantable accessories. As part of the initial implant procedure, the number and configuration of leads implanted as well as the implantable and non-implantable accessories used in the procedure are determined by the clinician depending on individual patient need and clinician preference and a Patient Remote Monitor is typically included. During a typical replacement implant procedure performed when the battery in our RNS neurostimulator reaches end of service, the RNS neurostimulator is replaced, while the previously implanted RNS leads remain in place and a new Patient Remote Monitor is typically included. Our product offerings also include our Physician Tablet, our Patient Data Management System, or PDMS, and our nSight Platform, which facilitate ongoing patient monitoring and streamline patient support.

We developed our RNS System to address the individualized nature of drug-resistant epilepsy with a differentiated technology that provides personalized, data-driven treatment. Our RNS System is the first and only closed-loop, brain-responsive neuromodulation device approved by the FDA for treatment of drug-resistant focal epilepsy. By continuously monitoring the brain's electrical activity, recognizing patient-specific abnormal electrical patterns, and responding in real time with imperceptible electrical pulses to prevent seizures, we believe our RNS System addresses the primary unmet needs in epilepsy care today.

The implantable components of our RNS System include a neurostimulator, which is placed within the patient's skull, and our RNS System leads with both cortical strip electrodes (on the surface of the brain) and depth electrodes (within the brain) that can be positioned according to clinician preference, as well as implantable accessories such as our burr hole cover. The neurostimulator is flush with the patient's skull, and under the scalp, so that it is not visible externally. Placing the neurostimulator in the skull minimizes external noise and movement artifact so that it is able to sense even the most subtle brain signals and eliminates the need for long tunneled connectors between the chest and head which reduces the risk for breakage, migration and discomfort that can be associated with some other neuromodulation devices.



The electrodes on the leads sense electrical activity from the brain, provide targeted stimulation only when abnormal activity is detected, and record iEEG data that is stored in the neurostimulator and transmitted wirelessly to a secure portal for remote review by the patients' clinicians. Once fully programmed, patients do not feel the stimulation bursts, which are typically 100 to 200 milliseconds long. Because our RNS System provides targeted, responsive stimulation only when abnormal electrical activity is detected, patients receive approximately three minutes of stimulation on average per day and do not experience stimulation-related side effects at therapeutic settings.

In addition to the implantable components of our RNS System, our RNS System also includes external components such as the Patient Remote Monitor, as well as optional accessories.

Our Patient Remote Monitor is provided to each patient in order to collect and transmit data from the neurostimulator to our PDMS, a secure online database. It consists of a handheld wand and a specially programmed tablet or laptop computer. The patient holds the wand adjacent to the implanted device to wirelessly upload the data from the neurostimulator to the tablet or laptop, and then sends that encrypted data to our PDMS using an internet connection.

Additionally, we provide our Physician Tablet and access to our PDMS and nSight Platform for use with our RNS System.

Our Physician Tablet is used by the prescribing or managing clinicians for programming implanted devices and managing patient care. Using the tablet's simple, intuitive interface, the clinician retrieves and reviews iEEG data, detections, and stimulations that were recorded by our RNS System, and can program new detection and stimulation settings that are personalized to each patient's brain activity. While the patient is in clinic, the clinician can look at real time iEEG data or test stimulation settings.

Our PDMS is a secure online database that collects data that have been recorded by our RNS System. These data, which include all programmed parameters, detections, stimulations, and stored iEEG activity for RNS System patients, can be accessed through our Physician Tablet or from any internet browser. The clinician may choose to view recent data or to look at longer term trends in order to assess the effects of RNS System treatment, antiepileptic drugs or even changes to the patient's routine. This information, combined with the patient's own reports, is used by the clinicians to make treatment decisions.

In addition to the extensive data set available on our PDMS, our nSight Platform is designed to provide clinicians with personalized patient reports as well as programming suggestions. Our nSight Platform, which is designed to streamline patient care, includes objective iEEG data recorded by our RNS System, patient-reported seizure diary data, prior programmed settings, and programming suggestions which are available in a simple and comprehensive report that provides the clinician actionable information about their patient's seizure trends and treatment outcomes. This quick snapshot gives clinicians a more complete picture of their patient's health and enables them to remotely manage certain portions of the patient's care in a telehealth environment.

As we collect iEEG data from our RNS System, our database of iEEG records continues to grow. As of December 31, 2024, over 6,000 epilepsy patients have received our RNS System, yielding an extensive database of over nineteen million iEEG records. We believe that we are able to continue to learn and innovate by leveraging this database and our monitoring and data analytics capabilities, thereby improving and enhancing our products and creating actionable insights for clinicians that improve clinical outcomes for patients.

Patient and Clinician Experience

Once an adult patient has been determined to have drug-resistant focal epilepsy, we believe the patient should be considered for our RNS System. Our RNS System is initially implanted by a neurosurgeon in an inpatient procedure. Detection is turned on at the end of the implant procedure when the neurostimulator is placed. The patient typically remains in the hospital overnight, then returns home and resumes normal activities. Prior to the first in-person follow up visit, which typically occurs approximately two weeks to four weeks after the implant procedure, an epileptologist will review the iEEG data recorded by our RNS System and identify patient specific patterns that are associated with the early onset of seizures. During the follow-up visit, the epileptologist will make

programming adjustments to the device's detection parameters in order to optimize for early detection. Once the patient-specific detection parameters are established, the epileptologist will turn on the stimulation feature, activating the closed-loop treatment of our RNS System.

Once the device has been programmed, our RNS System integrates seamlessly into the typical cadence of care that clinicians currently utilize to manage epilepsy patients. Patients visit their clinician on average every three months during the first year after the procedure. During these visits, clinicians review the iEEG data and may fine-tune programming of the device to optimize clinical outcomes. Once the device settings have been sufficiently fine-tuned, patients typically visit their clinician every three to six months, or on an as needed basis. At any point, clinicians can remotely review patient data and connect with the patient on next steps.

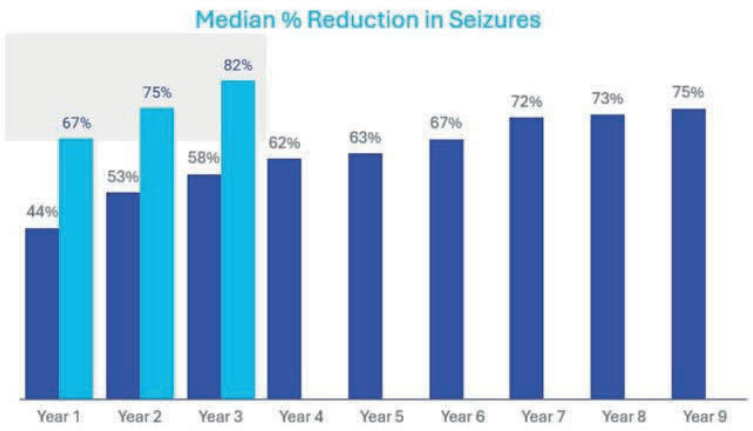
Additionally, we believe that patients find that seeing and learning about their own brain data is empowering and engaging. We believe that for the first time, clinicians can show patients their own seizure patterns and seizure cycles recorded by our RNS System, so that patients can directly see the effects on brain activity with changes in activity or treatment. Patients also appreciate that the device is not visible to themselves or others.

Our RNS System has an average battery life of nearly eleven years, an increase from the previous model of the device. The device requires replacement once it approaches the end of its battery life. We believe that patients prefer a longer battery life as it reduces the number of procedures they will require over their lifetime. Replacement procedures are typically performed on an outpatient basis and take approximately one hour. Clinicians are able to view the device's battery status through our Patient Data Management System or on our Physician Tablet, and can plan accordingly with the patient for replacement procedures. In 2019, more than 90% of patients whose RNS System reached the end of its battery life chose to have a replacement RNS System implanted.

Key Clinical Advantages

We believe the key advantages of our RNS System relative to both alternative neuromodulation devices and resective or ablative surgery include:

Significant and improving seizure reduction in all areas of the brain. Four multi-center FDA approved prospective clinical trials and multiple retrospective studies have demonstrated that our RNS System provides significant, sustained and improving reductions in disabling seizures. In our Pivotal Study, patients experienced a median reduction in seizure frequency of 44% after the first year. The patients from the Pivotal Study, all of whom received implants prior to 2010, were followed in a Long-term Treatment Trial, or LTT, in which outcomes reached a 75% median reduction in seizure frequency at nine years. 28% of these patients, who had previously experienced disabling seizures for an average of 20 years, had at least 6 months of seizure freedom and approximately 20% achieved one year or more of seizure freedom. Additionally, we believe the insights obtained from our extensive brain data set are driving improvements in overall therapy effectiveness across patient cohorts over time. The real-world results published in 2020 from a retrospective study across eight epilepsy centers with patients implanted between 2013 and 2018 showed a statistically significant median seizure frequency reduction of 67% at one year ($p<0.05$), increasing to an 82% reduction in seizures by year three, which we believe is the highest published seizure frequency reduction for any neuromodulation study in adults with focal onset seizures. Recent three-year data from our Post-Approval Study confirmed this reduction in seizure frequency and showed a 100% reduction in seizure frequency among the top quartile of patients. Importantly, peer-reviewed studies have also indicated that our RNS System demonstrates similar efficacy outcomes regardless of the region of the brain being treated, whether there are one or two seizure foci, and whether the patient has been previously treated with VNS or resective or ablative surgery.



Real World Study Results (Light Blue); Original FDA Study Results (Dark Blue)

Lack of stimulation-related side effects. Our clinical studies have collectively demonstrated that RNS System therapy is well-tolerated. Patients do not perceive the therapeutic stimulation, which is delivered only when abnormal activity occurs. Unlike other neuromodulation devices for epilepsy, which provide hours of stimulation each day and have been shown to negatively impact sleep, mood, memory, or vocal characteristics, our RNS System provides stimulation only when needed, resulting in a highly effective therapy with approximately three minutes of stimulation on average per day in total.

Quality of life, cognition, and mood improvement. Reduced quality of life and cognitive function, as well as mental health-related comorbidities, are a significant burden for many patients with drug-resistant focal epilepsy. Improvements in these areas are critically important clinical outcomes for patients. In our Pivotal Study, at one and two years of follow-up, patients who began treatment less than ten years after epilepsy onset achieved statistically significant improvements in overall quality of life scores as well as in every subdomain of quality of life, including cognitive function, mental health, and physical health. Additionally, our clinical studies have demonstrated that treatment with our RNS System resulted in lasting improvements in overall quality of life, including cognitive function, sustained through nine years. Based on comprehensive neuropsychological assessments, there were no adverse cognitive effects and, in fact, significant cognitive improvements were demonstrated in areas such as naming, verbal learning, visual memory, and executive function.

Low risk, reversible procedure. As demonstrated by multiple clinical studies, our RNS System has a favorable safety profile relative to surgical procedures for epilepsy and a comparable risk profile to the implantation of other neuromodulation devices. Resective or ablative surgical procedures carry a risk of permanent damage to neurological and cognitive function, whereas the non-destructive RNS System implant procedure has not demonstrated a negative impact on neurological or cognitive function. Additionally, stimulation treatment with our RNS System is reversible and modifiable, and does not take away the option of a surgery in the future.

Reduction in sudden unexpected death in epilepsy. Epilepsy patients, particularly those with uncontrolled epilepsy, face a risk of what is called sudden unexpected death in epilepsy, or SUDEP. Each year, about 1 in 150 patients with uncontrolled epilepsy will die from SUDEP. According to clinical studies, the SUDEP rate is approximately 6.1 per 1,000 patient years in patients with drug-resistant epilepsy and 9.3 per 1,000 patient years in patients referred for resective or ablative surgery. By contrast, data from a published series of 707 patients across our clinical studies and post-market experience indicated that our RNS System was associated with a lower rate of dying from SUDEP, 2.0 per 1,000 patient years, relative to other treatment-resistant epilepsy groups.

The results of our prospective clinical studies, which are the largest and longest published studies in the field of neuromodulation for epilepsy, as well as the data that has been published in multiple retrospective studies of our RNS System, provide evidence that our RNS System is a safe and effective treatment for focal onset seizures and offers a lower risk profile than that of resective or ablative surgery. In addition, we believe our RNS System is

superior in tolerability and efficacy to other neuromodulation approaches. We anticipate that the accruing evidence base from our ongoing Post-Approval Study and commercial experience with our RNS System will continue to demonstrate strong and improving clinical outcomes over time, which will support continued adoption.

Benefits to Other Stakeholders

In addition to offering important clinical benefits to patients, we believe our RNS System offers important distinctions for providers and payors.

Providers

We believe the unprecedented insights into brain activity that are enabled by our RNS System's differentiated ability to record iEEG data offer clinicians the opportunity to more thoroughly understand patient specific brain activity in order to optimize treatment for their patients. With the benefit of objective, long-term data on seizure trends and treatment response, clinicians are better able to actively manage patient care and support improved outcomes over time. In a survey of 50 epileptologists and neurosurgeons at Level 3 and Level 4 epilepsy centers, 88% agreed that having 24/7 monitoring with chronic high-resolution intracranial EEG data is an important consideration and advantage in choosing RNS versus VNS or DBS.

Importantly, in addition to the availability of established clinician and facility reimbursement for the initial and replacement implant procedures, the patient's managing clinician can seek reimbursement for in-person or remote iEEG data review up to once per month and for device programming. Because our RNS System is the only neuromodulation device that records iEEG data, we believe it is also the only neuromodulation device with established reimbursement for data review by clinicians during and between in-person clinic visits, which we believe is an important element of optimizing patient care.

Payors

Drug-resistant epilepsy is a costly condition that places a significant economic burden on healthcare systems as well as on patients and their families. The estimated direct costs of epilepsy alone are approximately $28 billion annually in the United States and are disproportionately accrued by individuals with uncontrolled drug-resistant epilepsy. By offering drug-resistant focal epilepsy patients a safe, effective treatment alternative that significantly reduces ongoing seizure frequency without stimulation-related side effects at therapeutic settings, we believe our RNS System has the potential to reduce the cost burden associated with drug-resistant epilepsy. We believe the established and favorable reimbursement paradigm for our RNS System, which covers both the implantation procedure and ongoing patient treatment provided by clinicians, endorses the value proposition that it offers payors.

We also believe that the unique ability for clinicians to review their patients' RNS System data online can facilitate telehealth delivery, potentially reducing the overall cost of care, while improving the patient experience. For example, many patients who might otherwise schedule a clinic visit because of a concern about seizures can now contact their clinician from their home, who can then review their RNS System data online and provide care remotely.

Clinical Data Supporting Our RNS System

The safety, effectiveness. and clinical benefits of our RNS System are supported by data from four multi-center, FDA approved prospective clinical studies representing nearly 600 patients and multiple retrospective studies reporting real-world outcomes. Our robust and growing body of clinical evidence, which includes nine-year follow-up with over 3,400 years of patient data, provides the largest and longest published prospective clinical data set in the field of neuromodulation devices for epilepsy. Data from these studies collectively demonstrate that our RNS System provides significant, sustained, and improving reductions in disabling seizures with enduring improvements in quality of life and cognition for patients with drug-resistant focal epilepsy.

Our first prospective clinical trial, which we refer to as the Feasibility Study, was initiated to assess the safety and performance of our RNS System and to provide preliminary evidence of effectiveness for patients living with drug-resistant focal epilepsy. Data from the two-year Feasibility Study supported IDE approval for our two-year

Pivotal Study, a double blinded, randomized, sham-stimulation controlled multi-center study that was initiated in 2005 and provided Class I evidence of the safety and effectiveness of our RNS System. Data from the Pivotal Study supported FDA PMA approval of our RNS System. Patients from the Feasibility and Pivotal Studies were subsequently enrolled in our LTT study that followed these patients for an additional seven years, culminating in a total of nine years of follow-up data. We are currently conducting a prospective Post-Approval Study evaluating "real world" outcomes across more than 300 additional patients. We are also pursuing studies to support label expansion for our RNS System in additional epilepsy populations.

Across the 256 patients that were enrolled in the Feasibility and Pivotal studies, the average age was 34 years old and the patients had experienced an average of 10.2 disabling seizures per month for an average of 19.6 years. All patients had previously tried multiple anti-epilepsy drugs, or AEDs, 32% of patients had previously been treated with VNS, and 34% had previously undergone resective or ablative surgery.

Feasibility Study

The Feasibility Study was a two-year prospective, primarily open-label study of our RNS System in adult drug-resistant focal epilepsy patients that demonstrated safety and provided sufficient evidence of effectiveness to support the commencement of a pivotal study. Beginning in 2004, 65 patients were treated with our RNS System and 59 patients completed the study.

The primary safety endpoints were the rate of serious adverse events during the first month post-implant and the first three months post-implant. The serious adverse events rates at one month post-implant and three months post-implant of 6.2% and 9.2%, respectively, were not worse than the serious adverse event rates associated with the implantation of intracranial electrodes for localization procedures and epilepsy surgery at one month post-implant of 19%, or the historical adverse event rate for DBS for treatment of movement disorders at three months post-implant of 36%. During this two-year study, 53 serious adverse events, or SAEs, were reported, 18 of which were either associated with the RNS System or were inconclusive as to association with the RNS System. These SAEs included increased seizure frequency, wound erosion, confusion, death (one instance for which we were unable to conclude whether there was association with the RNS System), depression, headaches, or the requirement for explant surgery to remove the RNS System.

This safety experience combined with encouraging data on seizure outcomes supported commencement of the subsequent Pivotal Study.

Pivotal Study

The Pivotal Study was a two-year prospective, double-blinded, randomized, and sham-stimulation controlled study that provided Class I evidence indicating that our RNS System is safe and effective as an adjunctive treatment for adults with drug-resistant focal epilepsy arising from one or two seizure foci. Between December 2005 and November 2008, 191 patients were enrolled in the study and 175 of those patients completed the study.

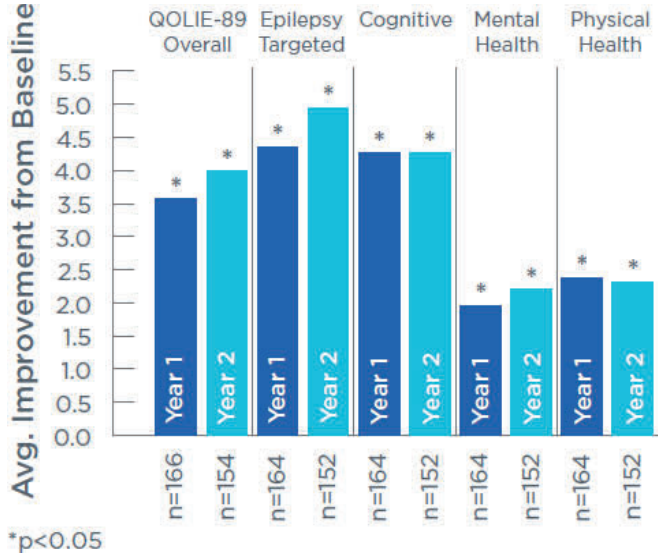
The primary effectiveness endpoint was assessed by comparing seizure reduction in the group receiving active stimulation (treatment group) relative to the group receiving no stimulation (sham group) during a 12-week blinded evaluation period relative to a 12-week pre-implant baseline. The primary effectiveness endpoint was met with a statistically significant difference between the reduction in seizure frequency for the treatment group relative to the sham group. In the final month of the blinded evaluation period (five months post-implant), patients in the treatment group reached a 41.5% reduction in seizures, compared to a 9.4% reduction for patients in the sham stimulation group.

The primary safety endpoint was also met, demonstrating that the serious adverse event rate at one month was not worse than the literature-derived serious adverse event rates for resective or ablative surgery, implantation of intracranial electrodes for seizure localization, and DBS for treatment of movement disorders.

Stimulation was also well-tolerated. There was no difference in stimulation-related side effects between active and sham patients in the blinded period and no adverse effects of responsive stimulation on cognitive function or mood. In fact, there were statistically significant improvements in a number of areas of cognitive function, including

executive function, language, and memory. Memory improvements were most evident in patients with seizure onsets in memory regions and verbal fluency improvements were most significant in those with seizure onsets in language areas. Patients also experienced modest improvements in mood and a decrease in seizure worry at two years of treatment. During this two-year study 220 SAEs were reported, 67 of which were either associated with the RNS System or were inconclusive as to association with the RNS System. These SAEs included procedural complications (such as device lead revision or damage, skin laceration, subdural hematoma, premature battery depletion, or implant site erosion), nervous system disorders (such as an increase in complex partial seizures, exacerbation or increase in tonic-clonic seizures, or hydrocephalus), implant site infections, death (seven instances with one for which we were unable to conclude whether there was association with the RNS System), pain, and discharge.

Patients were also assessed for changes in Quality of Life, or QOL, as measured by a comprehensive industry-recognized questionnaire that is validated and widely used for patients living with epilepsy. As shown in the graph below, there were statistically significant sustained improvements in overall QOL as well as in every subdomain of QOL for patients who began treatment less than ten years after epilepsy onset at both one and two years of follow-up.

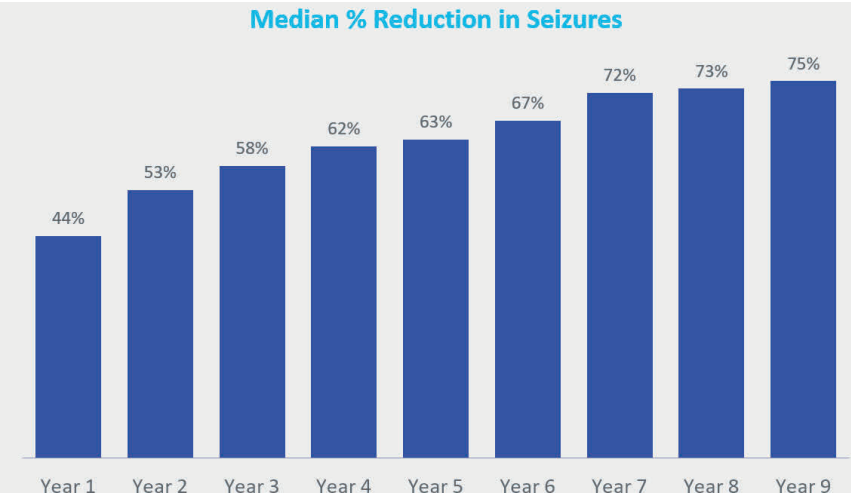


Long-Term Treatment (LTT) Study

The LTT study was a seven-year prospective, open-label study that followed patients originally treated in either the Feasibility or Pivotal Study. In total, this provided approximately nine years of prospective data on the safety and efficacy of our RNS System. The LTT study, which enrolled 230 patients, is the largest and longest prospective trial published in the field of neuromodulation to date and provided additional evidence that our RNS System is safe, reduces seizure frequency, and improves QOL in adults with drug-resistant focal epilepsy with one or two seizure foci. Enrolled patients were studied over a median follow-up of 8.97 years, representing 1,895 cumulative patient-implant years.

The primary effectiveness objective of the LTT study was to evaluate the long-term efficacy of our RNS System in reducing the frequency of disabling seizures in patients who participated in the Feasibility Study or Pivotal Study. As indicated in the figure below, the median percent reduction in seizure frequency improved from 44% after one year to 75% at nine years. We believe the substantial improvement in seizure reduction that was observed over time

is due, in part, to the brain-responsive nature of our RNS System and the personalized, data-driven, and iterative therapy that it enables.



Additionally, at nine years, 35% of patients had a greater than 90% reduction in seizure frequency, with some of those patients being seizure-free for years, and 28% had at least one seizure-free period of six months or longer. These improvements were particularly notable given that at baseline the patients in this trial had on average more than 10 disabling seizures a month, with an average of nearly 20 years of epilepsy, and had failed multiple other epilepsy therapies. Overall QOL as well as the sub-domains of the comprehensive QOL score remained significantly improved relative to baseline at each year of treatment.

During this seven-year study 576 SAEs were reported, 93 of which were either associated with the RNS System or were inconclusive as to association with the RNS System. These SAEs included procedural complications (such as device lead revision or damage, skin laceration, fractures from falls, premature battery depletion, wound dehiscence, or implant site erosion), nervous system disorders (such as an increase in complex partial seizures, exacerbation or increase in tonic-clonic seizures, or headaches), implant site infections, device removal, death (nine instances with two for which we were unable to conclude whether there was association with the RNS System).

Post-Approval Study

We are currently engaged in follow up and data collection for our FDA-mandated prospective open-label "real-world" study of our RNS System in drug-resistant focal epilepsy patients with a planned follow up period of five years, or the Post-approval Study. As of November 2024, all patients in the Post-approval Study have completed three years of follow up, and the associated safety and effectiveness data have been submitted to and accepted by the FDA.

In this clinical study, our RNS System was implanted in 324 patients across 32 centers. The objectives of the clinical study are to collect additional information on the safety and effectiveness of our RNS System and to analyze patient outcomes and responses according to center experience and stimulation parameters. An interim analysis of 160 patients followed for one year that was presented at the American Epilepsy Society Annual Meeting in 2019 showed a 67% median reduction in seizure frequency compared to baseline, demonstrating significantly better outcomes than were seen in our Feasibility Study and Pivotal Study at that same time point. In addition, 38.5% of patients followed for more than one year experienced a greater than 90% reduction in seizure frequency.

During this ongoing five-year study, 224 SAEs have been reported, 19 of which were attributed to the implant procedure and none of which were attributed as specific to treatment with the RNS System. These SAEs included nervous system disorders (such as cerebral or intracranial hemorrhage and tinnitus), implant site infections, subdural hematoma, status epilepticus, and implant site dehiscence.

We recently announced our primary effectiveness endpoint data in the Post-approval Study. Of the 324 patients in the trial across 32 participating centers, 271 patients completed three years in the study and 255 patients provided complete seizure data. The data showed that the RNS System efficacy improved over time, with 62.5% median seizure reduction at six months after implant (n=314) and an 82.0% median seizure reduction at 36 months after implant (n=255). Additionally, 42.5% of patients experienced a period of seizure-freedom for at least six months, and 22% of patients were seizure free for at least one year. Results will be presented at the American Academy of Neurology Annual Meeting, held April 5 through 9, 2025.

Current Label Expansion Studies

RESPONSE Study

We are conducting studies to support label expansion for our RNS System in additional epilepsy populations. We have IDE approval for an open label study of our RNS System in adolescent patients between ages 12 and 17 who have drug-resistant focal epilepsy from one or two foci. The objective of this study, referred to as the RESPONSE study, is to demonstrate safety and effectiveness in this pediatric population, and to obtain data on quality of life, neuropsychological function, and social function. Importantly, our RNS System does not require any modifications to conduct this study. We began enrollment in RESPONSE in late 2021. We recently announced our collaboration with the National Evaluation System for health Technology, or NEST, and the FDA to pursue the use of real-world data from the Pediatric Epilepsy Research Consortium, or PERC, to supplement the RESPONSE study. We are planning to file the expanded label submission to the FDA in the second half of 2025.

NAUTILUS Study

Supported by evidence published in peer-reviewed journals, we also believe that our current RNS System may be able to effectively treat patients with drug-resistant generalized epilepsy. In February 2021, our RNS System received Breakthrough Device Designation from the FDA for the treatment of IGE. In the second half of 2021, we received IDE approval to initiate a study in IGE, called the NAUTILUS study, and in March 2024, we completed implanting patients in NAUTILUS, for a total of 87 patients implanted across 23 centers. In March 2025, the last patient is expected to complete one year of follow up post-implant, with the data lock and subsequent commencement of data analyses expected to begin in the second quarter of 2025. We plan to use this data to support our expected expanded label submission to the FDA in the second half of 2025 and we anticipate the final patient two-year completion in the first half of 2026.

Commercial Strategy

Our commercial strategy historically targeted epileptologists and neurosurgeons at Level 4 CECs in the United States. Within Level 4 CECs, epileptologists are the primary specialists who prescribe and manage therapy for drug-resistant focal epilepsy patients and neurosurgeons are the specialists who implant our RNS System. We estimate that there are approximately 1,200 epileptologists and 400 neurosurgeons associated with the approximately 200 Level 4 CECs in the United States. We also aim to improve flow of appropriate patients to Level 4 CECs with sales and marketing initiatives designed to enhance awareness of our RNS System and increase referrals of drug-resistant epilepsy patients to these centers.

In 2023, we received FDA approval of a PMA-S, which updated the qualification criteria for centers and clinicians that may prescribe and implant the RNS System. This PMA-S approval allows us to expand our commercial efforts to target and be able to qualify the approximately 1,800 additional epileptologists outside of Level 4 CECs and the entire population of functional neurosurgeons, empowering them to provide the RNS System as a much-needed treatment option for their patients directly and expanding their ability to refer appropriate patients to Level 4 CECs for more enhanced diagnostic and treatment options.

We market and sell our RNS System in the United States through a direct sales organization that consists of sales representatives, known as Therapy Consultants, and clinical and programming support specialists, known as Field Clinical Engineers. Substantially all of our sales of the RNS System are in the United States. Our Therapy Consultants are highly skilled and technically trained with substantial experience launching new disruptive therapies, particularly in neuromodulation, and establishing them as a standard of care by increasing clinician

adoption and utilization. Our Field Clinical Engineers have substantial experience training clinicians on the use of sophisticated technology and providing ongoing support for medical centers as they increase adoption of new therapies.

Our Therapy Consultants are responsible for developing territory business plans, targeting and onboarding new accounts, and increasing adoption of our RNS System within accounts. In addition, Therapy Consultants support epileptologists and their staff in incorporating our RNS System into their practice and provide resources to help with patient education within the CECs and community setting, as well as working to expand our referral pathways to increase referrals into Level 4 CECs. Together with our Field Clinical Engineers, they provide information that epileptologists can use to inform the development of appropriate patient selection protocols, and partner with the epilepsy care team to help incorporate our RNS System into their workflow. Our Field Clinical Engineers are responsible for ongoing account management including training clinicians on the use of our RNS System, promoting its benefits within existing accounts, and driving increased clinician utilization.

We support our sales organization with marketing and training initiatives designed to educate clinicians about our RNS System and support clinician adoption. We have developed a robust professional education program that includes educational symposia, fellows training, programming workshops, and peer-to-peer forums. Through webinars, clinical briefs, and scientific conferences, we keep our clinician customers informed about the rapidly growing body of peer-reviewed publications and scientific research involving our RNS System. We also engage in direct-to-patient marketing activities including targeted online advertising and social media to increase awareness about the benefits of our RNS System among potential patients and their caregivers.

Collaborations and Partnerships

DIXI Medical Distribution Agreement

In August 2022, we entered into an exclusive distribution agreement, or the Distribution Agreement, with DIXI Medical, pursuant to which we became the exclusive U.S. distributor of DIXI Medical's stereo electroencephalography, or Stereo EEG, product line beginning in October 2022. These products are used in the epilepsy monitoring units, or EMUs, of Level 4 CECs to determine where epileptic seizures originate. In addition to providing us with an incremental revenue stream, the DIXI Medical partnership provides us with improved visibility of patients moving through the EMUs, many of whom may be candidates for our RNS System. This synergistic partnership leverages our field organization that is already calling on the same customers and supports our objective to engage earlier in the diagnostic and therapy selection process. The Distribution Agreement has an initial term of three years, which expires September 30, 2025. The Distribution Agreement automatically renews for additional one-year terms, unless either party provides written notice to the other party of its intention to not renew at least 180 days prior to the expiration of the then-current term. The current Distribution Agreement will automatically renew unless either party provides notice of intent not to renew by April 3, 2025.

Rapport Agreement

In November 2023, we entered into a collaboration agreement with Rapport Therapeutics, Inc., or Rapport, a clinical-stage biotechnology company, to leverage our data as well as our RNS System's unique biomarker monitoring and data analysis capabilities. The collaboration evaluates biomarker changes in currently implanted RNS System patients that enroll in Rapport's Phase 2a clinical trial of its product candidate. Pursuant to this agreement, we provide information to Rapport that will help evaluate the impact of their product candidate on certain biomarkers of patients with focal onset seizures.

Research and Development

We focus our research and development efforts on advancing the treatment of patients living with disabling neurological disorders. These efforts are enhanced by the strong relationships that we have developed with epileptologists and neurosurgeons, as well as other neuroscientists and experts, through our clinical and commercial activities. We believe our brain-responsive RNS System is a platform that can drive a better standard of care for patients living with drug-resistant epilepsy and can also offer a more personalized solution and improved outcomes to the large population of patients living with other brain disorders.

Our research and development activities encompass basic research, clinical research and product development. Our research and development team has mechanical, biomedical and electrical engineering, software development, project management, data science, and machine and deep learning expertise. In addition, our clinical organization has expertise as well as extensive experience in clinical trial design and management, data collection, data management, and clinical data analysis. Our clinical team has conducted three prospective clinical studies on our RNS System and completed enrollment in a fourth, prospective Post-Approval Study, in addition to the ongoing NAUTILUS and RESPONSE studies. We believe the strength and strategic vision of our research and development team, combined with our clinical and regulatory expertise, will continue to drive our leadership position in the emerging category of brain-responsive neuromodulation.

Our near-term research and development efforts are focused on continuing to improve therapy effectiveness, enhancing the patient and provider experience through increased ease of use and efficiency, and expanding the population of patients that can be treated with our RNS System. Our research and development activities have resulted in significant new releases of components of the RNS System that advanced these goals. Our near-term development pipeline includes enhancements that leverage our extensive database of iEEG data and our advanced data analysis, machine learning and AI capabilities, which provide clinicians with additional information that they can use to enhance their clinical assessment and establish appropriate program settings for each patient. We believe our unique data, as well as our data analysis, machine learning, and AI capabilities, provide a window into the brain and may be useful to other third parties doing work in or treating patients with epilepsy. In addition to our near-term efforts, we continue to focus on developing our next-generation neurostimulator and developing new features such as streamlined, remote programming capabilities.

We recently announced that in 2025 we plan to release an AI-powered electrographic seizure classifier tool as a part of the PDMS component of the RNS System. With this tool, we anticipate bringing greater efficiency in physician identification of electrographic seizures in patients.

We also maintain and will continue to build an intellectual property portfolio covering brain-responsive neuromodulation and AI assessment of brain data. In the future, we intend to leverage these assets to expand into other brain disorders that we believe could benefit from the physiologic and engineering advantages made possible by our brain-responsive neuromodulation solution.

Coverage and Reimbursement

We derive most of our revenue from sales of our RNS System to the hospital facilities, typically CECs, that implant our RNS System in the United States. These facilities, in turn, bill third-party payors, including private insurers, Medicare or Medicaid on a per procedure basis including for the implant procedure and post-implant programming and iEEG data review.

Given the relatively young average age of our patient population, many of our patients do not qualify for Medicare. As such, the third-party payor mix for patients implanted with our RNS System has historically been more heavily weighted toward private insurers. As of December 31, 2024, commercial insurance companies that address over 200 million covered lives in the United States have positive written coverage policies for responsive neuromodulation for drug-resistant focal epilepsy, which includes our RNS System. Medicare and Medicaid also routinely provide coverage for implantation of our RNS System and follow-up care. Based on our experience, less than 1% of potential RNS System patients have been unable to undergo an implant procedure with our RNS System due to lack of payor coverage.

Initial implantation of our RNS System takes place in a single hospital inpatient procedure. Hospitals are generally reimbursed for inpatient procedures based on Medicare Severity Diagnosis Related Group, or MS-DRG, classifications derived from ICD-10 codes that describe the patient's diagnoses and procedure(s) performed during the hospital stay. One single MS-DRG payment is intended to cover all hospital costs associated with treating an individual during his or her hospital stay, with the exception of clinician charges associated with performing medical procedures, which are reimbursed through CPT codes and payments. While these MS-DRG and CPT codes are generally employed by both private insurers and government payors, the payment rates typically differ substantially, with private insurers generally providing reimbursement at higher rates than Medicare or Medicaid.

Hospitals code for implantation of our RNS System neurostimulator and implantation of the leads using separate ICD-10 procedure codes. When combined with an ICD-10 diagnosis code for epilepsy, the codes map into MS-DRG 023 for payment to the hospital. In federal fiscal year 2025, which runs from October 2024 through September 2025, we expect the Medicare average payment rate for MS-DRG 023 at our customer accounts to be approximately $56,900. We believe that most DBS procedures for epilepsy map into MS-DRG 024 and we expect the Medicare average payment rate at these accounts will be approximately $38,400. We believe that VNS implantation procedures take place in a single outpatient procedure and map to Ambulatory Payment Classification, or APC, 5465. We expect the Medicare average payment rate in 2025 will be approximately $32,500.

The neurosurgeons who implant our RNS System may seek reimbursement for their services using a variety of Category I CPT codes, depending on the type of leads implanted. Effective in 2024, these codes include new CPT code 61889 for implantation of the RNS neurostimulator in addition to CPT codes 61850 or 61860 for cortical leads or CPT codes 61863 and 61864 for depth leads. We believe these codes for depth leads are the same CPT codes used for reimbursement of physician services for epilepsy DBS procedures. Based on 2025 Medicare national average payment rates, we expect that physician reimbursement under appropriate combinations of these codes may be between approximately $2,765 to $2,990 per procedure for our RNS System and approximately $2,645 for epilepsy DBS procedures. We believe physician services for the VNS implantation procedure are reimbursed under CPT code 64568 which is associated with a 2025 Medicare national average payment rate of approximately $590.

After implantation of our RNS System, the patient's ongoing care, including device programming and data review, is typically managed by an epileptologist or other qualified clinician. The patient's managing physician is able to seek reimbursement for programming on an as-needed basis. The physician can also seek reimbursement a maximum of once every 30 days for in-person or remote review of iEEGs, which are also referred to as electrocorticograms, or ECoGs. The codes utilized for device programming for both RNS and DBS are CPT codes 95983 and 95984 and the code for ECoG review is CPT code 95836. We believe this CPT code for ECoG review is only applicable to our RNS System as it is currently the only commercially available implanted brain neuromodulation system that records, stores, and enables online review of the patient's ECoG data.

Based on 2025 Medicare national average payment rates, reimbursement under CPT codes 95983 and 95984 is expected to range from $47 to $88, depending on length of programming time. Reimbursement under CPT code 95836 is expected to be approximately $101 for ECoG review. Accordingly, physician reimbursement for device programming and ECoG review during a typical RNS System follow-up visit could range from $148 to $189. We believe physicians submit claims for VNS device programming using code 95976 or 95977, depending on the number of device parameters changed. Based on Medicare national average payment rates, payment under these codes is expected to range from $36 to $48.

Competition

Our industry is competitive and has been evolving rapidly with the introduction of new products and technologies as well as the market activities of industry participants. Our RNS System is indicated for adult patients with drug-resistant focal epilepsy and we currently market our device primarily to the clinicians who treat these patients. In this patient population, there are two primary treatment options: (i) an ablative or resective surgery, or (ii) implantation of a neuromodulation device. Patients may also choose not to actively seek additional treatment for epilepsy or may choose to trial new therapeutic drugs that become available from time to time. However, none of the AEDs that have been approved in the last decade have been demonstrated to show additional sustained effectiveness beyond that of the established AEDs.

We estimate that approximately 80% of drug-resistant focal epilepsy patients are either not ideal candidates for ablative or resective surgery or are unwilling to undergo a destructive surgical procedure and we compete primarily with two manufacturers of neuromodulation devices for the treatment of these patients. Our competitors are LivaNova plc, which manufactures the VNS System and Medtronic plc, which manufactures the DBS System. These competitors are larger, well-capitalized companies with significant resources, which may include:

- established sales and marketing programs and networks, including internationally;
- broad product portfolios;

- long operating histories;
- established relationships with healthcare professionals;
- established manufacturing scale and supplier networks;
- financial resources for product development; and
- name recognition.

In addition to competing for market share, we also compete against these companies for qualified personnel.

We believe that our RNS System is a paradigm-shifting approach to treating drug-resistant focal epilepsy. By continuously monitoring the brain's electrical activity, recognizing and responding to patient-specific seizure onset patterns, and recording ongoing iEEG data that clinicians can use to optimize patient care, we believe our RNS System addresses the primary unmet needs in epilepsy care today. We compete primarily on the basis that our system is designed to offer superior tolerability and efficacy to other neuromodulation approaches, as well as access to continuous brain data. Our continued success depends on our ability to:

- continue to demonstrate safety and efficacy in our Post-Approval Study and in ongoing commercial use;
- expand our customer footprint within CECs and in the community setting, and increase utilization among these customers;
- increase the number of epileptologists recommending and the number of neurosurgeons implanting our RNS System;
- drive awareness to increase the number of drug-resistant epilepsy patients referred to CECs by expanding our referral pathways;
- maintain adequate reimbursement for procedures using our product;
- attract and retain skilled research, development, sales and clinical personnel;
- continue to innovate in order to improve therapy effectiveness and enhance the patient and provider experience;
- obtain and maintain regulatory clearances and approvals, including for expanded indications;
- cost-effectively manufacture, market and sell our product; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain intellectual property protection for our RNS System and any future products, to prevent others from infringing, misappropriating, or otherwise violating our intellectual property rights, to defend and enforce our intellectual property rights, and to operate without infringing, misappropriating, or otherwise violating valid and enforceable intellectual property rights of others. We actively seek to protect intellectual property that we believe is important to our business, which includes patents covering the components of our RNS System and the methods used for optimizing the therapy that our RNS System delivers. We also seek patent protection for other processes and inventions that are commercially or strategically important to developing and maximizing the value of our enterprise. We take steps to build and maintain the integrity of our brand, for example, with trademarks and service marks, and we seek to protect the confidentiality of trade secrets that may be important to the development of our business. We rely on a strategy that combines the use of patents, trademarks, trade secrets, know-how, and license agreements, as well as other

intellectual property laws, employment, confidentiality and invention assignment agreements, and contractual protections, to establish and protect our intellectual property rights.

Patents

Patent Portfolio

Our patent portfolio growth is primarily driven by AI and machine learning methods that may encompass future product features, as well as product hardware design advancements. Our patents and patent applications assert claims generally related to devices, methods and systems. As of December 31, 2024, we owned 95 issued U.S. patents and 16 non-provisional patent applications pending in the U.S. Patent and Trademark Office, or the USPTO. Our patents have claims that cover our current RNS System or related products, such as the system itself and methods of using it, including detection and stimulation methods, as well as the brain leads, lead connector, neurostimulator tray or ferrule, and elements used in the manufacture of the same. Additionally, we have patents with claims directed to: efficient communication or data transfer between implantable and external components of a neuromodulation system; and the use of data to optimize detection parameters and therapy outcomes, such as by using AI and machine learning and deep learning techniques. Our pending patent applications cover claims describing neural network models used to develop predictive analytical methods based on various biomarkers and the use of machine learning to develop methods for identifying, assessing, and treating various aspects of the epilepsy disease state. We continue to evaluate our intellectual property portfolio as patents reach end of life to determine the optimal course for continuing to protect our technology.

We cannot ensure that patents will issue from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology.

Patent Strategy

Our patent strategy is to seek patent protection for our inventions and to preserve our options to file additional, continuation applications pursuing claims covering specific commercial embodiments of the inventions, assuming these are strategically valuable. We also file patent applications covering innovations and developments to prevent third parties from developing competing products. For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel, as well as our business model and needs are also considered.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors. The patent positions of medical device companies like ours are generally uncertain and involve complex legal, scientific, and factual questions. The protection afforded by a patent varies on a product-by-product basis, from jurisdiction-to-jurisdiction, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of patent term adjustments and extensions, the availability of legal remedies, and the validity and enforceability of the patent.

In addition, the coverage claimed in a patent application can be significantly narrowed before the patent is issued, and patent claims can be reinterpreted or further altered even after patent issuance. We cannot predict whether the patent applications we are currently pursuing will issue as patents or whether the claims of any issued patents will provide sufficient protection from competitors. A competitor could develop systems, devices, or methods of manufacture or treatment that are not covered by our patents. Accordingly, our ability to stop third parties from commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, maintaining, defending, and enforcing patent claims that adequately cover our inventions.

Our commercial success will also depend, in part, on not infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. Third parties own numerous patents in the U.S. and in jurisdictions outside the U.S. with claims directed to inventions in the fields in which we operate or plan to operate. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, seek licenses, cease certain activities, or participate in USPTO proceedings. Moreover, such licenses may not be available on commercially reasonable terms or at all. Our breach of any license agreements or failure to obtain a license necessary to our business may have a material adverse impact on us.

On July 27, 2005, we entered into a cross-license agreement, or the Cross-License, with Medtronic, Inc., or Medtronic, directed to patent families in a field of use that is generally aligned with our business interests, including direct electrical stimulation or monitoring of the brain via electrodes attached to or implanted in the head for the treatment or diagnosis of epilepsy and other disorders, or the Field. Under the terms of the Cross-License, Medtronic granted to us a royalty-bearing, worldwide, non-exclusive, license in the Field to certain patent families owned or controlled by Medtronic or acquired by or licensed to Medtronic. In turn, we granted to Medtronic a royalty-bearing, worldwide, non-exclusive license in the Field to certain patents owned or controlled by us or acquired by or licensed to us. The term of the Cross-License extends through the life of the licensed patents, unless it is extended by the parties or otherwise terminated early pursuant to its terms. The Cross-License provides that each party may terminate the Cross-License if the other party materially breaches the Cross-License and does not cure the breach within a specified period of time.

Trademarks

Our trademark portfolio is designed to protect the brands of our RNS System and any future products. As of December 31, 2024, we own 26 trademark registrations, four of which are U.S. trademark registrations and the rest in various other countries or regions. We own trademark registrations for "NeuroPace," the "NeuroPace" logo, and "RNS" in the United States and various other countries, and "WINDOW TO THE BRAIN" in the U.S.

Trade Secrets

We also rely on trade secrets relating to our product and technology, and we maintain the confidentiality of such 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 and invention assignment agreements with employees, contractors, consultants, suppliers, customers, and other third parties, who have access to such information. These agreements generally provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us are to be kept confidential and not disclosed to third parties except in specific circumstances.

For more information regarding the risks related to our intellectual property, please see "Risk Factors—Risks related to our intellectual property."

Manufacturing and Supply

We currently manufacture our RNS System at and distribute all of our products from our approximately 53,000 square foot facility in Mountain View, California. This facility provides approximately 20,000 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our existing facility will be sufficient to meet our current and near-term manufacturing needs.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's Quality System Regulation, or QSR, for medical devices sold in the United States. The FDA monitors compliance with the QSR through periodic inspections of our facilities and may include our suppliers' facilities as well. We are also subject to applicable state and local regulations relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

Our failure, or the failure of our suppliers, to maintain acceptable quality requirements could result in substantial fines, the shutdown of our manufacturing operations or the recall of components of our RNS System, which would harm our business. In the event that one of our suppliers fails to maintain acceptable quality requirements, we may have to find and qualify a new supplier and could experience a material adverse effect to our manufacturing operations and result in manufacturing delays.

We believe our quality management system is compliant with FDA Quality Systems Regulations. We have been an FDA registered medical device establishment since 2014 and California licensed medical device manufacturer since 2004. We moved to our current Mountain View, California facility in March 2012.

The FDA conducted a PMA pre-approval inspection of our manufacturing facility in Mountain View, California prior to our PMA approval, as well as an establishment inspection in September 2014 which resulted in no 483 observations. We were accepted into the FDA Voluntary Improvement Program in 2018, and we are in our seventh year of participation in the program. The FDA Voluntary Improvement Program is part of the FDA's Case for Quality Program. As a participant in this program, we have an on-site appraisal once a year during which an appraisal team assesses our processes to determine areas for improvement, and we have subsequent quarterly check-in assessments that are designed to discuss our progress in continuous improvement. For companies that participate in this program, the FDA forgoes conducting routine facility inspections and pre-approval inspections in order to allow participants to shift resources to innovation and improvement efforts. We believe that we are in compliance, in all material respects, with applicable FDA and QSR requirements.

The materials, components, and sub-assemblies of our RNS System, as well as manufacturing services, are provided by qualified and approved suppliers, most of which are single source suppliers. For example, Micro Systems Technologies Management AG and Greatbatch Ltd are single source suppliers of key components of our products, including printed circuit assemblies and batteries. Other qualified and approved suppliers provide additional components, materials, and services, which include silicone adhesive, integrated circuits, and other components. We typically maintain several months' worth of inventory on critical components. From time to time, we have experienced issues with our suppliers. To date, these issues have not had a material impact on our operations. We estimate that qualifying a second source supplier would be a lengthy process. Our suppliers are evaluated, qualified and approved through our supplier management program, which includes various evaluations, assessments, qualifications, validations, testing and inspection to ensure the supplier can meet acceptable quality and regulatory requirements.

Order quantities and lead times for materials, components, and sub-assemblies purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. We perform assembly, testing, inspection and final release activities for our RNS System at our Mountain View, California facility.

Government Regulation

Regulation of Medical Devices in the United States

Our RNS System and our operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938 and its implementing regulations, collectively referred to as the FDCA, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing and research, manufacturing, safety, efficacy, packaging, labeling, storage, record keeping and reporting, clearance or approval, adverse event reporting, advertising, marketing, distribution, promotion, import and export and post-marketing surveillance, to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending premarket applications, issuance of warning letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA approval of a PMA, clearance of a 510(k) premarket notification, or grant of a de novo request for classification. 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 provide reasonable assurance of its safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device, making changes to the device, or otherwise using the device.

Class I devices include those with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's "general controls" for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse

medical events and malfunctions through the submission of Medical Device Reports, or MDRs, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I or low risk devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are moderate risk devices subject to the FDA's general controls, and any other "special controls" deemed necessary by the FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. When required, the manufacturer must submit to the FDA a premarket notification, or 510(k), submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous premarketing requirements.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices and devices deemed not substantially equivalent to a predicate device following a 510(k) submission. The safety and effectiveness of Class III devices cannot be reasonably assured solely by general or special controls. Submission and FDA approval of a PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless an exemption applies, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application is required, which is intended to demonstrate that the device is reasonably safe and effective for its intended use and must be supported by extensive data, typically including data from preclinical studies and clinical trials.

Some pre-amendment devices (devices that were on the market prior to May 28, 1976) are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

PMA Approval Pathway

Our RNS System is a Class III device, which required PMA approval before it could be marketed. Additionally, there are certain pre-amendment Class III devices for which the FDA has not yet required a PMA, which are cleared through the 510(k) process. The PMA process is generally more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is reasonably safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review may take and often takes significantly longer, sometimes taking up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical trial that supported PMA approval or requirements to conduct additional studies post-approval. The FDA may also condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic

reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, certain suppliers, methods, or quality control procedures, or changes in the design performance specifications, that affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. Changes to our existing product or the development of new products may require the approval of a PMA or additional submissions of PMA supplements.

510(k) Marketing Clearance Pathway

One of the components of our RNS System, our Burr Hole Cover, which may be used to cover the incision site for depth leads, is subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a 510(k) submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a pre-amendment device, a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information within 180 days before the FDA will proceed with additional review of the submission. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 calendar days to review and issue a determination. As a practical matter, clearance may take and often does take longer. Upon review, 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 grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, for example, due to a finding of a lack of a predicate device, that the device has a new intended use or different technological characteristics that raise different questions of safety or effectiveness when the device is compared to the cited predicate 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" 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. If the FDA determines that the information provided in a 510(k) submission is insufficient to demonstrate substantial equivalence to the predicate device, the FDA generally identifies the specific information that needs to be provided so that the FDA may complete its evaluation of substantial equivalence, and such information may be provided within the time allotted by the FDA or in a new 510(k) submission should the original 510(k) submission have been withdrawn.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k)

marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) submission is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) marketing clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. To market low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, a manufacturer may request a de novo classification. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request 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. A medical device may 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 or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 calendar days following receipt of the de novo application, although in practice, the FDA's review may take significantly longer. During the pendency of the FDA's review, the FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the de novo request for classification if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. In the event the FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request for classification. When the FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, through a 510(k) premarket notification. We currently do not have any products with a de novo classification.

Clinical Trials

Clinical trials are typically required to support a PMA, oftentimes for a de novo request for classification, and are sometimes required to support a 510(k) submission. As has and continues to be required for our RNS System, all clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must be approved prior to commencing clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, like our RNS System, purported or represented to be used in supporting or sustaining human life, is for a use that is substantially important in diagnosing, curing, mitigating, or treating disorders or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A clinical trial may begin 30 days after receipt of the IDE by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Acceptance of an IDE application for review does not guarantee that the FDA will approve the IDE and, if it is

approved, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

In addition, the clinical trials must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA.

If the device is considered a "non-significant risk," IDE submission to FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required. Abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements also apply to non-significant risk device studies.

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

Additionally, after a trial begins, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, there can be no assurance that the data generated during a clinical trial will meet the safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- Annual Reports: As is required for our RNS System, continued FDA approval may be contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA;
- Post-Approval Study Report: As is required for our RNS System, continued FDA approval may also be contingent upon the submission of Post-Approval Study data, as requested by the FDA;
- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers and contract manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness 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, if the malfunction were to recur;
- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product 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;
- 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 effectiveness data for the device.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In general, if the FDA determines that our promotional materials, technical guidance, or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training, technical guidance, or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional, technical guidance, or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Manufacturing processes for commercial products 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, design history file, device history records, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products, which would harm our business. The discovery of previously unknown problems with our product, 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 clinician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that 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:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our RNS System or any future products;
- operating restrictions or partial suspension or total shutdown of production;
- refusal of or delay in granting our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;

- withdrawing 510(k) clearance or PMA approvals that are already granted;
- refusal to grant export approval for our RNS System or any future products; or
- criminal prosecution.

Other Healthcare and Privacy Laws

Our RNS System and our operations are also subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations.

Violations of these laws can lead to significant civil and criminal penalties, including fines, disgorgement, imprisonment and exclusion from participation in federal healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the forced curtailment or restructuring of our operations. These laws are applicable to us as a medical device company and also apply to hospitals, epileptologists, neurologists, neurosurgeons, and other potential purchasers or users of our RNS System or any future products.

In particular, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including, for example, gifts, discounts, coupons, the furnishing of supplies or equipment, provision of items or services with independent value such as administrative support, credit arrangements, payments of cash, waivers of payments, ownership interests, relieving a referral source of a financial or administrative burden, and the provision of anything at less than its fair market value. The federal Anti- Kickback Statute and implementing regulations provide for certain narrow exceptions and "safe harbors" for certain defined practices including discounting, rebating or personal services arrangements, among other things. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of federal Anti- Kickback Statute, constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult.

Violations are also subject to civil monetary penalties, which can be further assessed under the federal False Claims Act. Violations of the federal Anti-Kickback Statute may also result in civil and criminal penalties, including criminal fines and imprisonment, or exclusion from Medicare, Medicaid or other governmental programs.

Certain arrangements between medical device companies and referring, or prescribing clinicians have been identified in fraud alerts issued by the OIG as implicating the Anti-Kickback Statute. Moreover, the provision of payments or other items of value by a medical device company to a referral source could be prohibited under the Stark Law (described below) unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to medical device companies.

Other federal healthcare fraud-related laws also provide criminal liability for violations. The Health Insurance Portability and Accountability Act, or HIPAA (18 U.S.C. § 1347), also created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-

Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted or caused the submission of a false claim to the federal government, and to share in any monetary recovery. These laws can apply to entities that provide information on coverage, coding, and reimbursement of their products and assistance with obtaining reimbursement to persons who bill payors. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines, award treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. In addition, various states have enacted false claim laws analogous to the federal False Claims Act.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

The Stark Law prohibits payments made by a clinician (as defined under such law) to a medical device company in exchange for the delivery of a product or provision of a services, presenting or causing to be presented claims to Medicare and Medicaid for products or services referred by clinicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the medical device company manufacturing the product or delivering the service, unless an exception applies. Similarly, medical device companies may not bill Medicare for services furnished pursuant to a prohibited self- referral. Any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties and possible exclusion from participation in federal governmental payor programs. Sanctions for violating the Stark Law include denial of payment, civil monetary and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for additional penalties for a circumvention scheme. In addition, many states, including California, also have state anti-"self-referral" and other laws that are not limited to Medicare and Medicaid referrals, with which we must comply.

The Federal Physician Payments Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain applicable manufacturers of devices, drugs, biologics, kits that required FDA approval or clearance, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, other healthcare professionals (such as physician assistants and nurse practitioners), and applicable manufacturers and group purchasing organizations, and to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties, which can be increased for "knowing failures", for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations.

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and other professions and employing or engaging physicians and other professionals to practice medicine, generally

referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed professional. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against the business corporation and/or the professional through licensure proceedings and programs and criminal penalties. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

Laws Governing Foreign Business Activities

We are subject to the Foreign Corrupt Practices Act of 1977, as amended, or FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with foreign government officials. We may also become subject to similar anti-bribery laws in other jurisdictions in which we decide to operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. Violations of these laws could result in severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures. Any violations of these laws, or allegations of such violations, could involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business operations and revenue.

U.S. Centers for Medicare and Medicaid Services

Medicare is a federal program administered by CMS through fiscal intermediaries, Medicare Administrative Contractors and carriers. Available to individuals aged 65 or over, and certain other individuals, the Medicare program provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedures of implanting or using our RNS System could have a material effect on our performance.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement vary from state to state and is subject to each state's budget restraints. Changes to the availability of coverage, method or level of reimbursement for our RNS System and supplemental procedures may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for the implantation of our RNS System and supplemental procedures.

United States Health Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our RNS System and future products. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our RNS System and future

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

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. The Further Consolidated Appropriations Act, signed into law on December 20, 2019, has repealed the medical device excise tax and as a result of the repeal and the prior moratorium, sales of taxable medical devices after December 31, 2015, are not subject to the tax. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and it implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We continue to evaluate the full impact that the Affordable Care Act will have on our business. During its history, there have been amendments to and judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the current administration will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken.

The American Rescue Plan Act of 2021 was signed into law on March 11, 2021, expanding the definition of covered employees as defined under IRC Section 162(m). The provisions under the expanded definition of covered employees have been considered and were determined not to be materially impactful on our tax positions.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed by the current administration or what the impact of such changes on our business, if any, may be. Certain of these changes could impose additional limitations on the rates we will be able to charge for our RNS System and future products or the amounts of reimbursement available for our RNS System and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information, or PHI. HIPAA also requires business associates and their covered subcontractors, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure. In addition, companies, such as many medical device companies, that would not otherwise be subject to HIPAA may become contractually obligated to follow certain HIPAA requirements through agreements with Covered Entities and Business Associates, and some of our customers may require us to comply with certain of these provisions.

As a company that maintains a substantial amount of patient-level data and interacts frequently with both Covered Entities and Business Associates, we may have certain obligations regarding the use and disclosure of any PHI that may be provided to us or data that is generated by us. If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, and similar state laws, we may be subject to significant penalties, including civil, criminal and administrative penalties, fines, imprisonment and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations.

We are also subject to numerous other federal, state, local, and foreign laws, rules, regulations and standards related to data privacy, security and protection, including consumer protection laws and regulations that govern the collection, dissemination, use, access to, confidentiality and security of patient health and other personal information, such as the Federal Trade Commission Act and the California Consumer Privacy Act of 2018, as amended.

In addition, Congress and various other states have enacted or are considering new laws and regulations regarding the privacy and security of heath and other personal information to which we may become subject. Further, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected individuals. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information.

In addition, as noted above, we are planning for regulatory clearances in non-U.S. jurisdictions, including the EU, Canada, and Japan, and may be subject to non-U.S. data privacy and security laws, rules, regulations and standards as our operations expand. For example, the collection, use, disclosure, transfer, or other processing of personal information regarding individuals in the EU, including personal health data, is subject to the European Union General Data Protection Regulation (EU) 2016/679, or EU GDPR.

For more information regarding the risks related to data privacy and security, please see "Risk Factors—Risks related to privacy, information technology and cybersecurity."

Human Capital Resources

NeuroPace was founded with a mission to transform the lives of people living with brain neurologic disorders. We are focused on developing high quality products that address critical patient needs and maintaining a work environment where employees are respected and encouraged to excel. As of December 31, 2024, we had 184 employees, all of which are based in the United States. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that we have strong employee relations.

Culture and Values

We strive to create a respectful work environment characterized by open communication and trust. As employees of NeuroPace, we each uphold the following core values that drive our culture and define the way we do business:

- Innovation: We develop world class technology
- Integrity: We do what's right
- Leadership: We are becoming the standard of care
- Patient Focus: We transform lives
- Science: We enable fundamental discoveries

It is our philosophy to foster open communication. Employee input on ways to improve our business strategy and tactics, work environment and organization is valued and encouraged. We believe that our ability to provide employees with a dynamic and challenging environment where they are empowered to succeed and accountable to lead further drives a culture embedded in our values.

Business Ethics

We are committed to conducting our business activities with employees, consultants, patients, vendors, customers, communities, and stockholders with integrity and fairness and in accordance with the highest ethical standards. We believe that our conduct has a direct impact on our reputation, our brand, and our stakeholders. We are focused on ensuring that our legal, compliance, and risk mitigation protocols further enhance our ability to comport ourselves with the highest levels of ethical standards.

Talent Attraction, Retention and Engagement

We have a strong employee value proposition that leverages our unique patient-driven culture, collaborative working environment, shared sense of purpose, desire to do the right thing and ground-breaking work, to attract talent to our Company. By focusing on individual performance, as well as teamwork and collaboration, we believe that we foster an environment that helps employees excel as individuals and as team members. Eighty-three employees, or 45% of our workforce, have been at NeuroPace for at least five years. To further engage and incentivize our workforce, we offer a wide range of programs and avenues for support, motivation, and professional development. For example, we utilize both instructor-led training and online learning to deliver proprietary, targeted training courses designed to position our commercial organization at the cutting edge of neuromodulation. For our talent pipeline development, we utilize a variety of tools and work closely with individual business functions to provide training and hands-on support for managers and leaders for assessing talent, identifying development opportunities, and discussing succession planning.

Communication is also key to our employee development and retention. We hold regular all-hands meetings designed to keep our employees informed and engaged. We also employ employee engagement surveys through which we incorporate critical employee feedback into our culture, operations, and strategic plans.

Compensation Philosophy

We strive to provide comprehensive and competitive compensation packages, including cash, equity, benefits and services that attract, motivate and retain exceptional employees. Compensation is driven by local market conditions, internal equity, and employee performance.

Health and Wellness

We offer a comprehensive benefits package including: 401(k) plan, medical, dental, and vision insurance, life and long-term disability insurance, health care and childcare spending accounts, Section 529 college savings plan, three weeks paid vacation for most employees at start, 12 paid holidays, and PTO for sick time and family

emergencies. Other benefits include hybrid work schedules, online wellness program, patent awards, company picnics, parties and barbecues, and more.

Corporate and Available Information

We were incorporated under the laws of the state of Delaware in November 1997 under the name NeuroPace, Inc. Our principal executive offices are located at 455 N. Bernardo Avenue, Mountain View, California 94043, and our telephone number is (650) 237-2700.

Our website address is www.neuropace.com. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. We file electronically with the U.S. Securities and Exchange Commission, or SEC, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.neuropace.com, free of charge, copies of these reports and other information as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. All SEC filings are also available at the SEC's website at www.sec.gov.

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report on Form 10-K, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. You should not interpret our disclosure of any of the following risks to imply that such risks have not already materialized.

Risks related to operational, commercial and manufacturing matters

We currently rely on our RNS System, which can only be marketed in the United States for use in adults with drug-resistant focal epilepsy, as our primary source of revenue. If we fail to successfully market and sell our RNS System cost effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected.

Our business currently depends primarily on our ability to successfully market our RNS System, which includes increasing the number of patients treated at CECs, increasing adoption of our RNS System across CECs and in the community setting, as well as driving utilization by clinicians within CECs and in the community setting. Currently, our RNS System can only be marketed for use in adults with drug-resistant focal epilepsy in the United States. Historically our RNS System was primarily recommended and implanted at Level 4 CECs, which provide advanced diagnosis and management of epilepsy. We only recently began expanding our commercial efforts to target and be able to qualify the additional 1,800 epileptologists outside of Level 4 CECs and the entire population of functional neurosurgeons as a result of the FDA approval of a PMA-S in 2023, which updated the qualification criteria for centers and clinicians that may prescribe and implant the RNS System. Therefore, we have been dependent on widespread market adoption of our RNS System within a limited number of accounts. We are aiming to increase awareness about our RNS System, including earlier in the diagnostic process through our partnership with DIXI Medical, expand the population of patients we can treat with our RNS System, and increase utilization and adoption across physicians that prescribe and implant our RNS System both within Level 4 CECs and outside of Level 4 CECs, in the community setting, but there can be no assurance that we will succeed.

The commercial success of our RNS System will continue to depend on a number of factors, including the following:

- the degree to which drug-resistant epilepsy remains a chronic and debilitating condition;
- the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our RNS System, especially relative to alternative neuromodulation devices such as VNS or DBS;
- the prevalence and severity of any adverse patient events involving our RNS System;
- our ability to provide earlier awareness of and education about our RNS System to patients and clinicians, including through our partnership with DIXI Medical;
- the degree to which clinicians, patients and hospital facilities, including at CECs and outside of CECs, in the community setting, adopt our RNS System;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for epilepsy;
- the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our RNS System;

- whether key thought leaders in the medical community accept that our clinical efficacy and safety results are sufficiently meaningful to influence their decision to adopt our RNS System over other neuromodulation therapies;
- the extent to which we are successful in educating clinicians, patients, and hospital facilities about the benefits of our RNS System, including as a result of the extended battery life of the neurostimulator;
- our reputation among clinicians, patients and hospital facilities;
- our ability to predict product performance;
- the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our RNS System, our ability to expand referral pathways to CECs and beyond, and our ability to grow the market outside of Level 4 CECs, in the community;
- our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, including in and to our RNS System;
- our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our RNS System;
- our ability to continue to maintain a commercially viable manufacturing process at our manufacturing facility that is compliant with current Good Manufacturing Practices, or cGMP, and Quality Systems Regulations, or QSR;
- our ability to maintain our contractual relationships with our vendors and component suppliers, including single-source vendors and suppliers, through which we obtain critical components for our RNS System;
- the continued coverage of and adequate payment for the implantation procedure and for clinicians to provide ongoing care for patients implanted with our RNS System by third-party payors, including both private and government payors; and
- our ability to continue to attract and retain key talent.

If we fail to successfully market and sell our RNS System cost-effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected.

Our commercial success will continue to depend on attaining significant market acceptance of our products and increasing the number of patients treated. If we are unable to successfully achieve substantial market acceptance and drive adoption of our RNS System both within Level 4 CECs and in the community, our sales, business, financial condition and results of operations would be harmed.

Our commercial success will depend in large part on the further acceptance by clinicians, patients and hospital facilities of our RNS System as safe, useful, and cost-effective, and increasing the number of patients treated at Level 4 CECs and in the community setting. We cannot predict how quickly, if at all, additional clinicians, patients, and hospital facilities will adopt our RNS System over continued noninterventional therapies or competing neuromodulation devices or surgical treatment options. For example, clinicians may be reluctant to use our RNS System due to familiarity with neuromodulation devices that are more established. Alternatively, in the community setting, neuromodulation may not be a common practice, if it is done at all. Clinicians, patients, and hospital facilities may continue to prefer noninvasive therapeutic options, resective or ablative surgery, or alternative neuromodulation therapies such as VNS and DBS. Moreover, we cannot predict how quickly, if at all, those currently living with epilepsy but who are not being treated will seek treatment. Our ability to grow sales of our RNS System and drive market acceptance will depend on successfully educating clinicians, patients, and hospital facilities of the relative benefits of our RNS System.

Additionally, patients rely on their healthcare providers, including epileptologists and neurosurgeons to recommend a course of treatment. If we are unable to successfully achieve substantial market acceptance and

adoption of our RNS System by additional clinicians, patients, and hospital facilities, or to expand the clinicians' perspective as to the types of patients that can benefit from our RNS System, patients may be reluctant to use our products over alternative neuromodulation therapies. If we are unable to successfully drive patient interest in our RNS System, including through our partnership with DIXI Medical, our business, financial condition and results of operations would be harmed.

Our commercial success will depend on a continued flow of patient referrals to CECs from treating primary care physicians, neurologists, and other healthcare providers and from caregiver support and encouragement around physician referrals and self-referrals to CECs. If we are unable to successfully expand our referral pathways to achieve an increased patient referral pipeline into CECs or develop opportunities outside of Level 4 CECs, in the community setting, our sales, business, financial condition and results of operations would be harmed.

Our commercial success will depend in large part on continued referrals of appropriate patients from treating primary care physicians, neurologists, and other healthcare providers to epileptologists, neurosurgeons, and other clinicians, primarily at Level 4 CECs. We cannot predict how quickly, if at all, we can grow utilization and adoption at the Level 4 CECs and in the community setting to build a pipeline through our sales and marketing efforts and whether primary care physicians, neurologists, and other healthcare providers, as well as caregivers will support use of our RNS System in the community setting or patient referrals to epileptologists and neurosurgeons at CECs over other therapy options.

Primary care physicians, neurologists, and other healthcare providers may continue to prefer traditional treatments, such as additional attempts to treat with new therapeutic drugs that become available from time to time, including for fear of losing management of the patient's care. If we are unable to educate clinicians to follow national guidelines, which recommend that patients whose seizures have not been brought under control after three months of care by a primary care physician or after 12 months of seeing a general neurologist be referred to a CEC, or that patients that are considered drug resistant because they failed to achieve sustained seizure freedom after trying two antiseizure medications be referred to a tertiary epilepsy center to evaluate potential interventions, or if we are unable to convince them as to the merits of our RNS System inside a CEC or in the community setting, we may be unable to successfully build our patient pipeline. This could harm our business, financial condition and results of operations.

Various factors outside our direct control may negatively impact our manufacturing of our RNS System, which could harm our business, financial condition, and results of operations.

We manufacture our RNS System at our manufacturing facility in Mountain View, California. This facility supports our production operations, including manufacturing, quality control, and raw material and finished goods storage. We believe that we currently have adequate manufacturing capacity and supplies for our products sufficient to meet our demand forecasts. If demand for our RNS System increases more rapidly than we anticipate, if we encounter problems with one or more of our suppliers, or if we secure regulatory approval to commercialize our products in additional geographies or indications, we may need to either expand our manufacturing capabilities, qualify new suppliers, or outsource to other manufacturers.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's Quality System Regulation, or QSR, for medical devices sold in the United States. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations, to the extent applicable. If we fail to manufacture our products in compliance with QSR, or if our manufacturing facility suffers disruptions, supply chain issues, machine failures, slowdowns or disrepair, we may not be able to fulfill customer demand and our business would be harmed. Further, we typically do not maintain more than several months of inventory on hand and we manufacture our products using near-term demand forecasts. As a result, deviations from our forecasts could cause us to fail to meet demand for our products.

Since we produce our products in one manufacturing facility, any contamination of the controlled environment, equipment malfunction, supply issues, personnel issues, including human error, or failure to strictly follow

procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources. In addition, if demand for our products shifts such that our manufacturing facility is operated below our forecasts for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

The manufacturing, sterilization and distribution of our products are technically challenging. Changes that our suppliers may make, or additional requirements from regulatory agencies, outside of our direct control can have an impact on our processes, on quality and on the successful or timely delivery of our products to our customers. Mistakes and mishandling may occur, which can affect supply and delivery. As a result, our dependence on third-party, including single source, suppliers, subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, financial condition, and results of operations, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of our products;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and other Federal and state regulatory authorities;
- delays in regulatory approvals of any changes to manufacturing, including the use of new suppliers;
- latent defects that may become apparent after our products have been released and that may result in an adverse event or a recall of such products;
- inclusion of vendors of raw materials not in compliance with regulatory requirements;
- natural or other disasters, global pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment, international conflict or war, or other forms of disruption to business operations affecting our manufacturer or its suppliers;
- production delays related to the evaluation and testing of our products or the use of components from alternative suppliers;
- failure to complete sterilization on time or in compliance with the required regulatory standards; and
- delays in delivery by our suppliers of components, materials, or services due to changes in demand from us or their other customers.

The occurrence of any of these issues could significantly harm our ability to manufacture our products and maintain sufficient quality standards, which would negatively impact our sales, business, financial condition, and results of operations.

We depend on a limited number of single-source suppliers and vendors in connection with the manufacture of our RNS System, which makes us vulnerable to supply shortages and price fluctuations that could harm our business, financial condition, and results of operations.

We source and rely upon materials, components, and sub-assemblies of our RNS System, as well as manufacturing services from approved suppliers, most of which are single-source suppliers. For example, Micro Systems Technologies Management AG and Integer Holdings Corporation (formally known as Greatbatch Ltd) are single-source suppliers of several key components of our products, including printed circuit assemblies and batteries. In addition, certain of our suppliers are not under long-term contracts with us.

These components, materials, and services, which also include silicone adhesive, integrated circuits and other components, are critical and there are relatively few alternative sources of supply. We believe our single-source suppliers are capable of continuing to meet our specifications and maintaining quality, but any significant problem experienced by one of our single-source suppliers may result in a delay or interruption in the supply of components, materials, or services to us. Our suppliers may experience manufacturing delays or issues, stop producing our components, materials, or services, increase the prices they charge us, or elect to terminate their relationships with us. In any of these cases, we could face a delay of several months to identify, perform appropriate testing, and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier transition plans. In addition, the failure of our third-party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products. If one of our suppliers fails to maintain acceptable quality requirements, we may have to identify and qualify a new supplier. Although we require our third-party suppliers to supply us with materials, components and services that meet our specifications and comply with applicable provisions of the FDA's QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the materials and components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

The number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited and certification of a new supplier may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate regulatory authorities, including the FDA. The added time and cost to arrange for alternative suppliers could harm our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property or other proprietary rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

Our results of operations may be harmed if we are unable to accurately forecast customer demand for our products.

We do not maintain large amounts of excess inventory at any given time. To ensure adequate supply, we must forecast inventory needs and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products, including our sales of DIXI Medical products, could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, our inability to forecast the lifecycle of our products, an increase or decrease in customer demand for our products or for competitor products, our failure to accurately forecast customer adoption of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our products, our manufacturing team, or that of DIXI Medical, may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand,

additional supplies of components, materials, or services, or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, which may negatively affect our business, financial condition, and results of operations.

If we fail to optimize our sales and marketing capabilities and develop widespread brand awareness cost-effectively, our growth will be impeded and our business may suffer.

We are actively expanding our presence in the United States through additional sales and education efforts to drive awareness of our RNS System amongst patients, clinicians and hospital facilities, to drive adoption of our RNS System at Level 4 CECs and in the community setting and to increase utilization and adoption of our RNS System within new and existing accounts. We also plan to explore regulatory and reimbursement approval pathways to expand our presence in international territories.

We take a measured approach to optimize our sales infrastructure to grow our customer base and our business. Identifying and recruiting qualified personnel and training them on the use of our RNS System, on applicable federal and state laws and regulations and on our internal policies and procedures, requires significant time, expense and attention, particularly given our strategy of having each Therapy Consultant, or sales representative, cover many accounts. It can take significant time before our Therapy Consultants are fully trained and productive and before they have established relationships with their target accounts. Our business may be harmed if our efforts to optimize do not generate a corresponding increase in revenue or result in a decrease in our operating margin. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue. Additionally, if we do not hire the correct type of or appropriate number of sales personnel as we expand into the community setting, our efforts to grow our market and business outside of the Level 4 CECs may be harmed.

We dedicate significant financial and other resources to our customer outreach and training programs, which may require us to incur significant upfront costs. For example, we may need to conduct additional physician trainings across hospital facilities, both at CECs and as we expand into the community setting. Our sales force may also need to develop additional efficiencies and approaches to address potential growth as we expand referral pathways, expand into additional existing Level 4 CECs as well as new CECs, grow our presence in the community setting, offer new products, including those distributed through our partnership with DIXI Medical, increase the number of epileptologists recommending, and neurosurgeons implanting, our RNS System, and increase the numbers and types of patients being prescribed and implanted with the RNS System by current clinicians. Our business would be harmed if our programs and associated expenditures do not generate a corresponding increase in revenue.

In addition, we believe that developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad adoption of our RNS System.

We may be unable to compete successfully with other treatment options for drug-resistant focal epilepsy, which could harm our sales, business, financial condition and results of operations.

Our industry is competitive and has been evolving rapidly with not only existing treatment options, but also the introduction of new products and technologies as well as the market activities of industry participants. Our RNS System is indicated for adult patients with drug-resistant focal epilepsy in the United States and we have historically primarily marketed our device to clinicians within Level 4 CECs that treat these patients. As a result of the recent approval of a PMA-S, we are now able to expand our commercial efforts to the additional epileptologists and functional neurosurgeons practicing outside of Level 4 CECs, in the community setting. In our target patient population, there are two primary treatment options (i) an ablative or resective surgery, or (ii) implantation of a neuromodulation device. Patients may also choose not to actively seek additional treatment for epilepsy or may

choose to try new therapeutic drugs that become available from time to time. We estimate that approximately 80% of drug-resistant focal epilepsy patients are either not ideal candidates for ablative or resective surgery or are unwilling to undergo a destructive surgical procedure and we compete primarily with two manufacturers of neuromodulation devices for the treatment of these patients. Our primary competitors are LivaNova plc, which manufactures the VNS System, and Medtronic plc, which manufactures the DBS System. Third-party payors may encourage the use of competitors' products or other neuromodulation therapies due to lower costs of competing products or alternatives. Additionally, treating physicians, including epileptologists and neurosurgeons may promote the use of other competitors' products or alternative therapies. Further, as existing competitors and other companies develop new or improved products, we cannot predict what the standard of care will be in the future.

Our primary competitors are large, well-capitalized companies with significant market share and resources. They have more established sales and marketing programs than we do and have greater name recognition. These competitors also have long operating histories and may have more established relationships with potential customers. In addition to competing for market share, competitors may develop or acquire patents or other rights that may limit our ability to compete.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. There can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more effective or safer than our RNS System or that would render our RNS System obsolete or noncompetitive.

We believe that the clinical advantages of our RNS System and our focus on neuromodulation will be important factors in our future success. Our continued success depends on, among other things, our ability to:

- continue to demonstrate safety and efficacy in our Post-Approval Study and in ongoing commercial use;
- expand our referral pathways;
- expand the number of CECs implanting our RNS System and increase utilization across existing clinicians using the RNS System and adoption across new clinicians within these CECs;
- increase the utilization and adoption of our RNS System outside of Level 4 CECs, in the community setting;
- drive awareness to increase the number of drug-resistant epilepsy patients referred to CECs and treated outside of CECs, in the community setting;
- maintain adequate reimbursement for implant procedures and for clinicians to provide ongoing care of patients treated with our RNS System;
- attract and retain skilled research, development, sales, marketing and clinical personnel;
- continue to innovate in order to improve therapy effectiveness and enhance the patient and provider experience;
- adequately predict product performance;
- obtain and maintain regulatory clearances and approvals, including for expanded indications;
- cost-effectively manufacture, market and sell our RNS System;
- obtain, maintain, protect, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others;
- acquire products or technologies complementary to or necessary for our business; and
- source materials, components, and sub-assemblies from suppliers on a cost-effective and timely basis.

Adoption of our RNS System depends on positive clinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicians would harm our sales, business, financial condition, and results of operations.

The rate of adoption and sales of our products are heavily influenced by clinical data. Although we have positive clinical data across four multi-center FDA-approved prospective clinical studies going out as far as nine years, there can be no assurance that clinical data will continue to be positive for our ongoing studies, such as our Post-Approval Study. Additionally, there can be no assurance that future clinical studies, including those to continue demonstrating the efficacy of our products in currently approved patient populations and those to support label retention and expansion for our products will demonstrate safety and effectiveness. Unfavorable or inconsistent clinical data from ongoing or future clinical studies conducted by us, our competitors, or third parties, the negative interpretation of our clinical data internally and externally, including by customers, competitors, patients, and regulators, or findings of new or more frequent adverse events, could harm our business, financial condition, and results of operations.

The rate of adoption and sales of our products are also influenced by clinician perceptions. Negative perceptions of our products by clinicians, including due to negative clinical data, could result in decreased adoption or use of our products, which would harm our business, financial condition, and results of operations. Additionally, if key opinion leaders who support our products cease to recommend our products, our business, financial condition and results of operations will be harmed. Further, if we cannot maintain strong working relationships with clinicians and continue to receive their advice and input, the marketing of our products could suffer, which could harm our business, financial condition and results of operations. Certain restrictions on access to clinicians as well as hospital staffing shortages have impacted, and will likely continue to impact, our ability to maintain such relationships. Finally, although we have demonstrated the safety, effectiveness and clinical advantages of our products in pivotal clinical studies, neuromodulation is still a relatively new approach to treating drug-resistant focal epilepsy. The results of clinical studies of the products conducted to date and from commercial use do not necessarily predict future results. Any negative long-term results or adverse events from use of our products that arise in the future could harm our business, financial condition, and results of operations.

Our future success also depends upon patients having an understanding of how to properly use our RNS System and an experience with our products that meets their expectations in order to increase clinician demand for our products as a result of positive feedback and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results are not met or if they are not adequately trained on use of our RNS System. Patients may be dissatisfied if they experience adverse events or insufficient reduction in frequency of seizures. If the results of our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from continuing to use our device or referring our products to others. Dissatisfied patients may express negative opinions through social media, advocacy, or other publicity. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

If adequate reimbursement becomes unavailable for the procedures to implant our RNS System and for clinicians to provide ongoing care for patients treated with our RNS System, it could diminish our sales or affect our ability to sell our RNS System profitably.

The implant procedure for our RNS System and the ongoing patient care provided by clinicians, including monitoring and programming, are reimbursed under well-established physician and hospital codes. Our ability to increase sales of our RNS System depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations, and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. We do not bill any third-party payors for our RNS System. Instead, we invoice healthcare providers for our RNS System and the cost is bundled into the reimbursement received by healthcare providers for the procedures in which our RNS System is used.

We expect our RNS System will continue to be purchased by hospital facilities who will then seek reimbursement from third-party payors for brain-responsive neuromodulation for drug resistant focal epilepsy.

While third-party payors currently cover and provide reimbursement for both implant procedures of our RNS System as well as for clinicians providing ongoing patient care, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement, or that current reimbursement levels for diagnostic, implant or replacement procedures as well as clinician-provided ongoing patient care will continue.

Furthermore, the overall amount of reimbursement available for brain-responsive neuromodulation for drug resistant focal epilepsy could decrease in the future. Changes in reimbursement may not necessarily impact our sales. Additionally, we cannot be sure that the reimbursement amounts available for brain-responsive neuromodulation for drug resistant focal epilepsy will not reduce or otherwise negatively impact the demand for our marketed RNS System. Failure by users of our RNS System to obtain coverage and adequate reimbursement for the implant procedures or for clinicians providing ongoing patient care would cause our business, financial condition, and results of operations to suffer. Additionally, a third-party payor's decision to provide coverage for a brain-responsive neuromodulation for drug resistant focal epilepsy does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Use of our RNS System requires appropriate neurosurgeon training for implantation and epileptologist training for programming and ongoing patient care, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations.

The successful use of our RNS System depends in part on the training and skill of the neurosurgeon performing the implant procedure as well as the clinician, typically an epileptologist, performing the subsequent programming of our RNS System and monitoring the patient response. Clinicians, including those practicing outside of Level 4 CECs and in the community setting, could experience difficulty with the technique necessary to successfully implant and program our RNS System, and monitor patients if they do not receive appropriate training. Moreover, clinicians rely on their previous medical training and experience when recommending or implanting our RNS System, and we cannot guarantee that all neurosurgeons will have the necessary implantation skills to properly perform the procedure. We cannot be certain that physicians or healthcare providers that use our RNS System have received sufficient training, and physicians or healthcare providers who have not received adequate training may nonetheless attempt to use our RNS System with their patients. If clinicians implant or utilize our RNS System incorrectly, or without adhering to or completing all relevant training, their patient outcomes may not be consistent with the outcomes achieved in our clinical studies. Adverse safety outcomes that arise from improper or incorrect use of our RNS System may negatively impact the perception of patient benefit and safety of our RNS System, notwithstanding results from our clinical studies. These results could limit adoption of our RNS System in treatment for drug-resistant focal epilepsy, which would harm our sales, business, financial condition, and results of operations.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personnel and to integrate current and additional personnel in all departments.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without

notice. We also do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

We rely on our own direct sales force to market and sell our RNS System, and if we are unable to optimize our sales force, it could harm our business. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team. If our employees fail to adequately promote, market and sell our products, our sales could significantly decrease. As we launch new products, expand our product offerings and 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 with significant technical knowledge in various areas. An inability to attract, hire, train and retain employees will harm our sales, business, financial condition, and results of operations.

We expect to increase the size of our organization in the future, and we may experience difficulties in managing the operational elements or timing of this growth. If we are unable to manage or appropriately time the anticipated growth of our business, our future revenue and operating results may be harmed.

As of December 31, 2024, we had 184 employees. As our sales and marketing strategies evolve and as we continue operating as a public company, we may need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our RNS System will depend, in part, on our ability to effectively manage or time any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As demand for our RNS System increases, we will need to continue to scale our capacity at our manufacturing facility, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation will be harmed and our business will suffer. Additionally, additional growth may result in higher fixed costs and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

We may not be able to achieve or maintain satisfactory pricing and margins for our RNS System, which could harm our business and results of operations.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to maintain satisfactory prices for our RNS System at the levels we have historically achieved. The pricing of our products could be impacted by several factors, including pressure to reduce prices by our customers due to a decline in the amount that third-party payors reimburse for implant procedures using our RNS System for clinicians providing ongoing patient care. A decline in the amount that third-party payors reimburse our customers for ongoing patient care could also make it difficult for programming centers to conduct ongoing patient support without a corresponding reduction in prices for our products. If we are forced to lower or are unable to increase the price we charge for our RNS System, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode, which could harm our business and results of operations.

We are seeking expanded FDA labeling for our RNS System to be able to treat patients with generalized drug-resistant epilepsy as well as patients between the age of 12 and 17 with drug-resistant focal epilepsy, but if we are unable to broaden the indications for our RNS System to include these patients, or if the recent FDA staffing changes delay reviews of our applications for indication expansion, our growth potential could be harmed.

Our products are subject to extensive regulation by the FDA in the United States. Before a new medical device or a new intended use for an existing medical device can be marketed in the United States, we must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a PMA application or PMA-S from the FDA, unless an exemption applies.

If our clinical studies and collaborations with the National Evaluation System for health Technology to pursue the use of real-world data from the Pediatric Epilepsy Research Consortium do not produce results necessary to support regulatory clearance or approval to expand our indications to include patients with generalized drug-resistant epilepsy as well as patients age 12 to 17 with drug-resistant focal epilepsy, we will be unable to obtain and maintain necessary approvals to expand our indications to include these patients in accordance with our expected timelines, which could harm our growth potential. Furthermore, we could incur substantial costs and the attention of management could be diverted throughout this process. Recent cuts and staffing changes at the FDA could further delay our efforts to expand indications by creating significant and costly delays in the review process for our regulatory submissions; these delays would negatively impact our growth potential and ability to expand our market reach according to our financial plans.

Our growth prospects may be harmed if we are unable to successfully use our unique data asset and analysis capabilities, either internally or through collaboration, or if our expectations with respect to our ability to leverage our unique data asset prove to be incorrect.

In November 2023, we entered into a collaboration with Rapport to leverage our RNS System's unique biomarker monitoring and data analysis capabilities. We may seek to leverage our unique data asset or our data monitoring and analysis capabilities by entering into similar collaborations in the future. If we are unable to continue to build our data asset and our monitoring and analysis capabilities, either internally or through further collaborations, or if our expectations with respect to our ability to leverage our unique data asset prove to be incorrect, our growth prospects may be harmed.

We may expand sales of our RNS System internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our RNS System internationally even if approved. A variety of risks associated with marketing our RNS System internationally could harm our growth potential.

While our RNS System is not yet approved for sale outside the United States, we may pursue regulatory and reimbursement approval pathways in markets outside of the United States. Sales of our RNS System outside of the United States will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post-approval requirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operating in foreign countries include:

- differing regulatory requirements in foreign countries, including with respect to data privacy and security;
- differing reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenue;

- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights as well as intellectual property theft or compulsory licensing, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- business interruptions resulting from geopolitical actions, including tariffs, war and terrorism.

These and other risks associated with international operations may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential.

In addition, there can be no guarantee that we will receive approval to sell our RNS System in every international market we target, nor can there be any guarantee that any sales would result even if any such approval is received. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional studies and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our RNS System in those countries. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could harm our growth potential.

Risks related to government regulation and our industry

If we fail to comply with U.S. federal and state laws and regulations, including fraud and abuse and other healthcare laws and regulations, such as those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed.

Healthcare providers play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with healthcare professionals and hospital facilities, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies, procedures, and ongoing training, but it is not always possible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. There are also similar laws in other countries that we may become subject to if we expand internationally.

The laws that may affect our ability to operate include, among others:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including the FCA, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Health Insurance Portability & Accountability Act of 1996, or HIPAA, which applies to our customers and some of their downstream vendors and contractors, imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a 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; and

- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians, as defined by such law, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or the BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient care programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil FCA and HIPAA's healthcare fraud and privacy provisions.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, 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 our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling federal civil FCA, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the Office of Inspector General, or OIG, in order to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companies to ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the U.S. Department of Justice, or the DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could harm our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical studies.

We have adopted a code of conduct, employee handbook, compliance policies, and compliance training programs for all employees, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 be in compliance with such laws or regulations. If any such 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, disgorgement, imprisonment, reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in integrity issues, or a negative impact to our reputation or brand. Whether or not we are successful in defending against any 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, which could harm our business, financial condition and results of operations.

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacturing (including suppliers and materials) and testing;
- laboratory, preclinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;

- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our products are subject to extensive regulation by the FDA and if we expand internationally in the future may be subject to extensive regulation by non-U.S. regulatory agencies. Further, improvements of or changes to our existing products, any potential new products, and new indications for use of our current products will be subject to extensive regulation, and we may require permission from regulatory agencies and ethics boards to conduct clinical studies, as well as clearance or approval from the FDA prior to commercial sale. In order to commercialize and distribute our products in markets outside of the United States, it will require approval from non-U.S. regulatory agencies.

The FDA and foreign regulatory bodies can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from clinical studies;
- serious and unexpected adverse device effects experienced by participants in our clinical studies;
- the data from our preclinical studies and clinical studies may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our RNS System, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, and total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could harm our business, financial condition and results of operations.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- removal from FDA’s Voluntary Improvement Program pilot;
- unanticipated expenditures to address or defend such actions;

- form 483s, or other compliance or enforcement notices, communications or correspondence, including customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our RNS System;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;
- operating restrictions;
- seizure or detention of products;
- withdrawing 510(k) clearances or PMAs that have already been granted;
- refusal to grant export approval for our RNS System;
- criminal prosecution; or
- civil penalties.

If any of these events were to occur, it would have a negative impact on our business, financial condition and results of operations.

The FDA also regulates the advertising and promotion of our RNS System to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Additionally, our manufacturing facility is required to comply with extensive requirements imposed by the FDA, including ensuring that quality control and manufacturing procedures conform to the QSR. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) or PMA application.

The 510(k) or PMA process can be expensive, lengthy and unpredictable and we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We may not be able to obtain necessary clearances or approvals or may be unduly delayed in doing so, which would negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained PMA approval to market our RNS System, our approval can be revoked if safety or efficacy problems develop.

Our operations are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our growth potential, and our business, financial condition and results of operations.

Before a new medical device or service, or a new intended use for an existing product or service, or a change to an existing product or service can be marketed in the United States, a company must first submit and receive either 510(k) clearance or 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.

In the process of obtaining PMA approval, which was required for our RNS System, 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, preclinical, clinical study, manufacturing and labeling data. The PMA process is typically

required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable device. The FDA could decline to approve any supplemental application that we submit in the future to expand the indications for which our RNS System can be used, which would harm our growth potential.

The FDA and state and international authorities have broad enforcement powers. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices and product quality management. Such reviews and investigations may result in: civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may harm our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of interactions with healthcare providers. For example, Open Payments requires us to annually report to CMS payments and other transfers of value to U.S. physicians and certain other clinicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which could harm our business, financial condition and results of operations.

Modifications to our products or products we sell may require new 510(k) clearances or PMAs or may require us to recall or cease marketing these products until clearances or approvals are obtained, which could harm our business, financial condition and results of operations.

In the United States, our RNS System is marketed pursuant to a PMA order issued by the FDA. Any modifications to a PMA-approved device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, materials, or technology requires approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement - Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this 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 approvals are necessary for products that we manufacture and distribute. If the FDA disagrees with our determination and requires us to seek new PMA approvals for modifications to our previously approved products for which we have concluded that new 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.

For products that have received 510(k) clearance, such as our Burr Hole Cover product, modifications that could significantly affect safety and effectiveness, such as changes to the intended use or technological characteristics, may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance, or if such modification put the device into Class III, possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future 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.

We have made modifications to our RNS System in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could harm our business, financial condition and results of operations.

Our products or products we distribute may be subject to recalls after receiving FDA approval or clearance, which could divert managerial and financial resources, harm our reputation and our business.

The FDA has the authority to require the recall of our products or products we sell because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products or products we distribute could divert managerial and financial resources, harm our reputation and negatively impact our business.

If we initiate a correction or removal of one of our products to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report 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 and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports has been and could be used by competitors against us and could harm our reputation, which could cause customers to delay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in and decide not to implant our RNS System.

If any of our products or products that we distribute cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, or MDRs, which can result in voluntary corrective actions or agency enforcement actions and harm our reputation, business, financial condition and results of operations.

Under MDRs, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would be costly, distract management from operating our business, could be used by competitors against us, and may harm our reputation, business, financial condition and results of operations.

From time to time, we engage outside parties to perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incur significant additional costs.

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage may interact with clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as the FDA's Good Clinical Practice, or GCP, guidelines and FDA human subject protection regulations. We may face delays in completing our clinical studies if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical study protocols or for

other reasons, our clinical studies or trials may need to be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs.

Healthcare reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could harm our business, financial condition and results of operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, 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 and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs, such as the recently enacted Inflation Reduction Act of 2022. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations.

Compliance with environmental laws and regulations could be expensive, and the failure to comply with these laws and regulations could subject us to significant liability.

Our research, development and manufacturing operations involve the use of hazardous substances, and we are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of hazardous substances. Our products may also contain hazardous substances, and they are subject laws and regulations relating to labeling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third-party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot be certain that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error,

accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third-party claims, could negatively affect our business, financial condition and results of operations.

Clinical studies may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to support label expansion for additional indications.

We plan to continue to develop and execute clinical studies to support label retention for our products and label expansion for our products into additional epilepsy populations. We may also develop and execute clinical studies for new products or for label expansion for our current products into patient populations living with other neurologic conditions. We do not know whether future clinical studies will begin on time, need to be redesigned, enroll an adequate number of patients or be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion for additional indications or for new products may be delayed, suspended or terminated as a result of many factors, including:

- the delay or refusal of regulators or Institutional Review Boards, or IRBs, to authorize us to commence a clinical study at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies and delays in or the inability to monitor enrolled patients;
- the inability to enroll a sufficient number of patients in studies to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a study;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical studies;
- our CROs or clinical studies sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical study sites; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical studies.

We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such studies are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements, including GCP regulations, or our clinical protocols, inspection of the clinical study operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study.

In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of

the data generated at the applicable clinical study site or the utility of the clinical study itself. Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansion for our RNS System.

We may become subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act, in which violations of these laws could result in substantial penalties and prosecution.

We currently do not market and sell our products outside the United States. However, if we choose to conduct business outside the United States, our business will be subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, we may have to incur substantial costs to enhance our controls if we begin doing business outside the United States, and even so, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws to which we become subject could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could harm our business, financial condition and results of operations.

Risks related to privacy, information technology and cybersecurity

Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information may subject us to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our data privacy and security practices, which may disrupt our business operations and harm our business and reputation, financial conditions, results of operations and prospects and cause other adverse business consequences.

In the course of our operations, we receive, collect, use, generate, store, disclose, transfer, make accessible, protect, secure, dispose of, transmit, share and otherwise process (collectively, process) an increasing volume of sensitive and personal information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and detailed recordings of iEEGs from patients as well as information from our employees and third parties with whom we conduct business. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, rules, regulations, guidance and industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security, including data breach notification laws. Numerous

U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. As applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal information, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. While the laws and regulations of other states also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties with whom we work. Additionally, our customers may be subject to additional federal and state privacy and security laws, rules, regulations and standards, including HIPAA, that they require us to comply with through contractual obligations. This patchwork of obligations may give rise to conflicts or differing views of personal privacy rights.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR, the United Kingdom's GDPR, or UK GDPR, and Canada's Personal Information Protection and Electronic Documents Act, or PIPEDA, impose strict requirements for processing personal information. Under EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, four percent of annual global revenues, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

We use artificial intelligence, or AI, including generative AI, and machine learning, or ML, technologies in our products and services (collectively, AI/ML). The development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering laws governing the development and use of AI/ML, such as the EU's AI Act and Colorado's AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are or may become subject to such obligations in the future.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal information on our behalf.

We or the third parties with whom we work may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; and orders to destroy or not use personal information. For example, one of our primary competitors has been subject to class action lawsuits and government investigations in connection with their alleged failure to comply with their privacy and security obligations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Disruptions in our information technology systems or data or those of third parties with whom we work, whether through breaches or failures of our systems, ransomware, unauthorized access or otherwise, may result in both an adverse impact to our products, as well as the unauthorized use, disclosure, modification or misappropriation of patient or other personal or sensitive information, the occurrence of fraudulent activity, or other information security-related incidents, all of which could result in adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences, which could have a material and adverse impact on our business, financial condition and results of operations.

We are dependent on complex information technology systems for the functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management purposes. We process and collect data about trial participants in connection with clinical trials and patient data, such as detailed recordings of iEEGs to help clinicians make more informed treatment decisions and optimize their patients' care. These data are recorded by our RNS System and can be viewed by the physician during regular patient visits using the Physician Tablet or on demand through a secure website. Further, in addition to clinical trial and patient data, we and the third parties with whom we work process a growing volume of personal information and confidential, proprietary and sensitive information, which include procedure-based information and sensitive healthcare data, credit card and other financial information, and insurance information (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and originate from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, cyber criminals, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work are vulnerable to a heightened

risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which are increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software and zero-day vulnerabilities, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third parties and third-party technologies to operate critical business systems to process sensitive information in a variety of contexts, such as and without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

We expend resources or may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities on a timely basis. Further, we have (and may in the future) experienced delays in deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats may in the future cause a security incident or other interruption that may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of

unsuccessful phishing attempts in the past and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Applicable data privacy and security obligations require us, or we may voluntarily choose, to notify relevant stakeholders of certain security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products and services, deter new customers from using our products and services, and negatively impact our ability to grow and operate our business.

Some of our contracts do not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We currently maintain a cybersecurity insurance policy and business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposed and may not be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Therefore, failure to maintain or protect our information systems and data integrity effectively could harm our business, financial condition, and results of operations.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies. Any sensitive information that we input into a third-party generative AI/ML platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI/ML model. Additionally, where an AI/ML model ingests personal data and makes connections using such data, those technologies may reveal other sensitive information generated by the model. Moreover, AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination"). We may use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

We face potential liability related to the privacy of health information we obtain.

We may maintain, use, and share sensitive health information that we receive directly from patients that use our products, throughout the clinical study process, in the course of our research collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive, maintain, use, or transfer individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, including certain health information, which is a broader class of information than the health information protected by HIPAA.

Moreover, patients about whom we or our contractors or collaborators obtain or share health information, as well as the providers who share this information with us or whom we share this data with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third-party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our products and could harm or prevent sales of our products, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Additionally, data collection, privacy and security have become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adversely affect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consent to the collecting of their health information, and patients that have opted-in to the collection of their health information may revoke their consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implemented or may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health information from our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or our consent practices are found to be unlawful, this could negatively impact the growth potential for our business.

Risks related to our intellectual property

If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products, our ability to continue to commercialize our RNS System, or our other products, may be harmed.

As with other medical device companies, our success depends in large part on our ability to obtain, maintain, protect, enforce and defend a proprietary position for our products, which will depend upon our success in obtaining and maintaining effective patent and other intellectual property protection in the United States and other countries into which we may expand our business in the future that covers our RNS System and any other products, their manufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defend those patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents covering our products which are sufficient to prevent third parties, such as our competitors, from utilizing our products, or our competitors may have rights under current or future out-licenses of our intellectual property, which could result in our competitors developing and commercializing products similar to or competitive with our products. Any failure to obtain, maintain, protect, enforce or defend patent and other intellectual property

protection with respect to our RNS System or other aspects of our business could harm our business, competitive position, financial condition and results of operations.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, protect, enforce, and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection in one, several, or all geographies. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, 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 or license to third parties, including by way of our cross-license with Medtronic, and we are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any of our current or future licensors or licensees fail to obtain, maintain, protect, enforce or defend such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products, including our RNS System. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products, including our RNS System. Furthermore, even if they are unchallenged, our patents may not adequately protect our RNS System or any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by the patents we hold or

pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting such products might expire before or shortly after such products are commercialized. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our RNS System or our other products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner, which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may be co-owned or cross-licensed with third parties. If we give up, do not pursue, or are unable to obtain an exclusive license to any such third-party co-owners' or licensee's interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

We may not be successful in obtaining necessary rights to any products or processes we may develop through acquisitions and in-licenses.

We may find it necessary or prudent to acquire or obtain licenses to intellectual property or proprietary rights held by third parties that we may identify as necessary or important to our business operations. However, we may be unable to acquire or secure such licenses to any or all intellectual property or proprietary rights from third parties that we identify as necessary for our RNS System or any future products we may develop. The acquisition or licensing of third-party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property or proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully acquire or license required third-party intellectual property or proprietary rights or maintain the existing licenses to intellectual property rights we have, we may have to spend time and resources to develop intellectual property ourselves or abandon development of the relevant product, both of which could harm our business, financial condition and results of operations.

Patents covering our products, including our RNS System could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would result in reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for the patents raised in such a claim. Such a loss of patent protection would harm our business, financial condition and results of operations.

The medical device industry is characterized by patent litigation and in the future we could become subject to patent or other intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends in part upon our ability and that of our suppliers to manufacture, market, sell, and use our proprietary products without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Additional third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third party's intellectual property rights, we could be required to incur costs to obtain a license from such third party to continue developing and marketing our products. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be

forced, including by court order, to cease commercializing the infringing product. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned products in commercially important territories, or force us to cease some of our business operations, which could harm our business and cause brand and reputational harm. We could also be forced to redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible. Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device, healthcare, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors 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 these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from their normal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations.

Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs and thus may subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act, and implementing regulations, which are amended from time to time. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which are also referred to as "march-in rights." The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation and may change in the future. Intellectual property generated under or in collaboration with a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our future ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in any current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are and may become party to license or collaboration agreements with third parties to advance our research or allow commercialization of our products. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our products, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours. We may further be required to cease our development and commercialization of certain of our products. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our sales, business, financial condition or results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, which could have a material adverse effect on our sales, business, financial conditions or results of operations.

If we are unable to obtain patent term extension under the Hatch-Waxman Amendments, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be adversely affected**.**

We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currently operate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. 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, which may impede on our ability to grow outside of the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we could continue incurring costs without being certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validity of patents at a cost must lower than district court litigation and on much faster timelines. This lower-cost, faster and potentially more potent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

We may be subject to claims, including third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownership or inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products.

The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. Additionally, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products, or could face third-party claims of intellectual property infringement, misappropriation or other violations, including by a licensor from whom we've licensed certain intellectual property.

Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

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. Any of the foregoing could harm our business, financial condition and results of operations.

Additionally, our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applications of which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non-practicing entities, or NPEs, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties, including NPEs, may in the future claim, that our products infringe or violate their patents or other intellectual property rights.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by our products, which could harm our ability to commercialize any product we may develop and any other technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such

intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation, including to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or the patents of any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce our patent rights against competitors who infringe our patents depends on our ability to detect such 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, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure that our employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary information or know-how of others in the work that they do for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their former university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to another person or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevant intellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. These assignment agreements may not be self-executing or adequate in scope, and may be breached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and such claims could harm our business, financial condition and results of operations.

To counter or defend against such claims can be expensive and time-consuming and it may be necessary or we may desire to enter into a license to settle any such claims; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace, including ability to hire new employees or contract with independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoing could harm our business, financial condition and results of operations.

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 harmed.

Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognition among potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to continue to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, domain names or other intellectual property, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs, diversion of resources, or adverse impact to our brand and could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, may evolve, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- our intellectual property strategy may be limited, we may not seek protection for intellectual property that may ultimately become relevant to our business or our invention disclosure process may prove insufficient to encourage inventors to come forward with protectable intellectual property;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- the claims of our patents or patent applications, if and when issued, may not cover our products or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and other confidential or proprietary information that is not patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, suppliers, customers, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such

third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights have or will be adequate. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or require costly efforts to protect our products.

We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for our RNS System includes the use of open-source software that is subject to the terms and conditions of the applicable open-source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitors could purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from our development efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adversely impact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar to and potentially competing with our products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

Our inability to use software licensed from third parties, or our use of open-source software under license terms that interfere with our proprietary rights, could disrupt our business.

Our products, including our RNS System, includes the use of open-source software that is subject to the terms and conditions of the applicable open-source software licenses that grant us permission to use such software. Although we monitor our use of open-source software, the terms of many open source licenses to which we are subject have not been interpreted by U.S. or foreign courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to provide our technology to our customers. Moreover, we cannot ensure that we have not incorporated additional open-source software in our products in a manner that is inconsistent with the terms of the applicable license or our current policies and procedures. In the future, we could be required to seek licenses from third parties in order to continue offering our solutions, which licenses may not be available on terms that are acceptable to us, or at all. Claims related to our use of open-source software could also result in litigation, require us to purchase costly licenses or require us to devote additional research and development resources to change the software underlying our technology, any of which

would have a negative effect on our business, financial condition and operating results and may not be possible in a timely manner. We and our customers may also be subject to suits by parties claiming infringement due to the reliance by our products on certain open-source software, and such litigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain open-source software.

Alternatively, we may need to re-engineer our products or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licenses may require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charging license fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of the applicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of our own software, or our inability to use open source or third-party software, could result in disruptions to our business or operations, or delays in our development of future products or enhancements of our existing products, such as our RNS System, which could impair our business.

Risks related to financial matters

We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. For the years ended December 31, 2024 and 2023, we reported net losses of $27.1 million and $33.0 million, respectively. As a result of these losses, as of December 31, 2024, we had an accumulated deficit of approximately $531.0 million. We expect to continue to incur significant business expenses as we continue to enhance our efforts to promote our brand, increase sales, improve therapy effectiveness, enhance the patient and provider experience, and expand the population of eligible patients. In addition, we expect our selling, general and administrative expenses to increase as we continue to operate as a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue and improve our gross margins in order to achieve and sustain profitability. It is possible that we will not achieve profitability or that, even if we do achieve profitability, we may not remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Our expected future capital requirements may and do depend on many factors including expanding our customer base, the expansion of our sales force, our efforts to manage our expenses, and the timing and extent of spending on updating our product to enhance our offering or expand our reach. We may need additional funding to fund our operations, but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay any dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

We are party to an existing Term Loan Agreement, which contains restrictive covenants as well as financial maintenance covenants, and if we are unable to comply with these covenants then the lenders could declare an event of default and we may need to immediately repay the amounts due under the Term Loan Agreement.

In September 2020, we entered into a Term Loan Agreement, or the Term Loan, pursuant to which we borrowed $50.0 million. The Term Loan contains customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments, merge or consolidate with any other person or engage in transactions with our affiliates, as well as minimum liquidity and annual revenue covenants. If we fail to

comply with the covenants or payments specified in the Term Loan, the lenders could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, borrowings under the Term Loan are secured by substantially all of our properties, rights and assets, including intellectual property. Any declaration by our lender of an event of default could significantly harm our business and could cause the price of our common stock to decline.

If our distribution agreement with DIXI Medical is not renewed or we fail to negotiate a new agreement, our revenue growth, financial condition and results of operations may be materially affected.

In August 2022, we entered into a distribution agreement with DIXI Medical, pursuant to which we became the exclusive U.S. distributor of DIXI Medical's stereo electroencephalography product line. The distribution agreement has an initial term of three years, which expires September 30, 2025, and which will be automatically renewed for additional one-year terms, unless either party provides written notice to the other party of its intention to not renew at least 180 days prior to the expiration of the then-current term. If either party provides notice of intent not to renew by April 3, 2025 or otherwise fail to negotiate a new agreement, we may not be able to continue to generate and grow revenue from the sales of DIXI medical products, which may materially affect our financial condition and our results of operations, and our stock price may decline.

Our actual operating results may differ significantly from any guidance provided.

Our guidance, including forward-looking statements, is prepared by management and is qualified by, and subject to, a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies. Many of these uncertainties and contingencies are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. We generally state possible outcomes as high and low ranges, which are intended to provide a sensitivity analysis as variables are changed but are not intended to represent that actual results could not fall outside of the suggested ranges.

Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions of the guidance furnished by us will not materialize or will vary significantly from actual results. In particular, guidance offered in periods of extreme uncertainty, such as the uncertainty caused by macroeconomic conditions, is inherently more speculative in nature than guidance offered in periods of relative stability. Accordingly, any guidance with respect to our projected financial performance is necessarily only an estimate of what management believes is realizable as of the date the guidance is given. Actual results will vary from the guidance and the variations may be material. Investors should also recognize that the reliability of any forecasted financial data will diminish the farther in the future that the data is forecasted.

Actual operating results may be different from our guidance, and such differences may be adverse and material. In light of the foregoing, investors are urged to put the guidance in context and not to place undue reliance on it. In addition, the market price of our common stock may reflect various market assumptions as to the accuracy of our guidance. If our actual results of operations fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially.

Our operating results may fluctuate across periods, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products and any future products, which may vary significantly from period to period;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;

- the timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future products or features;
- pricing pressures;
- our ability to expand the geographic reach of our commercial efforts;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to our products, and potential future products that compete with our products;
- the timing and success or failure of preclinical or clinical studies for expanding the indications of our RNS System or any future products we develop or competing products;
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;
- the timing of customer orders, scheduling or cancelling of implant procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, vacations, the mix of products sold and the geographic mix of where products are sold, including any related foreign currency impact;
- the impact of hospital accessibility and staffing shortages on procedure volume or otherwise;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period. Investors 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 revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could harm our business, financial condition, and results or operations.

To support our continued operations and the growth of our business, we may need to seek additional capital through new equity or debt financings, which sources of additional capital may not be available to us on acceptable terms or at all. If we are unable to obtain, if needed, adequate financing or financing on terms satisfactory to us, it could harm our business and growth prospects.

Our operations have consumed substantial amounts of cash since inception and we intend to continue to make significant investments to support our continued business operations and growth, respond to business challenges or opportunities, enhance our products, expand the population of eligible patients, and potentially acquire complementary businesses and technologies. For the years ended December 31, 2024 and 2023, our net cash used in operating activities was $17.9 million and $19.7 million, respectively. As of December 31, 2024, we had $52.8 million of cash, cash equivalents and short-term investments and $15.2 million in current liabilities.

Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including our growth rate, the growth of sales and marketing teams and activities, our expense management initiatives, the expansion of the population of eligible patients, geographies we may choose to enter and commercialize in, updates to our products, potential introduction of new products, either developed internally or acquired, the continued oversight of regulatory agencies, and the continuing market acceptance of our products. Accordingly, we may need to engage in equity or debt financings or collaborative arrangements to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, during times of economic instability, it has been difficult for many companies to obtain financing in the public markets or to obtain debt financing, and we may not be able to obtain additional financing, if needed, on commercially reasonable terms, if at all. If we are unable to access our existing capital or obtain adequate financing or financing on terms satisfactory to us, if needed, it could harm our business and growth prospects.

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

In general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. As of December 31, 2024, we had $152.5 million of federal net operating loss carryforwards and $162.7 million of state net operating loss carryforwards. The federal and state NOL carryforwards began expiring in 2026 and 2029, respectively. As of December 31, 2024, the amount of federal NOL carryforwards that does not expire is $114.0 million (subject to certain utilization limitations). We have conducted Section 382 studies and determined that we experienced ownership changes in 2016 and in 2021 which resulted in permanent limitation of our pre-change NOL and research and development credit carryforwards. In addition, future changes in our stock ownership, some of which are outside of our control, could result in an additional ownership change under Section 382 of the Code, further limiting our ability to utilize NOLs arising prior to such ownership change in the future. There is also a risk that due to statutory or regulatory changes, such as suspensions on the use of NOLs (including California legislation enacted in June 2020 that limited the ability to use California NOLs to offset California income for tax years beginning after 2019 and before 2023), or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

If we identify any material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations.

We cannot be certain that the actions we may take in the future will prevent or avoid potential future material weaknesses. If we identify any material weaknesses in our internal control over financial reporting and are unable to successfully remediate them, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result.

Our history of recurring losses and anticipated expenditures as well as the significant amount of debt that we have incurred may affect our ability to operate our business and secure additional financing in the future.

We have incurred operating losses to date and it is possible we may never generate a profit. Additionally, our obligations under the Term Loan Agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to engage in various activities, which management may deem important for the business. The covenants related to

the Term Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our Term Loan Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business.

Other risks facing our company

Our estimates of market opportunity and forecasts of market and revenue growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are subject to significant uncertainty. Our estimates of the annual total addressable markets for our RNS System are based on a number of internal and third-party estimates and assumptions, including, without limitation, our assumptions relative to the number of adults with drug-resistant focal epilepsy in the United States who are treated at CECs and outside of CECs each year; the number of neuromodulation procedures annually in the United States; the number and growth in number of CECs, epileptologists, and neurosurgeons in the CECs and in the community setting; the growth in number of patients referred to CECs; the patients receiving neuromodulation therapy outside in the community setting; and the potential growth of our market opportunity with the expansion of treatment to patients in the community setting, as well as to those suffering from generalized epilepsy or who are under age 18.

In addition, our projections related to being the exclusive U.S. distributor of DIXI Medical products have been based on a number of estimates and assumptions, including, without limitation, information obtained from DIXI Medical related to historical performance and future projections, and annual extensions of the current distribution agreement, which occur automatically unless one of the parties notifies the other of its intention to not renew the agreement or otherwise negotiate a new agreement. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our RNS System may prove to be incorrect. If the actual annual total addressable market for our RNS System is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Alternatively, if the actual annual total addressable market for our RNS System is bigger than we have estimated, we may not be ready to manage such growth, which may impair our sales and have an adverse impact on our business. Additionally, if our projections regarding the revenue we anticipate receiving from our collaboration with Rapport are inaccurate, we may not attain our revenue projections, which could harm our business, result in investors losing confidence in our financial reporting, and our stock price may decline.

If our distribution agreement with DIXI Medical is not renewed, it may have an adverse effect on our financial condition.

In August 2022, we entered into the distribution agreement with DIXI Medical, pursuant to which we became the exclusive U.S. distributor of DIXI Medical's stereo electroencephalography product line. The distribution agreement has an initial term of three years, which expires September 30, 2025, and which may be automatically renewed for additional one-year terms, unless either party provides written notice to the other party of its intention to not renew at least 180 days prior to the expiration of the then-current term. If we and DIXI Medical do not agree to extend our exclusive distribution relationship or otherwise negotiate a new agreement, it will negatively impact our overall revenue growth, financial condition and results of operations, and our stock price may decline

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm our business and our ability to sell our products, including our RNS System.

We face an inherent risk of product liability as a result of the marketing and sale of our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associated liabilities. For example, we may be sued if our RNS System causes or is perceived to cause injury or is found to be otherwise unsuitable during manufacturing, marketing, sale, or distribution. Any such product liability claim may include, but not be limited to, allegations of defects in manufacturing, defects in design, defects in clinical study design or performance, a failure to warn of dangers inherent in the product, negligence, strict liability or a potential breach of implied or expressed warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on healthcare providers to determine appropriate patients for our products and to properly and correctly implant and use our RNS System as part of a patient's treatment protocol. If these healthcare providers are not properly trained, do not properly screen the patient, are negligent in implanting or using our RNS System or implant or use our RNS System "off-label," the capabilities or reputation of our RNS System may be diminished or the patient may suffer critical injury. While we believe that we clearly describe the limitations of our label, we cannot prevent an epileptologist from referring a patient for an RNS System implant for off-label indications, prevent a neurosurgeon from implanting our RNS System for off-label applications, or having our RNS System programmed based on off-label considerations. In addition, we cannot guarantee that healthcare providers are adequately trained prior to incorporating our RNS System into their practice. Complications resulting from the use of our products, including use of our RNS System off-label or use by healthcare providers who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. We may also be subject to claims that are caused by the activities of our suppliers and vendors, such as those who provide us with components, materials, or services, which may have an impact on our products and result in product liability claims brought against us.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our brand or reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- increased insurance premiums;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We currently carry product liability

insurance in the amount of $7.0 million in the aggregate. In the future, we may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our patient-focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers may also have difficulty in procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business.

We rely on suppliers, vendors, partners, consultants, and other third parties to research, develop, and partake in both the manufacturing and commercialization of our products, as well as manage certain parts of our business. In addition, in August 2022 we entered into a distribution agreement with DIXI Medical pursuant to which we became the exclusive U.S. distributor of DIXI Medical's product line, under which DIXI Medical provides us with ongoing commercial support and supplies us with DIXI Medical products, as ordered by us. Additionally, in November 2023, we entered into a collaboration agreement with Rapport, whereby we agreed to provide them certain data, biomarker monitoring and data analysis capabilities. Using these third parties poses a number of risks, such as:

- they may not extend or renew their agreement with us;
- they may not perform to our standards or legal requirements;
- they may not produce reliable results;
- they may not perform in a timely manner;
- they may not maintain confidentiality of our proprietary information;
- disputes may arise with respect to ownership of rights to products developed with our partners; and
- disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration.

Moreover, some third parties may be located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business.

Future legislation, potential changes in federal regulatory agency leadership, and new policies and priorities under the current Administration may adversely impact our company.

In light of the recent U.S. Presidential and Congressional elections, we expect additional state and federal health reform measures may be adopted in the future, and of which could adversely affect our business. Although the prospects for the imminent enactment of major legislation are not certain at this time, the enactment of more targeted measures may be more likely due to the increased possibility of federal executive and legislative branch support for consideration of such measures. Moreover, changes in the leadership and senior staffs of the FDA could impact the

rulemaking, supervision, examination and enforcement priorities and policies of the agency. The potential impact of changes in agency personnel, policies and priorities on the medical device sector, including us, cannot be predicted at this time.

We may not be able to respond quickly or effectively to regulatory, legislative, and other developments, and these changes may in turn impair our ability to offer our current or planned products, or increase our cost of doing business. Disruption to federal funding during the current administration may disrupt our access to federal funding for research into expanded indications for our product. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, or criminal or civil sanctions, all of which may have an adverse effect on our reputation, business, financial condition and results of operations.

Risks related to ownership of our common stock

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may, from time to time, issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of December 31, 2024, there were 3.8 million shares of common stock issuable upon the exercise of outstanding stock options or subject to vesting of outstanding restricted stock units, or RSU, awards. We have registered all of the shares of common stock issuable upon exercise of outstanding stock options and upon the settlement of RSU awards for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance subject to compliance with applicable securities laws. Including the aforementioned outstanding equity awards, as of December 31, 2024, there were approximately 6.5 million shares of common stock reserved for future issuance under our equity incentive plans which may become available for public resale to the extent we issue future equity incentive awards pursuant to these plans.

In addition, certain of our stockholders have registration rights that would require us to file registration statements for the public resale of the common stock issuable upon conversion of such shares or to include such shares in registration statements that we may file on our behalf or for other stockholders.

Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based on the number of shares of common stock outstanding as of February 28, 2025, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own, approximately 57.9% of our common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders and they may want us to pursue strategies that deviate from the interests of other stockholders.

Our stock price has been volatile, an active or liquid market in our common stock may not be sustainable and the value of our common stock may decline.

Historically, our stock price has been volatile. During the year ended December 31, 2024, our stock traded as high as $18.15 per share and as low as $5.45 per share. An active or liquid market in our common stock may not be sustainable and the market price of our common stock may continue to be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- actual or anticipated fluctuations in our financial condition and results of operations;
- variance in our financial performance from expectations of securities analysts or investors;
- changes in the coverage decisions, reimbursement or pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- publicity associated with issues related to our products;
- our involvement in regulatory investigations or litigation;
- future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of our common stock;
- changes in the anticipated future size and growth rate of our market;
- general economic, regulatory, and market conditions, including economic recessions or slowdowns;
- changes in the structure of healthcare payment systems; and
- developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small public float of shares of our common stock on the Nasdaq Global Market, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our reputation and our business.

We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements

of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements.

We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these 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.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the first fiscal year after our annual gross revenues exceed $1.235 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year**.**

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management without the consent of our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated convertible preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock entitled to vote at an election of directors to adopt, to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is

responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These provisions do not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation, including those described in the preceding sentences.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provide that the federal district courts of the United States be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could harm our business, financial condition, results of operations, and prospects.

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 lawsuits

against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business and financial condition.

General risk factors

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, changes in interest rates and uncertainty about economic stability. For example, the Russia-Ukraine war and the conflict in the Middle East has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Trade tensions or restrictions on free trade, including the tariffs that have been proposed by the current administration, could exacerbate these effects. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruptions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health crises, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our ability to obtain components for our products could be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters and manufacturing facility is located in Mountain View, California, near major earthquake faults and fire zones. Should our facilities be significantly damaged or destroyed, it could take months to relocate or rebuild, during which time our manufacturing would cease or be delayed and our RNS System may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and, to some extent, lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could harm our business, financial condition, and results of operations.

Litigation and other legal proceedings may harm our business.

We are involved in, and from time to time in the future we may become involved in, legal proceedings relating to patent and other intellectual property matters, product liability claims, employee matters, tort or contract claims, federal regulatory investigations, private rights of action, securities matters and class actions as well as other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts, judgements, and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. We may fail to enter into settlements or to obtain rulings for matters we believe we have resolved. There may be an increase in the scope of these or other matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us, irrespective of outcome, could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

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

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not continue to publish research or reports about our business, delay publishing reports about our business or publish negative or unfavorable reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We expect that only a limited number of analysts will cover our company and we do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our reputation may be adversely impacted and our stock price would likely decline.

We are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may negatively impact investor confidence in our company and, as a result, the value of our common stock.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act to include in our annual reports a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the Securities and Exchange Commission, or the SEC, following the date we are no longer an emerging growth company, and no longer qualify for certain scaled disclosure requirements as a smaller reporting company. We have not yet commenced the costly and challenging process of compiling the system and process documentation necessary to perform such evaluation required by our auditors under Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public

company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. We cannot be certain that the actions we may take in the future will prevent or avoid potential future material weaknesses. If we are unable to conclude that our internal control over financial reporting is effective, or if we identify additional material weaknesses in our internal control over financial reporting and are unable to successfully remediate them, our reputation could be negatively impacted, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities and our access to the capital markets could be restricted in the future.

We will continue to incur significant costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we have and will continue to incur significant legal, accounting, and other expenses. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies. Our management, board of directors, and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will drive high legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of these additional costs or the timing of such costs.

We may partner with or acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and harm our results of operations.

As part of our business strategy, we may in the future partner with, make acquisitions of or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and the patients they serve. In the future, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such partnership or acquisitions in an appropriate timeframe and on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable partnerships or acquisitions, whether or not they are consummated. If we do complete partnerships or acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by management, as well as our employees, customers, investors and industry analysts.

Future partnerships or acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay into or for any such partnerships or acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such partnerships or acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such partnerships or acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be harmed by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, partnerships or acquisitions may require large, one-time charges and can result in increased debt or contingent liabilities, a negative impact to our gross margins, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, client data and patient data, or, collectively, Information Systems and Data.

Our information security function is overseen by our Privacy and Security Officer and is supported by our Director of Information Technology and Chief of Operations and Development, as well as our engineering operations and third-party service providers. This function helps to identify, assess, and manage our cybersecurity threats and risks, including through the use of our risk register. Our information security function helps identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: evaluating our industry's risk profile, deploying manual and automated tools in certain environments, subscribing to reports and services that identify certain cybersecurity threats, evaluating certain threats reported to us, engaging third parties to conduct threat assessments, conducting internal and external vulnerability and threat scans and assessments of certain environments, conducting internal audits, and penetration testing of certain systems.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response, vulnerability management and disaster recovery policies, risk assessments, data encryption and data segregation of certain data, access controls and network security controls in certain environments, physical security controls, employee training, phishing simulation exercises, penetration testing, systems monitoring, cybersecurity insurance and asset and vendor management programs.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our Privacy and Security Officer works with Information Technology, Legal, and other NeuroPace leadership to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example: professional service firms, including outside legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity service provider, and penetration testing firms.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes security questionnaires and risk assessments for certain vendors, vulnerability scans for certain vendors, security assessment calls with certain vendor's security personnel, imposition of information security contractual obligations on certain vendors, verification of relevant industry standard security certifications for certain vendors, and other vendor management program elements. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under the section titled "*Risks related to privacy, information technology and cybersecurity"* located in Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K.

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain NeuroPace management, including our Privacy and Security Officer, who has more than 20 years of experience in healthcare privacy and security, in coordination with our Director of Information Technology, who has more than 30 years of experience with information technology operations and seventeen years as a corporate privacy and security officer.

Our Privacy and Security Officer, Director of Information Technology, and NeuroPace leadership are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our Privacy and Security Officer in coordination with our Director of Information Technology is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our incident response and vulnerability management policies are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Privacy and Security Officer, Director of Information Technology, Chief of Operations and Development and other designated individuals. Our Privacy and Security Officer works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response and vulnerability management policies include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The board of directors receives periodic reports from our Privacy and Security Officer concerning significant cybersecurity threats to us and risk and the processes we have implemented to address them. The board of directors also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

We currently lease approximately 53,000 square feet for our corporate headquarters and manufacturing facility located in Mountain View, California under a lease agreement which terminates in 2030 and we have an option to extend for another five years. We believe that this facility is sufficient to meet our current and anticipated needs in the near term and that suitable additional or alternative space can be obtained in the future on commercially reasonable terms, as needed.

Item 3. Legal Proceedings.

Legal Proceedings

We are, and from time to time may become, involved in legal proceedings in the ordinary course of business. Such legal proceedings may negatively impact our business and financial position, result in brand or reputational harm, and divert the attention of our management from core operations of our business.

Item 4. Mine Safety Disclosures.

None.

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 listed on the Nasdaq Global Select Market under the symbol "NPCE" since April 22, 2021. Prior to this date, there was no public market for our common stock.

Holders of Common Stock

As of February 28, 2025, there were approximately 145 stockholders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and therefore we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

In April 2021, we closed our initial public offering of 6,900,000 shares of our common stock, including shares issued upon the exercise in full of the underwriters' option to purchase 900,000 additional shares of common stock, at a public offering price of $17.00 per share. We received gross proceeds to us of $117.3 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-254663), which was declared effective by the SEC on April 21, 2021. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC acted as joint lead book-running managers for the offering. Wells Fargo Securities, LLC and SVB Leerink LLC also acted as book-running managers for the offering. Shares of our common stock began trading on the Nasdaq Global Market on April 22, 2021 and, following the sale of all the shares upon the closing of the initial public offering on April 26, 2021, the offer terminated.

The net proceeds to us after deducting underwriting discounts and commissions of $8.2 million and net offering expenses of approximately $3.6 million were $105.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in the final prospectus for our initial public offering dated as of April 21, 2021 and filed with the SEC pursuant to Rule 424(b)(4) on April 23, 2021 and those disclosed in this Annual Report on Form 10-K. As of December 31, 2024, approximately $92.7 million of the net proceeds had been used for general corporate purposes including cash used in operations and capital expenditures.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, which are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Risk Factors" under Part I, Item 1A of this report and elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical device company focused on transforming the lives of people living with epilepsy by reducing or eliminating the occurrence of debilitating seizures. Our novel and differentiated RNS System is the first and only commercially available, brain-responsive neuromodulation system that delivers personalized, real-time treatment at the seizure source. By continuously monitoring and analyzing the brain's electrical activity, recognizing patient-specific abnormal electrical patterns, and responding in real time with imperceptible electrical pulses to prevent seizures, our RNS System delivers the precise amount of therapy when and where it is needed and provides exceptional clinical outcomes with approximately three minutes of stimulation on average per day. Our RNS System is also the only commercially available device that records continuous brain activity data and allows clinicians to monitor patients not only in person, but also remotely, providing them the data they need to make more informed treatment decisions, thus optimizing patient care. We believe the therapeutic advantages of our RNS System, combined with the insights obtained from our extensive brain data set, offer a significant leap forward in epilepsy treatment.

Our RNS System is currently indicated in the United States for use in adult epilepsy patients, meaning patients who are 18 years of age or older, with drug-resistant focal epilepsy. We recently announced our primary effectiveness endpoint data in our Post-approval Study in this patient population. The data showed that the RNS System efficacy improved over time, with a 62.5% median seizure reduction at six months after implant (n=314) and an 82.0% median seizure reduction at 36 months after implant (n=255). Additionally, 42.5% of patients experienced a period of seizure-freedom for at least six months, and 22% of patients were seizure free for at least one year. Results will be presented at the American Academy of Neurology Annual Meeting, held April 5 through 9, 2025.

We are conducting studies to expand our indication for use to patients with drug-resistant generalized epilepsy and patients with drug-resistant focal epilepsy under the age of 18. In March 2024, we completed implanting patients in our NAUTILUS study for generalized epilepsy and expect that the last patient will complete one year of follow up in March 2025, with the data lock and subsequent commencement of data analyses expected to begin in the second quarter of 2025. To support our RESPONSE study for label expansion in focal epilepsy patients under the age of 18, we recently announced our collaboration with the National Evaluation System for health Technology, or NEST, and the FDA to pursue the use of real-world data from the Pediatric Epilepsy Research Consortium, or PERC. We are planning to file the expanded label submissions to the FDA for both of these indications in the second half of 2025.

Our commercial efforts have historically been focused on growing adoption and utilization across Level 4 comprehensive epilepsy centers, or CECs, in the United States that facilitate appropriate care for drug-resistant epilepsy patients. In 2023, we received FDA approval of a Premarket Approval Supplement, or PMA-S, which updated the qualification criteria for centers and clinicians that may prescribe and implant the RNS System. We initiated a pilot program to begin our outreach to these centers and clinicians in 2024 and have commenced program expansion that will continue through 2025. We plan to address this opportunity in a targeted manner with incremental expansion of our sales force.

Since our inception, we have generated significant losses. We have financed our operations primarily through sales of our products, issuance of equity securities, and debt financing. As of December 31, 2024, we had an

accumulated deficit of $531.0 million, cash, cash equivalents and short-term investments of $52.8 million, and $59.5 million of outstanding debt under a term loan, net of debt discount and issuance costs.

We have invested heavily and expect to continue to invest in research and development and commercial activities. Our research and development activities include clinical studies to demonstrate the safety and effectiveness of our RNS System, including in expanded indications, and to obtain, as well as retain, FDA approval. We intend to continue making significant investments in research and development, clinical studies and regulatory affairs to support ongoing and future regulatory submissions for retaining and expanding indications of our RNS System, including to patients with drug-resistant generalized epilepsy and patients under the age of 18, support continuous improvements to our RNS System, and develop future products that address neurological disorders. We have also made significant investments in building our field commercial team and intend to make significant investments in sales and marketing efforts in the future, including initiatives to drive awareness and expand our referral channel to increase the number of drug-resistant epilepsy patients referred to CECs. We may in the future seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or enhance our products, enhance our technical capabilities or otherwise offer growth opportunities, although we currently have no agreements or understandings with respect to any such acquisitions or investments. Because of these and other factors, we expect to continue to incur net losses and negative cash flows for the next several years. We may require additional funding to support operations and pay our obligations or may opportunistically seek to raise additional capital, which may include future equity or debt financings.

Based on our current planned operations, we believe our existing cash, cash equivalents and short-term investments will allow us to continue our operations for at least the next 12 months. See “Liquidity and Capital Resources - Future Funding Requirements” for additional information.

Collaborations and Partnerships

DIXI Distribution Agreement

In August 2022, we entered into an exclusive distribution agreement, or the Distribution Agreement, with DIXI Medical USA Corp., or DIXI Medical, pursuant to which we became the exclusive U.S. distributor of DIXI Medical’s stereo electroencephalography, or Stereo EEG, product line beginning in October 2022. These products are used in the epilepsy monitoring units, or EMUs, of comprehensive epilepsy centers to determine where epileptic seizures originate. In addition to providing us with an incremental revenue stream, the DIXI Medical partnership provides us with improved visibility of patients moving through the EMUs, many of whom may be candidates for our RNS System. This synergistic partnership leverages our field organization that is already calling on the same customers and supports our objective to engage earlier in the diagnostic and therapy selection process. The Distribution Agreement has an initial term of three years, which expires September 30, 2025, and which will be automatically renewed for additional one-year terms, unless either party provides written notice to the other party of its intention to not renew at least 180 days prior to the expiration of the then-current term.

Rapport Agreement

In November 2023, we entered into a collaboration agreement with Rapport Therapeutics, Inc., or Rapport, a clinical-stage biotechnology company, to leverage our data as well as our RNS System’s unique biomarker monitoring and data analysis capabilities. The collaboration evaluates biomarker changes in currently implanted RNS System patients that enroll in Rapport’s Phase 2a clinical trial of its product candidate. Pursuant to this agreement, we provide information to Rapport that will help evaluate the impact of their product candidate on certain biomarkers of patients with focal onset seizures.

Factors Affecting Our Performance

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

Clinician, Hospital and Patient Awareness and Acceptance of Our RNS System

Our goal is to establish our RNS System as a standard of care for drug-resistant epilepsy. We intend to continue to promote awareness of our RNS System within existing and new accounts through additional investments in training and education of clinicians, epilepsy centers, hospitals and patients on the clinical benefits of our RNS System for the treatment of drug-resistant epilepsy. In addition, we intend to publish additional clinical data in scientific journals and to continue presenting at medical conferences. We plan to continue building patient awareness through direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue supporting patient and referring clinician outreach efforts to help increase the number of appropriate patients with drug-resistant epilepsy being treated at CECs and outside of CECs, including by way of our expansion into the community setting. These efforts require significant investment by our marketing and sales organization.

Our Ability to Retain Our Experienced Commercial Team and Increase its Productivity

We have made significant investments in, and will continue to invest in, recruiting, training and retaining our experienced and specialized direct sales team, which includes Therapy Consultants and Field Clinical Engineers. Significant education and training is required for our team to achieve the level of technical competency with our products that is expected by clinicians and to gain experience building demand for our RNS System. Upon completion of initial training, our personnel typically require time in the field to grow their network of accounts, build relationships with clinicians and increase their productivity to the levels we expect. We believe successfully training, developing and retaining our Therapy Consultants and Field Clinical Engineers will be required to achieve growth. In addition, the loss of any productive sales personnel would have a negative impact on our ability to grow our business.

Competition

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and the marketing activities of industry participants. There are two primary treatment alternatives for adults with drug-resistant epilepsy: (i) an ablative or resective surgery; and (ii) implantation of a neuromodulation device. Within neuromodulation, we currently compete with two manufacturers of neuromodulation devices. These companies have longer operating histories, significantly greater resources and name recognition, and established relationships with physicians and hospitals that treat patients with epilepsy. In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business.

Leveraging Our Manufacturing Capacity to Further Improve Our Gross Margin

With our current operating model and infrastructure, we believe that we have the capacity to significantly increase our manufacturing production. If we grow our revenue and sell more RNS Systems, our fixed manufacturing costs will be spread over more units, which we believe will reduce our manufacturing costs on a per-unit basis and in turn improve our gross margin. In addition, we intend to continue investing in manufacturing efficiencies in order to reduce our overall manufacturing costs. However, other factors will continue to impact our gross margin such as the cost of materials, components and subassemblies, pricing, procedure mix, and geographic sales mix to the extent that we commercialize our RNS System outside of the United States.

Investing in Research and Development, Including Clinical Studies, to Expand Our Addressable Market

We intend to continue investing in clinical studies and existing and next generation technologies to further improve our RNS System and clinical outcomes, enhance the patient and provider experience and broaden the patient population that can be treated with our RNS System. In addition, we are continuing to develop AI-enabled software tools, leveraging our extensive database of intracranial electroencephalogram, or iEEG, data and our advanced data analysis capabilities to equip clinicians with the data they need to establish optimal program settings for each patient.

While research and development and clinical studies are time consuming and costly, we believe that a pipeline of product enhancements and new products that improve effectiveness, safety and ease of use is important for supporting increased adoption of our RNS System.

Change in Product Mix

We derive revenue from sales of our RNS System to hospital facilities both for initial RNS System implant procedures and for replacement procedures when our implanted devices reach end of service. We launched our current neurostimulator model in 2018. This device has an average battery life of nearly eleven years, an increase from the previous model of the device. We have experienced and may continue to experience changes in the percentage of our revenue from replacement procedures over the next few years as a result of the extended replacement cycle of the newer device, which may cause variability in our gross margin. We also derive revenue from sales of DIXI Medical products. A change in product mix between sales of our RNS System and DIXI Medical products would cause variability in our gross margin.

Components of Our Results of Operations

Revenue

We derive most of our revenue from sales of our RNS System to the hospital facilities that implant our RNS System. Our revenue fluctuates primarily based on the volume of procedures performed and the procedure mix between initial and replacement implants. Our revenue has also fluctuated and will continue to fluctuate in the future from quarter-to-quarter due to a variety of factors, including the success of our sales force in expanding adoption of our RNS System in new accounts and the number of physicians who are aware of and prescribe our RNS System.

We also derive revenue from sales of DIXI Medical products, primarily to our current customer base. Our revenue from the sale of DIXI Medical products will fluctuate in the future due to a variety of factors, including our ability to take market share from competitive Stereo EEG products.

Beginning in the fourth quarter of 2023, we also derive revenue from services provided to Rapport pursuant to our collaboration agreement with Rapport. Our revenue from this collaboration fluctuates due to the timing of services provided and other factors.

Nearly all of our revenue results from sales in the United States, but we also have limited sales of our RNS System in Canada pursuant to a special program that involves case-by-case approvals of the use of our RNS System in adult patients with drug-resistant focal epilepsy.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs related to materials, components and subassemblies, personnel-related expenses for our manufacturing and quality assurance employees, including stock-based compensation, manufacturing overhead and charges for excess, obsolete and non-sellable inventories. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management personnel, an allocation of facilities and information technology expenses, including rent and utilities, and equipment depreciation. Cost of goods sold also includes certain direct costs such as those incurred for shipping our RNS System. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. Cost of goods sold also includes costs of procuring and shipping DIXI Medical products. We expect cost of goods sold to increase in absolute dollars as more of our RNS Systems and DIXI Medical products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our manufacturing costs, pricing and product mix. Our gross margin may increase over the long term to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units, thereby reducing our per-unit manufacturing costs. We expect our gross margin will fluctuate from period to period, however, based upon the factors described above.

Operating Expenses

Our operating expenses consist of research and development costs and selling, general and administrative costs.

Research and Development Expenses

Our research and development activities primarily consist of engineering and research programs associated with our products under development and clinical studies. Research and development expenses include personnel-related costs for our research and development employees, including stock-based compensation, and expenses related to consulting services, clinical trials, regulatory activities, prototyping, testing, materials and supplies, and allocated overhead including facilities and information technology expenses. Our clinical trial expenses include costs associated with clinical trial design, clinical trial site development and study costs, data management costs, related travel expenses, the cost of products used for clinical activities, and costs associated with our regulatory compliance. We expense research and development costs as they are incurred. We expect our research and development expenses will increase in absolute dollars as we continue to develop new product offerings and product enhancements and conduct studies for expanded indications for use.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of personnel-related costs for our sales and marketing employees, including stock-based compensation and sales-based variable compensation, travel expenses, consulting, public relations costs, direct marketing, customer training, trade show and promotional expenses and allocated facility and information technology expenses, and for administrative personnel that support our general operations such as executive management and information technology, finance, accounting, customer services, human resources and legal personnel. We expense sales variable compensation when revenue related to the underlying sale is recognized. Selling, general and administrative expenses also include costs attributable to professional fees for legal, accounting and tax services, insurance and recruiting fees.

We intend to continue to increase our sales and marketing spending to support increased adoption of our RNS System. We expect our sales and marketing expenses will increase in absolute dollars as we hire additional personnel and add programs in order to more fully penetrate the market opportunity. We expect our administrative expenses, including stock-based compensation expense, will increase as we increase our headcount to support our growth. Additionally, we may incur increased expenses related to audit, legal, regulatory and tax-related services, compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, and director and officer insurance premiums. Our selling, general and administrative expenses may fluctuate from period to period as we continue to grow.

Interest Expense and Income

Interest expense consists primarily of interest expense related to our term loan facility, including amortization of debt discount and issuance costs. Interest income is predominantly derived from investing surplus cash in money market funds and short-term marketable securities.

Other Income (Expense), Net

Other income (expense), net primarily consists of gain and loss from short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands):

	Years Ended December 31,			
	2024	2023	Change	% Change
Revenue	$ 79,906	$ 65,421	$ 14,485	22 %
Cost of goods sold	20,821	17,299	3,522	20 %
Gross profit	59,085	48,122	10,963	23 %
Operating expenses				
Research and development	23,653	20,778	2,875	14 %
Selling, general and administrative	57,103	54,518	2,585	5 %
Total operating expenses	80,756	75,296	5,460	7 %
Loss from operations	(21,671)	(27,174)	5,503	(20)%
Interest income	3,024	3,050	(26)	(1)%
Interest expense	(8,798)	(8,517)	(281)	3 %
Other income (expense), net	304	(315)	619	(197)%
Net loss	$ (27,141)	$ (32,956)	$ 5,815	(18)%

Revenue

Revenue increased by $14.5 million, or 22%, to $79.9 million during the year ended December 31, 2024, compared to $65.4 million during the year ended December 31, 2023. The increase in revenue was primarily due to an increase in the number of RNS System units sold and an increase in sales of DIXI Medical products. Revenue from sales of DIXI Medical products represented approximately 17% of our total revenue for the year ended December 31, 2024, as compared to approximately 15% for the year ended December 31, 2023. All of our revenue, with the exception of $0.2 million and less than $0.1 million for the years ended December 31, 2024 and 2023, was generated from sales in the United States.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased by $3.5 million, or 20%, to $20.8 million during the year ended December 31, 2024, compared to $17.3 million during the year ended December 31, 2023. The increase was primarily due to an increase in the number of RNS Systems sold and the costs of distributing DIXI Medical products. Our gross margin increased from 73.6% for the year ended December 31, 2023 to 73.9% for the year ended December 31, 2024 primarily due to lower fixed costs per unit as a result of increased production volume of the RNS System, partially offset by the lower gross margin from distribution of DIXI Medical products.

Research and Development Expenses

Research and development expenses increased by $2.9 million, or 14%, to $23.7 million during the year ended December 31, 2024, compared to $20.8 million during the year ended December 31, 2023. The increase in research and development expenses was primarily due to an increase of $2.4 million in personnel-related expenses, including stock-based compensation, driven by an increase in personnel during the year ended December 31, 2024, and an increase of $1.2 million in product development expenses. The increases were offset in part by an increase of $0.5 million in grant funds received primarily under the NIH funding agreement which are recognized as a reduction in research and development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $2.6 million, or 5%, to $57.1 million during the year ended December 31, 2024, compared to $54.5 million during the year ended December 31, 2023. The increase in selling, general and administrative expenses was primarily due to an increase of $2.4 million in personnel-related expenses driven by an increase in our sales and field support personnel during the year ended December 31, 2024, compared to the year ended December 31, 2023, an increase of $0.3 million in sales, field support and marketing

costs, including travel, and an increase of $0.4 million in expenses related to commercial operations. The increases were partially offset by a decrease of $0.4 million in general and administrative expenses.

Interest Expense and Income

Interest expense increased by $0.3 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, due to an increase in the average balance of our Term Loan as a result of using the PIK interest option for the payment dates from January 2023 through June 2024. Interest income decreased by less than $0.1 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to a decrease in average balances of our money market funds and short-term marketable securities, partially offset by higher interest yields in the year ended December 31, 2024.

Other Income (Expense), net

Other income (expense), net increased by 0.6 million to $0.3 million during the year ended December 31, 2024, compared to ($0.3) million during the year ended December 31, 2023, primarily due to unrealized gain, net on short-term investments in the year ended December 31, 2024.

Liquidity and Capital Resources

We have financed our operations primarily through sales of our products, issuance of equity securities and debt financing. As of December 31, 2024, we had cash, cash equivalents and short-term investments of $52.8 million and $59.5 million outstanding under the Term Loan, net of debt discount and issuance costs.

2025 Follow-on Offering

In February 2025, we received approximately $69.8 million in net proceeds after deducting underwriting discounts and commissions and offering expenses from the sale of 7,475,000 shares of our common stock, including 975,000 shares from the exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share. We used $49.5 million of the net proceeds from the offering to repurchase all of the shares held by our significant stockholder, KCK Ltd. We intend to use the remaining net proceeds from the offering for general corporate purposes, which may include clinical trial and other research and development expenses, selling, general and administrative expenses, debt reduction and working capital.

At-the-Market Equity Program

In November 2022, we entered into a Sales Agreement with Leerink Partners LLC, or Leerink, to sell shares of our common stock, from time to time, through an at-the-market, or ATM, equity offering program under which Leerink will act as our sales agent and pursuant to which we may sell common stock for aggregate gross sales proceeds of up to $50.0 million. During the year ended December 31, 2023, we received net proceeds of approximately $7.6 million from the sale of shares of common stock pursuant to our ATM offering program, after deducting sales commission and offering expenses. During the year ended December 31, 2024, we received net proceeds of approximately $3.2 million after deducting sales commissions and offering expenses. On February 20, 2025, we terminated the Sales Agreement and closed the ATM program. On the date of termination, we had $38.3 million remaining under our ATM program.

Term Loan

In September 2020, we entered into the Term Loan with CRG Partners IV L.P. and its affiliates for total borrowings of up to $60 million and borrowed $50 million. The remaining $10.0 million expired without being drawn.

The Term Loan currently bears interest at a rate of 13.5% per year. Payments under the loan are made quarterly with payment dates fixed at the end of each calendar quarter. From January 2023 through June 2025, we had the option to pay interest as follows: 8.5% per annum in cash and 5.0% per annum PIK by increasing the principal of the Term Loan. For each payment date from January 2023 through June 2024, we elected the PIK option.

The Term Loan was interest-only through its original final maturity of September 30, 2025. Following the interest-only period, principal payment would have been due in one installment on September 30, 2025. In May 2024, we amended the Term Loan to extend the final maturity by one year to September 30, 2026 and eliminate the PIK interest option after June 30, 2024. The Term Loan includes a fee upon repayment of the loan equal to 10% of the aggregate principal amount being prepaid or repaid.

The Term Loan is collateralized by substantially all of our assets. The loan agreement contains customary representations and warranties, covenants, events of default and termination provisions. The financial covenants require that we achieve minimum annual revenue thresholds and maintain a minimum balance of cash and cash equivalents. See Notes 1 and 6 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Material Cash Requirements

We have future minimum payments for the Term Loan totaling $75.0 million, with $7.7 million due within twelve months. In addition, we lease our office and manufacturing facilities in Mountain View, California under a non-cancelable operating lease which expires in June 2030. Future minimum lease payments under non-cancelable operating leases were $17.3 million as of December 31, 2024. See Note 5 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Future Funding Requirements

We expect to incur continued expenditures in the future in support of our commercialization efforts in the United States. In addition, we intend to continue to make investments in clinical studies, development of new products, and other ongoing research and development programs. We may incur additional expenses to expand our commercial organization to support our continued growth. We may incur additional expenses to further enhance our research and development efforts and to pursue commercial opportunities outside of the United States.

Based on our current planned operations, we expect that our cash, cash equivalents and short-term investments will enable us to fund our operating expenses for at least twelve months from the issuance of our financial statements as of and for the year ended December 31, 2024. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of medical devices, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the costs of activities related to commercializing and marketing our RNS System in the United States and elsewhere, and manufacturing and distribution costs;
- our revenue and costs related to the DIXI Medical distribution agreement;
- the research and development activities we intend to undertake, including product enhancements and clinical studies for indication expansions that we intend to pursue;
- the cost of obtaining, maintaining, defending, enforcing, and protecting any patents and other intellectual property rights;
- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- the degree and rate of increased market acceptance of our RNS System in the United States and market acceptance elsewhere;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and

- the emergence of competing technologies or other adverse market developments.

If we raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to, and volatility in, the financial markets in the United States and worldwide, as well as those more specifically impacting our industry. If we are unable to raise capital when needed, we will need to delay, limit, reduce or terminate planned commercialization or product development activities in order to reduce costs.

Summary Statements of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (17,949)	$ (19,701)
Investing activities	8,994	23,027
Financing activities	4,327	8,127
Net (decrease) increase in cash and cash equivalents	$ (4,628)	$ 11,453

Cash Flows Used in Operating Activities

Net cash used in operating activities was $17.9 million for the year ended December 31, 2024. Cash used in operating activities was primarily a result of the net loss of $27.1 million, adjusted for non-cash charges of $14.6 million and change in operating assets and liabilities of $5.4 million. The non-cash charges primarily consisted of $10.3 million of stock-based compensation, $1.6 million of amortization of right-of-use assets, $1.4 million of interest incurred but paid-in-kind, $1.0 million of non-cash interest expense related to our Term Loan, and $0.3 million of inventory write-downs. The change in operating assets and liabilities was due to an increase in inventories of $2.4 million largely due to an increase in work-in-process inventory and finished goods, a decrease in operating lease liabilities of $1.6 million, a decrease in accrued liabilities of $1.4 million largely due to accrued payroll and related expenses, an increase in accounts receivable of $0.5 million, and a decrease in deferred revenue of $0.5 million, offset in part by an increase in accounts payable of $0.7 million, and a decrease in prepaid expenses and other assets of $0.4 million.

Net cash used in operating activities was $19.7 million for the year ended December 31, 2023. Cash used in operating activities was primarily a result of the net loss of $33.0 million, adjusted for non-cash charges of $15.7 million and change in operating assets and liabilities of $2.5 million. The non-cash charges primarily consisted of $9.6 million of stock-based compensation, $2.7 million of interest incurred but paid-in-kind, $1.4 million of amortization of right-of-use assets, $1.1 million of non-cash interest expense related to our Term Loan, $0.3 million of amortization of debt discount and issuance costs and $0.3 million of loss from short-term investments. The change in operating assets and liabilities was due to an increase in accounts receivable of $4.9 million primarily due to an increase in sales of our products, including our RNS System and DIXI Medical products, an increase in inventories of $1.7 million largely due to an increase in raw materials and finished goods, partially offset by a reduction in work-in-process inventory, a decrease in operating lease liabilities of $1.4 million due to cash paid for rent net of the accretion of imputed interest, offset in part by a decrease in prepaid expenses and other assets of $0.4 million, an increase in accrued liabilities of $3.8 million primarily due to an increase in accrued employee bonuses and payroll related expenses, and an increase in deferred revenue of $1.1 million related to our collaboration agreement with Rapport.

Cash Flows Provided by Investing Activities

Net cash provided by investing activities was $9.0 million for the year ended December 31, 2024, which primarily consisted of sales of short-term investments of $9.3 million, partially offset by purchases of property and equipment of $0.3 million.

Net cash provided by investing activities was $23.0 million for the year ended December 31, 2023, which primarily consisted of sales of short-term investments of $23.2 million, partially offset by purchases of property and equipment of $0.2 million.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities was $4.3 million for the year ended December 31, 2024, which primarily consisted of $3.3 million of net cash proceeds from our At-the-Market offering and proceeds from the issuance of common stock under employee plans of $1.9 million, partially offset by taxes withheld and paid related to net share settlement of equity awards of $0.9 million.

Net cash provided by financing activities was $8.1 million for the year ended December 31, 2023, which primarily consisted of $7.9 million of net cash proceeds from our At-the-Market offering and proceeds from the issuance of common stock under employee plans of $0.8 million, partially offset by taxes withheld and paid related to net share settlement of equity awards of $0.3 million and payment of deferred offering costs of $0.3 million.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. For information on our significant accounting policies, see Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K. The preparation of our financial statements requires us to make estimates and assumptions that affect the amounts and disclosures in the financial statements. Our estimates are based on our historical experience, knowledge of current events and actions we may undertake in the future, and on various other factors that we believe are reasonable under the circumstances. Our most critical accounting estimates subsequent to our IPO are those affecting the provision for excess and obsolete inventories.

We regularly review inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. We write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily depends on our estimate of future demand for a particular product. If our estimate of future demand is too high, we may have to write-down excess inventory for the product and record a charge to cost of goods sold, which could have a material adverse effect on our results of operations. Inventory write-downs were $0.3 million and $0.2 million for the years ended December 31, 2024 and December 31, 2023, respectively.

JOBS Act Accounting Election

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We will cease to be an emerging growth company on the date that is the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years, or (iv) the

date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

Recent Accounting Pronouncements

See "Recent Accounting Pronouncements" in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2024, we had cash, cash equivalents and short-term investments of $52.8 million, compared to $66.5 million at December 31, 2023, consisting of interest-bearing money market funds and fixed income mutual funds for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents and short-term investments, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents and short-term investments.

We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NeuroPace, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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.

Emphasis of Matter

As disclosed in Note 6 to the financial statements, the Company has a term loan maturing in September 2026. Management's evaluation of the events and conditions related to this matter are described in Note 1.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 4, 2025

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

NeuroPace, Inc.
Balance Sheets

(in thousands, except share and per share amounts)	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 13,430	$ 18,058
Short-term investments	39,325	48,396
Accounts receivable	12,851	12,314
Inventory	13,381	11,214
Prepaid expenses and other current assets	2,352	2,737
Total current assets	81,339	92,719
Property and equipment, net	1,052	1,003
Operating lease right-of-use asset	11,843	13,405
Restricted cash	122	122
Deferred offering costs	276	387
Other assets	15	15
Total assets	$ 94,647	$ 107,651
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,954	$ 2,332
Accrued liabilities	9,787	11,180
Operating lease liability	1,860	1,627
Deferred revenue	555	1,090
Total current liabilities	15,156	16,229
Long-term debt	59,525	56,954
Operating lease liability, net of current portion	11,953	13,814
Total liabilities	86,634	86,997
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized and no shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 30,145,039 and 27,823,465 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	30	28
Additional paid-in-capital	538,933	524,435
Accumulated deficit	(530,950)	(503,809)
Total stockholders' equity	8,013	20,654
Total liabilities and stockholders' equity	$ 94,647	$ 107,651

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

NeuroPace, Inc.
Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)	Year Ended December 31, 2024	2023
Revenue	$ 79,906	$ 65,421
Cost of goods sold	20,821	17,299
Gross profit	59,085	48,122
Operating expenses		
Research and development	23,653	20,778
Selling, general and administrative	57,103	54,518
Total operating expenses	80,756	75,296
Loss from operations	(21,671)	(27,174)
Interest income	3,024	3,050
Interest expense	(8,798)	(8,517)
Other income (expense), net	304	(315)
Net loss and comprehensive loss	$ (27,141)	$ (32,956)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.93)	$ (1.27)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	29,126,314	25,851,813

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

NeuroPace, Inc.
Statements of Stockholders' Equity

(in thousands, except share amounts)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at January 1, 2023	25,045,751	$ 25	$ 506,713	$ (1,108)	$ (470,853)	$ 34,777
Net loss	—	—	—	—	(32,956)	(32,956)
Unrealized loss adjustment for short-term investment	—	—	—	1,108	—	1,108
Issuance of common stock pursuant to stock option exercises	889,968	1	148	—	—	149
Issuance of common stock pursuant to Employee Stock Purchase Plan	280,599	—	654	—	—	654
Issuance of common stock as part of At-the-Market offering, net of sales commission and offering expenses of $509	933,500	1	7,621	—	—	7,622
Issuance of common stock upon vesting of restricted stock units	728,986	1	(1)	—	—	—
Shares withheld for taxes	(53,999)	—	(259)	—	—	(259)
Repurchase of common stock	(1,340)	—	—	—	—	—
Change in early exercise liability	—	—	1	—	—	1
Stock-based compensation	—	—	9,558	—	—	9,558
Balances at December 31, 2023	27,823,465	28	524,435	—	(503,809)	20,654
Net loss	—	—	—	—	(27,141)	(27,141)
Issuance of common stock pursuant to stock option exercises	556,718	1	809	—	—	810
Issuance of common stock pursuant to Employee Stock Purchase Plan	202,616	—	1,121	—	—	1,121
Issuance of common stock as part of At-the-Market offering, net of sales commission and offering expenses of $212	444,555	—	3,167	—	—	3,167
Issuance of common stock upon vesting of restricted stock units	1,184,284	1	(1)	—	—	—
Shares withheld for taxes	(65,317)	—	(881)	—	—	(881)
Repurchase of common stock	(1,282)	—	—	—	—	—
Change in early exercise liability	—	—	1	—	—	1
Stock-based compensation	—	—	10,282	—	—	10,282
Balances at December 31, 2024	30,145,039	$ 30	$ 538,933	$ —	$ (530,950)	$ 8,013

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

NeuroPace, Inc.
Statements of Cash Flows

(in thousands)	Year Ended December 31, 2024	2023
Cash flows from operating activities		
Net loss	$ (27,141)	$ (32,956)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	10,282	9,558
Depreciation	207	172
Amortization of debt discount and issuance costs	228	283
Non-cash interest expense	954	1,075
PIK interest incurred but not paid on term loan	1,389	2,683
Amortization of right-of-use asset	1,562	1,433
(Gain) loss on short-term investments	(229)	315
Inventory write-downs	251	196
Other	1	24
Changes in operating assets and liabilities		
Accounts receivable	(537)	(4,850)
Inventory	(2,418)	(1,698)
Prepaid expenses and other assets	384	381
Accounts payable	671	240
Accrued liabilities	(1,392)	3,768
Deferred revenue	(534)	1,090
Operating lease liabilities	(1,627)	(1,415)
Net cash used in operating activities	(17,949)	(19,701)
Cash flows from investing activities		
Acquisition of property and equipment	(306)	(173)
Proceeds from sale of short-term investments	9,300	23,200
Net cash provided by investing activities	8,994	23,027
Cash flows from financing activities		
Proceeds from issuance of common stock under employee plans	1,931	803
Taxes withheld and paid related to net share settlement of equity awards	(881)	(259)
Proceeds from At-the-Market offering, net of sales commission	3,277	7,888
Payment of deferred offering costs	—	(305)
Net cash provided by financing activities	4,327	8,127
Net (decrease) increase in cash and cash equivalents	(4,628)	11,453
Cash, cash equivalents and restricted cash		
Beginning of year	18,180	6,727
End of year	$ 13,552	$ 18,180
Reconciliation of cash, cash equivalents and restricted cash to balance sheets:		
Cash and cash equivalents	$ 13,430	$ 18,058
Restricted cash	122	122
Total cash, cash equivalents and restricted cash	$ 13,552	$ 18,180
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 6,226	$ 4,476
Supplemental disclosures of non-cash investing and financing information:		

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

Net change in accrued liabilities from early exercise of options	$	(1)	$	(1)
Purchase of property and equipment included in accounts payable	$	19	$	69
Deferred offering costs offset against additional paid-in capital	$	110	$	265

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

1. The Company

NeuroPace, Inc., or the Company, was incorporated in the state of Delaware on November 19, 1997. The Company is a medical device company that has developed the RNS System, the only commercially available brain-responsive neuromodulation system designed for treating drug-resistant focal epilepsy by delivering personalized, real-time treatment at the seizure source. The Company began commercializing its products in the United States in 2014.

At-the-Market Equity Offering

In November 2022, the Company filed a Registration Statement on Form S-3, or Shelf, with the Securities and Exchange Commission, or the SEC, in relation to the registration of common stock, preferred stock, debt securities, warrants or any combination thereof for up to an aggregate of $150.0 million, of which $50.0 million may be issued and sold pursuant to an at-the-market, or ATM, offering program for sales of the Company's common stock under a sales agreement, or Sales Agreement, with Leerink Partners LLC, or Leerink (formerly SVB Securities LLC). The Company agreed to pay Leerink up to 3.0% of the gross proceeds of sales of common stock made through the Sales Agreement. The Company's common stock would be sold at prevailing market prices at the time of the sale and, as a result, prices may vary. During the year ended December 31, 2023, the Company sold 933,500 shares of common stock under the Sales Agreement for gross proceeds of $8.1 million, or $7.6 million after deducting sales commissions and offering expenses. During the year ended December 31, 2024, the Company sold 444,555 shares of common stock under the Sales Agreement for gross proceeds of $3.4 million, or $3.2 million after deducting sales commissions and offering expenses. As of December 31, 2024, the Company has $38.5 million remaining under its ATM program. Refer to Note 12 for information on the termination of the ATM program in February 2025.

Liquidity and Capital Resources

The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of $531.0 million as of December 31, 2024. For the years ended December 31, 2024 and 2023, the Company used $17.9 million and $19.7 million, respectively, of cash in its operating activities. As of December 31, 2024, the Company had cash, cash equivalents and short-term investments of $52.8 million. Historically, the Company has funded its operations principally through the sales of its products, issuance of equity securities and debt financing.

The Company's financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company's cash, cash equivalents and short-term investments will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these financial statements.

In connection with the Term Loan described in Note 6, the Company will need to be in compliance with a minimum annual net revenue covenant determined in accordance with generally accepted accounting principles of $70.0 million in each of the years ending December 31, 2024 and December 31, 2025 and maintain a minimum cash and cash equivalents balance of $5.0 million. If the Company cannot generate sufficient revenue in the future, the Company may not be in compliance with the annual net revenue covenant and the lender may call the debt resulting in the Company immediately needing additional capital, and resulting in a going concern. The Company's ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to, and volatility in, the financial markets in the United States and worldwide. If the Company is unable to raise capital when needed, it will need to delay, limit, reduce or terminate planned commercialization or product development activities in order to reduce costs. As of December 31, 2024, the Company was in compliance with all covenants of the Term Loan.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP, as defined by the Financial Accounting Standards Board, or the FASB.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. The Company uses significant judgment when making estimates related to the provision for excess and obsolete inventories. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Revenue Recognition

The Company derives most of its revenue from sales of RNS Systems to hospital facilities (typically comprehensive epilepsy centers, or Level 4 CECs) that implant its products. Beginning in the fourth quarter of 2022, the Company also derives revenue from sales of DIXI Medical products, primarily to its current customer base. Beginning in the fourth quarter of 2023, the Company also derives revenue from services provided to Rapport Therapeutics, Inc., or Rapport.

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price;

iv. allocate the transaction price to the performance obligations in the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, the Company assesses the products or services promised within each contract and determines those that are performance obligations. The Company's contracts with customers for the RNS System often include a promise to transfer products, as well as an implied promise to provide a service to the customer, which is access to the Company's Patient Data Management System, or PDMS, and nSight Platform. The Company has concluded that the RNS System and its related products represent a single performance obligation, as the customer cannot benefit from the products individually, and that access to the PDMS and nSight Platform represent separate performance obligations, as the clinicians can utilize them with other components of the RNS System that are readily available.

The Company determines the transaction price based on the amount it expects to be entitled to in exchange for transferring the promised product or service to the customer, which is based on the invoiced price for the products or services. All prices are at fixed amounts per the sales agreement with the customer and there are no discounts, rebates or other price concessions.

When a contract contains multiple performance obligations, the Company allocates the transaction price to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells its products or services. If a standalone selling price is not directly observable, the Company estimates the standalone selling price considering market data, cost, gross margin, and other available information.

The Company typically delivers its RNS System and related products to a hospital on the date of the scheduled procedure. There is no commitment or contract until the delivery of the product and the procedure may be canceled

at any time. Once the device has been implanted in or otherwise provided to a patient, the customer is considered to have accepted the delivery (i.e., has approved the contract) and both parties are committed to perform their respective obligations. Assuming all other revenue recognition criteria are met, the Company recognizes revenue from the sale of its RNS System and related products at a point in time when the procedure is completed and the device is implanted in a patient.

The Company also ships the RNS System and related products to customers who place orders ahead of scheduled procedures. Such orders or contracts generally include a promise to transfer products only. As such, the Company recognizes revenue from these orders or contracts at a point in time when the customer obtains control of the products.

The Company recognizes service revenue related to the PDMS and the nSight Platform on a ratable basis over the period in which the Company expects to provide access to clinicians. The Company has concluded that such service revenue is immaterial.

The Company's contracts with customers for DIXI Medical products generally include a promise to transfer products only. As such, the Company recognizes revenue from the sale of DIXI Medical products at a point in time when the customer obtains control of the products.

The Company recognizes revenue under its contract with Rapport to provide biomarker monitoring and data analysis services. Revenue from biomarker monitoring is recognized ratably over the two-year contractual support period, as the benefits provided by the Company's performance are simultaneously consumed by the customer. Revenue related to data analysis is recognized upon completion of the services. The Company's contract with Rapport commenced during the fourth quarter of 2023. The related revenue recognized for the years ended December 31, 2024 and 2023 were $1.2 million and $0.4 million, respectively.

The Company recognizes revenue for arrangements where it has satisfied its performance obligations but has not issued invoices. These amounts are recorded as unbilled receivables, which are included in accounts receivable on the balance sheet, as the Company has an unconditional right to payment at the end of the applicable period.

Payment terms are typically 30 days from the fulfillment of the orders and fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. Sales taxes that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales, however, most of the Company's sales are tax exempt. The Company believes that collection is probable as it has no history of uncollectible accounts and the customers are large, creditworthy institutions.

As allowed under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. Costs associated with product sales include commissions, where the Company applies the practical expedient and recognizes commissions as expense when incurred because the expense is incurred over a period of time of less than one year. Commissions are reported in selling, general and administrative expense in the statements of operations and comprehensive loss.

The Company's contract balances were accounts receivable of $12.9 million and $12.3 million as of December 31, 2024, and December 31, 2023, respectively.

The Company's contract liabilities consist of deferred revenue of $0.6 million and $1.1 million as of December 31, 2024 and 2023, respectively. The Company's deferred revenue balance was $0.6 million as of December 31, 2024, which is expected to be recognized as revenue in 2025. Revenue recognized during the year ended December 31, 2024 that was included in the deferred revenue balance at the beginning of the year was $1.1 million.

As of December 31, 2024, the aggregate amount of the transaction price allocated to the remaining performance obligations that are unsatisfied or partially unsatisfied was $1.7 million, which the Company expects to recognize as revenue by December 2025.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value because of the short-term nature of these instruments. The Company has a short-term investment in a fixed income mutual fund, which is classified as equity security and carried at fair value based on quoted market prices. Changes in the fair value of the short-term investment are recorded in income or loss. The Company believes that its borrowings bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value. The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three levels of inputs that may be used to measure fair value (see Note 3).

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents that are available-for-sale investments are recorded at fair value, based on quoted market prices. As of December 31, 2024 and December 31, 2023, the Company's cash equivalents are entirely comprised of investments in money market funds.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash for the years ended December 31, 2024 and December 31, 2023 consists of collateral for the amended letter of credit that was issued in connection with the Company's facility lease (see Note 5).

Concentration of Credit Risk, and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, short-term investments and accounts receivable to the extent of the amounts recorded on the balance sheets. The Company's cash is invested in major financial institutions in the United States. Deposits in these financial institutions may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default of the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation. The Company's cash equivalents are invested in money market funds.

The Company's accounts receivable, with the exception of $0.1 million, are due from a variety of health care organizations in the United States. For the years ended December 31, 2024 and December 31, 2023, there were no customers that represented 10% or more of revenue. As of December 31, 2024 and December 31, 2023, no customer represented 10% or more of the Company's accounts receivable.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company makes estimates on the collectability of customer accounts based primarily on analysis of historical trends and experience, the age of the receivable and changes in customers' financial condition. The Company uses its judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. The Company determined that no allowance was required as of December 31, 2024 and December 31, 2023. To date, the Company has not experienced any material credit-related losses.

Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. The Company's policy is to

write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of goods sold. Inventory write-downs were $0.3 million and $0.2 million for the years ended December 31, 2024 and December 31, 2023, respectively.

Property and Equipment, net

Property and equipment, net is stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet, and any resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition are less than their carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived assets exceeds their fair value. The Company did not record any impairment of long-lived assets for the years ended December 31, 2024 and December 31, 2023.

Leases

The Company determines if an arrangement is a lease, or contains a lease, at inception. Operating leases are included in operating lease right-of-use, or ROU, assets, operating lease liability, and operating lease liability, net of current portion on the Company's balance sheets.

ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Since the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment at commencement date in determining the present value of future payments. The ROU asset also includes any lease payments made to the lessor at or before the commencement date, minus lease incentives received, and initial direct costs incurred. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company elected certain practical expedients under ASC 842, *Leases*, including the package of practical expedients, which among other things, allowed the Company to carry forward prior conclusions about lease identification and classification, as well as elections to not record leases with an initial term of twelve months or less on the balance sheet, and to combine the lease and non-lease components in determining the lease liabilities and ROU assets.

Deferred Offering Costs

The Company capitalizes, within other assets, certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including its ATM offering, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs are immediately written off to operating expenses. Upon issuing shares under the ATM offering during the years ended December 31, 2024 and 2023, $0.1 million and $0.3 million, respectively, of deferred offering costs were recorded against the proceeds from the ATM offering and recorded in stockholders

equity as a reduction of additional paid-in capital. As of December 31, 2024 and 2023, $0.3 million and $0.4 million of deferred offering costs related to the ATM offering were recorded on the balance sheets, respectively.

Government Programs

In May 2021, the Company was awarded a grant by the National Institutes of Health, or NIH, to support research of thalamocortical responsive neurostimulation for the treatment of Lennox-Gastaut Syndrome, a type of epilepsy. The award was issued for a five-year period and has a total budget of over $9.3 million, which includes approximately $5.5 million in funding for subawards to third-party academic epilepsy centers that are collaborating on the study and are subinvestigators on the study funded by NIH. The subawardees are determined by NIH. The Company's responsibility for the subawards is to submit the funding requests on behalf of the subawardees. The funding of subawards does not have any impact on the Company's financial statements. Initially funding was approved for the first year beginning June 1, 2021 and provides for reimbursement of qualified direct and indirect expenses in the amount of $0.8 million, including $0.4 million for subawards. Approvals of funds for years two through five are subject to the completion of certain milestones. On July 30, 2022, the Company received funding approval for year two in the amount of $2.6 million, which includes $1.6 million for subawards. On May 25, 2023, the Company received funding approval for year three in the amount of $3.0 million, which includes $1.5 million for subawards. On July 22, 2024, the Company received funding approval for year four in the amount of $1.7 million, which includes $1.0 million for subawards.

For funds received under the NIH funding agreement, the Company recognizes a reduction in research and development expenses in an amount equal to the qualifying expenses incurred in each period up to the amount awarded by the NIH. The Company received $1.7 million and $1.4 million in funding during the years ended December 31, 2024 and 2023, respectively. Through December 31, 2024, $3.8 million of qualifying expenses have been incurred and funded by the NIH related to the first to fourth year of funding.

Qualifying expenses incurred by the Company in advance of funding by the NIH are recorded within prepaid expenses and other current assets on the balance sheets. As of December 31, 2024, the Company recorded prepaid expenses and other current assets of less than $0.1 million related to the fourth year of funding.

Warranty

Warranty costs are accrued based on the Company's best estimates when management determines that it is probable a charge or liability has been incurred and the amount of loss can be reasonably estimated. While the Company believes that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates. The warranty liability as of December 31, 2024 and December 31, 2023 was immaterial.

Cost of Goods Sold

The Company manufactures its products at its facility. Cost of goods sold consists primarily of costs related to materials, components and subassemblies, manufacturing overhead, direct labor, and reserves for excess and obsolete inventories. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of facilities, material procurement, inventory control, quality assurance, equipment and operating supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs. Shipping and handling costs are considered a fulfillment activity and are included in cost of goods sold as incurred.

Research and Development Expenditures

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of engineering, product development, clinical studies to develop and support the Company's products, regulatory expenses, medical affairs and other costs associated with products and technologies that are in development, including quality assurance. Research and development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, research and development expenses

include costs associated with clinical studies including clinical trial design, clinical site reimbursement, data management, travel expenses, the cost of products used for clinical trials and costs associated with regulatory compliance and submitting and maintaining regulatory filings.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs include design and production costs, including website development, physician and patient testimonial videos, written media campaigns, and other items. Advertising costs of $0.7 million and $0.7 million were expensed during the years ended December 31, 2024 and December 31, 2023, respectively.

Stock-Based Compensation

The Company accounts for stock-based employee compensation in accordance with ASC 718, *Stock Compensation*. ASC 718 requires the measurement of compensation based on the grant date fair value of the stock option or restricted stock unit (see Note 8). The Company amortizes the fair value of each award on a straight-line basis over the requisite service period of the award.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, common stock subject to repurchase related to early exercise of stock options, and restricted stock units are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of the shares issued upon early exercise of stock options subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In accordance with Accounting Standards Codification, or ASC, 280, *Segment Reporting*, the Company operates as one operating and reportable segment. In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amended guidance requires all public entities, including public entities with a single reportable segment, to disclose in interim and annual periods significant segment expenses that are regularly provided to the chief operating decision maker, or CODM, to allocate resources and assess performance, as well as the aggregate amount of other segment items included in the reported measure of segment profit or loss. The Company adopted this ASU effective for the fiscal year ended December 31, 2024 on a retrospective basis. Refer to Note 11 for further information on the Company's reportable segment.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. This ASU requires greater disaggregation of information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. This ASU applies to all entities subject to income taxes and is intended to help investors better understand an entity's exposure to potential changes in jurisdictional tax legislation and assess income tax information that affects cash flow forecasts and capital allocation decisions. This ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted, and should be applied on a prospective basis although retrospective application is permitted. The Company is currently evaluating the impact this standard will have on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*. This ASU is intended to provide more detailed information about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. This ASU may be applied either prospectively to financial statements issued for reporting periods after its effective date or retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the impact this standard will have on its financial statement disclosures.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

The following table summarizes the Company's financial assets (cash equivalents and marketable securities) at fair value as of December 31, 2024 (in thousands):

	Fair Value as of December 31, 2024	Basis for Fair Value Measurements		
		(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 13,349	$ 13,349	$ —	$ —
Fixed income mutual funds, included in short-term investments	39,325	39,325	—	—
Total	$ 52,674	$ 52,674	$ —	$ —

The following table summarizes the Company's financial assets (cash equivalents and marketable securities) at fair value as of December 31, 2023 (in thousands):

	Fair Value as of December 31, 2023	Basis for Fair Value Measurements		
		(Level 1)	(Level 2)	(Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 16,125	$ 16,125	$ —	$ —
Fixed income mutual funds, included in short-term investments	48,396	48,396	—	—
Total	$ 64,521	$ 64,521	$ —	$ —

There were no liabilities measured at fair value on a recurring and non-recurring basis as of December 31, 2024 and December 31, 2023.

The money market funds are highly liquid and primarily invest in short-term fixed income securities issued by the U.S. government and U.S. government agencies.

The Company's available-for-sale investment comprises a short-term investment in a fixed income mutual fund, which primarily invests in debt securities issued by the U.S. government and U.S. government agencies and corporate bonds and notes. Interest income from short-term investment is recorded in interest income. During the years ended December 31, 2024 and 2023, the Company recognized $0.2 million and $1.0 million in unrealized gains from its short-term investment, respectively. As of December 31, 2024, the Company's short-term investment had a cumulative unrealized net gain of $0.1 million. As of December 31, 2023, the Company's short-term investment had a cumulative unrealized net loss of $0.1 million, which included an adjustment of $1.1 million unrealized loss recorded in other income (expense), net in the year ended December 31, 2023. The adjustment was not material to any previously issued financial statements.

4. Balance Sheet Components

Inventory

Inventories consist of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 4,248	$ 4,090
Work-in-process	1,778	627
Finished goods	7,355	6,497
Total	$ 13,381	$ 11,214

Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2024	2023
Machinery, equipment, furniture and fixtures	$ 4,659	$ 4,522
Computer equipment and software	1,932	1,822
Leasehold improvements	2,435	2,426
	9,026	8,770
Less: Accumulated depreciation	(7,974)	(7,767)
Property and equipment, net	$ 1,052	$ 1,003

Depreciation expense for the years ended December 31, 2024 and December 31, 2023 was $0.2 million and $0.2 million, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Payroll and related expenses	$ 8,178	$ 9,655
Inventory purchases	575	588
Professional fees	50	30
Other	984	907
	$ 9,787	$ 11,180

5. Commitments and Contingencies

Facility Lease

In August 2011, the Company entered into a non-cancelable operating lease for combined office and manufacturing facilities in Mountain View, California. The lease was scheduled to expire in April 2019 and was amended in May 2018 to extend it through June 2024. In August 2022, the Company amended the lease to extend it through June 2030. The second amendment contained a rent-free period from September 2022 through December 2022. The Company has an option to extend the lease for a period of five years, commencing on July 1, 2030 and expiring on June 30, 2035. In conjunction with the original lease agreement, the Company obtained a letter of credit for $0.9 million in lieu of a security deposit. In May 2019, the letter of credit was amended and reduced to $0.7 million. In June 2021, the letter of credit was amended and further reduced to $0.2 million.

The terms of the facility lease provide for rental payments on a graduated scale; however, rent expense is recognized on a straight-line basis over the lease term. Rental payments range from $2.8 million to $3.3 million per year over the extended term of the lease.

The maturities of operating lease liabilities as of December 31, 2024 are as follows (in thousands):

2025	$ 2,942
2026	3,031
2027	3,122
2028	3,215
2029	3,312
Thereafter	1,704
Total undiscounted lease payments	17,326
Less: imputed interest	3,513
Total operating lease liability	13,813
Less: current portion	1,860
Operating lease liability, net of current portion	$ 11,953

Operating lease cost was $2.8 million and $2.8 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the remaining term for the operating lease in Mountain View, California was 5.5 years, and the discount rate used to measure the lease liability for such operating lease upon recognition was 8.5%.

During the years ended December 31, 2024 and 2023, cash paid for amounts included in operating lease liabilities of $2.9 million and $2.8 million, respectively, was included in cash flows from operating activities on the statements of cash flows.

Distribution Agreement

In August 2022, the Company entered into an exclusive distribution agreement, or the Distribution Agreement, with DIXI Medical USA Corp, or DIXI Medical, pursuant to which the Company became the exclusive U.S. distributor of DIXI Medical's stereo electroencephalography product line. The Distribution Agreement has an initial term of three years, which expires September 30, 2025. The Distribution Agreement automatically renews for additional one-year terms, unless either party provides written notice to the other party of its intention to not renew at least 180 days prior to the expiration of the then-current term. The current Distribution Agreement will automatically renew unless either party provides notice of intent not to renew by April 3, 2025.

To maintain the distribution rights, the Company is required to purchase a minimum of $2.4 million of DIXI Medical's products during the twelve months beginning October 2022, and to increase the minimum purchase by 10% for each of the two subsequent years. The Company met the purchase commitment for the first two years and expects to meet the purchase commitment for the third year, which is through September 2025.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. The Company may, from time to time, be subject to claims or be required to defend actions related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director or officer is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as the director or officer may be subject to any proceeding arising out of acts or omissions of

such individual in such capacity. The maximum amount of potential future indemnification is unlimited. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2024 and December 31, 2023.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company determined that no accrual related to contingencies was required as of December 31, 2024 and December 31, 2023.

Legal Proceedings

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its business, results of operations, financial condition, or cash flows. From time to time, the Company may pursue litigation to assert its legal rights and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business. The Company regularly evaluates current information to determine whether any accruals should be adjusted and whether new accruals are required. Such accruals, if any, reflect the estimable and probable costs that the Company may incur from the outcomes of its legal proceedings. Legal costs are expensed as incurred. There were no contingent liabilities requiring accrual as of December 31, 2024 and 2023.

6. Debt

Term Loan

In September 2020, the Company entered into a Term Loan Agreement with CRG Partners IV L.P. and its affiliates for total borrowings of up to $60.0 million, or the Term Loan, and borrowed $50.0 million. The remaining $10.0 million of the Term Loan was available to the Company for borrowing until March 31, 2022 if the Company achieved a revenue-based milestone in 2021. The revenue-based milestone was not achieved, and the remaining $10.0 million of the Term Loan expired without being drawn.

The Term Loan initially bore interest at a rate of 12.5% per year. In February 2023, the Term Loan was amended which increased the annual interest rate from 12.5% to 13.5% effective March 1, 2023. The amendment was accounted for as a debt modification in accordance with ASC 470, *Debt* and the Term Loan's effective interest rate increased from 15.7% to 16.8%. Payments under the Term Loan are made quarterly with payment dates fixed at the end of each calendar quarter. Through December 2020, the Company had the option to pay the entire interest paid-in-kind, or PIK, by increasing the principal of the Term Loan. From January 2021 through December 2022, the Company had the option to pay interest as follows: 7.5% per annum paid in cash and 5.0% per annum PIK by increasing the principal of the Term Loan. From January 2023 through June 2025, the Company had the option to pay interest as follows: 8.5% per annum paid in cash and 5.0% per annum PIK by increasing the principal of the Term Loan. For each payment date from April 2022 through June 2024, the Company elected the PIK option, increasing the principal of the Term Loan by $6.0 million.

The Term Loan was interest-only through September 2023, which could be extended through September 2025 at the Company's option if the Company completed its initial public offering, or IPO, on or prior to September 30, 2023. In connection with closing the IPO in April 2021, the Company extended the interest-only period to September 30, 2025. Following the interest-only period, principal payment was to be due in one installment on September 30, 2025. In May 2024, the Term Loan was amended to extend the final maturity by one year to September 30, 2026 and eliminate the PIK interest option after June 30, 2024. The amendment was accounted for as a troubled debt restructuring in accordance with ASC 470 and no gain or loss was recognized. The Term Loan includes a fee upon repayment of the loan equal to 10% of the aggregate principal amount being prepaid or repaid, or the backend fee. As of December 31, 2024, the Term Loan had an annual effective interest rate of 15.5% per year.

The Term Loan is collateralized by substantially all of the Company's assets. The Term Loan Agreement contains customary representations and warranties, covenants, events of default and termination provisions. The

financial covenants require that the Company achieve minimum annual revenue thresholds commencing in 2021 and maintain a minimum balance of cash and cash equivalents (see Note 1). In February 2023, the Term Loan was amended to reduce the minimum annual net revenue covenant to $45.0 million for the year ended December 31, 2023.

The Company paid $1.0 million in fees to the lender and third parties which is reflected as a discount on the loan and is being accreted over the life of the loan using the effective interest method. Also, the Company issued warrants to the lender for a total of 346,823 shares of Series B' redeemable convertible preferred stock. The warrants had a fair value of $0.6 million as of the issuance date, which was accounted for as debt issuance costs.

During the years ended December 31, 2024 and December 31, 2023, the Company recorded interest expense related to debt discount and debt issuance costs of the Term Loan of $0.2 million and $0.3 million, respectively.

Interest expense on the Term Loan was $8.8 million and $8.5 million during the years ended December 31, 2024 and December 31, 2023, respectively.

As of December 31, 2024, future minimum payments for the Term Loan are as follows (in thousands):

	Term Loan
2025	$ 7,666
2026	67,341
Total	75,007
Less: Unamortized debt discount and issuance cost	(392)
Less: Unaccreted backend fee	(1,690)
Less: Interest	(13,400)
Term Loan	$ 59,525

7. Common Stock

The Company's Amended and Restated Certificate of Incorporation authorizes the Company to issue 200,000,000 shares of $0.001 par value common stock.

The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors. As of December 31, 2024 and December 31, 2023, no dividends had been declared.

As of December 31, 2024 and December 31, 2023, the Company had reserved common stock for future issuance as follows:

	Year Ended December 31,	
	2024	2023
Outstanding options under the 2021 Plan	1,987,784	2,208,341
Shares available for future grant under the 2021 Plan	2,201,012	1,314,502
Outstanding options under the 2023 Inducement Plan	380,424	380,424
Outstanding restricted stock units under the 2021 Plan	1,480,338	2,430,803
Common stock available for ESPP	475,416	399,798
Total	6,524,974	6,733,868

8. Stock Plans

2020 Stock Plan

In August 2020, the Company adopted the 2020 Stock Plan, or the 2020 Plan, which provides for the granting of stock options to employees, directors and consultants of the Company. Stock options granted under the 2020 Plan may be either incentive stock options, or ISOs, nonqualified stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards or other stock awards. ISOs may only be granted to Company employees (including officers and directors who are also employees). Stock awards other than ISOs may be granted to company employees, directors and consultants.

The maximum term of each stock option grant is ten years. The exercise price of ISOs and NSOs granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant as determined by the Company's board of directors.

2021 Equity Incentive Plan

In April 2021, prior to the IPO closing, the Company's board of directors and stockholders approved the 2021 Equity Incentive Plan, or the 2021 Plan, which became effective upon the IPO closing. The Company initially reserved 2,900,000 shares of common stock for issuance of share-based compensation awards, including ISOs, NSOs, stock appreciation rights, restricted stock units and other stock-based awards. ISOs may be granted only to Company employees (including officers and directors who are also employees). Shares of common stock subject to awards granted under the 2020 Plan that are forfeited or lapse unexercised will be available for issuance under the 2021 Plan. Once the 2021 Plan became effective, no further grants were made under the 2020 Plan.

Options under the 2021 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of the Company's common stock on the date of grant; provided, however, that the exercise price of an ISO granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. Vesting conditions determined by the plan administrator may apply to stock options and other stock-based awards and may include continued service, performance and/or other conditions. Generally, options and restricted stock units vest over a three or four-year period.

In January 2025, the number of shares of common stock available for issuance under the 2021 Plan was increased by 1,507,251 shares as a result of the automatic increase provision in the 2021 Plan.

A summary of shares available for grant under the 2021 Plan is as follows:

	Shares Available for Grant
Shares available for grant as of January 1, 2023	1,443,946
Authorized	1,252,287
Granted/Awarded	(2,758,399)
Canceled	1,322,669
Withheld for taxes	53,999
Shares available for grant as of December 31, 2023	1,314,502
Authorized	1,391,173
Granted/Awarded	(1,157,793)
Canceled	587,813
Withheld for taxes	65,317
Shares available for grant as of December 31, 2024	2,201,012

2023 Inducement Plan

In July 2023, the Company's Compensation Committee of the Board of Directors approved the 2023 Inducement Plan, or the Inducement Plan. The terms of the Inducement Plan are similar to the terms of the 2021 Plan with the exception that incentive stock options may not be issued under the Inducement Plan and awards under the Inducement Plan may only be issued to eligible recipients under the applicable Nasdaq rules. The Inducement Plan was adopted by the Compensation Committee without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. The Company has initially reserved 380,424 shares of its common stock for issuance pursuant to awards granted under the Inducement Plan, and granted an option to purchase 380,424 shares of its common stock to its Chief Executive Officer, or CEO, as a material inducement for the CEO to join the Company.

A summary of stock option activity for the years ended December 31, 2024 and 2023 is set forth below:

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)
Balances as of January 1, 2023	3,446,583	$ 3.61	8.06
Granted	695,225	$ 3.85	
Exercised	(889,968)	$ 0.17	
Canceled	(663,075)	$ 5.00	
Balances as of December 31, 2023	2,588,765	$ 4.51	7.17
Granted	510,654	$ 12.04	
Exercised	(556,718)	$ 1.45	
Canceled	(174,493)	$ 15.89	
Balances as of December 31, 2024	2,368,208	$ 6.01	7.27
Vested and exercisable at December 31, 2024	1,568,345	$ 4.51	6.49
Vested and expected to vest at December 31, 2024	2,368,208	$ 6.01	7.27

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at period end. The total intrinsic value of stock options exercised was $6.0 million and $5.3 million during the years ended December 31, 2024 and December 31, 2023, respectively, determined at the date of each stock option exercise.

Early Exercise of Stock Options

The terms of the Company's 2020 Plan and 2021 Plan permit the exercise of options granted under the plans prior to vesting, subject to required approvals. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest over the original implied service period. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options in accrued liabilities on the accompanying balance sheet and will be transferred into common stock and additional paid-in capital as the shares vest. As of December 31, 2024 and December 31, 2023 there were 0 and 30,211 shares of common stock, respectively, issued pursuant to early exercised options and subject to repurchase.

Employee Stock Purchase Plan

In April 2021, the Company adopted the 2021 Employee Stock Purchase Plan, or ESPP. The Company allows eligible employees to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each offering period, which is typically six months. There were 580,000 shares of common stock initially reserved for issuance

under the ESPP. In January 2025, the number of shares of common stock available for issuance under the ESPP was increased by 301,450 shares as a result of the automatic increase provision in the ESPP.

The Company issued 202,616 and 280,599 shares under the ESPP for the years ended December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024, 475,416 shares under the ESPP remain available for purchase. The offering period and purchase period is determined by the board of directors. A new offering period of six months has been authorized beginning December 7, 2024 through June 6, 2025.

Compensation expense is calculated using the fair value of the employees' purchase rights under the Black-Scholes model, which was estimated using the following assumptions:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	0.5	0.5
Expected volatility	76% - 78%	63% - 90%
Weighted average risk-free interest rate	4.34% - 5.40%	5.36% - 5.43%
Fair value of common stock	$6.47 - $10.95	$4.20 - $8.49
Dividend yield	—%	—%

Restricted Stock Units

Activity with respect to restricted stock units, or RSUs, was as follows:

	Number of Shares Underlying Outstanding Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested, January 1, 2023	1,756,209	$ 10.15
Granted	2,063,174	$ 4.77
Vested	(728,986)	$ 9.76
Canceled	(659,594)	$ 7.14
Unvested, December 31, 2023	2,430,803	$ 6.52
Granted	647,139	$ 13.00
Vested	(1,184,284)	$ 6.65
Canceled	(413,320)	$ 7.68
Unvested, December 31, 2024	1,480,338	$ 8.92

The fair value of RSUs is based on the Company’s closing stock price on the date of grant.

Stock-Based Compensation

The Company recognized stock-based compensation as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Cost of goods sold	$ 723	$ 606
Research and development	3,270	2,749
Selling, general and administrative	6,289	6,203
Total stock-based compensation	$ 10,282	$ 9,558

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	Year Ended December 31,	
	2024	2023
Stock options and restricted stock units	$ 9,745	$ 9,271
ESPP	537	287
Total stock-based compensation	$ 10,282	$ 9,558

As of December 31, 2024, the total unrecognized stock-based compensation expense related to unvested stock options and restricted stock units was $15.0 million, which will be amortized on a straight-line basis over a weighted average remaining period of 2.1 years.

As of December 31, 2024, the Company had unrecognized stock-based compensation expense relating to the ESPP awards of approximately $0.2 million, which is expected to be recognized over a weighted-average period of 0.4 years.

The total fair value of options that vested during the years ended December 31, 2024 and December 31, 2023 was $8.8 million and $7.8 million, respectively. The options granted during the years ended December 31, 2024 and December 31, 2023 had a weighted average grant date fair value of $8.13 per share and $3.85 per share, respectively.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following assumptions for the years ended December 31, 2024 and December 31, 2023:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	5.27 - 6.25	5.27 - 6.25
Expected volatility	71% - 78%	60% - 63%
Weighted average risk-free interest rate	3.62% - 4.64%	3.74% - 3.94%
Fair value of common stock	$6.00 - $17.11	$1.54 - $4.50
Dividend yield	—%	—%

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company does not have sufficient historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term of options and has opted to use the “simplified method,” whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected stock price volatility assumption was determined by a combination of the Company’s historical stock trading volatility and the historical volatilities of industry peers, as the Company does not have sufficient trading history to solely rely on the volatility of its common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company’s common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company’s stock options. The expected dividend assumption is based on the Company’s history and expectation of not to declare and pay dividends.

The fair value of the Company’s common stock is determined based on its closing market price on the date of grant.

The Company accounts for forfeitures as they occur.

9. Income Taxes

The Company’s operations and income tax components are solely in the United States. From inception through 2024, the Company has only generated pretax losses in the United States and has not generated any pretax income or

loss outside of the United States. The Company did not record a provision (benefit) for income taxes for the years ended December 31, 2024 and 2023. The Company accounts for income taxes in accordance with ASC 740, *Income Taxes*, which requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	December 31,	
	2024	2023
Tax at federal statutory rate	21.0 %	21.0 %
State taxes, net of federal benefit	6.4 %	4.5 %
Research and development tax credit	5.1 %	1.8 %
Stock-based compensation	5.5 %	(0.8)%
Nondeductible interest expense	(2.0)%	(0.5)%
FIN 48 reserve	(1.2)%	(0.3)%
Change in valuation allowance	(21.8)%	(23.3)%
Federal net operating loss expiration	(10.2)%	— %
Other	(2.8)%	(2.4)%
Total	— %	— %

The tax effects of temporary differences that give rise to significant components of the deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 42,043	$ 41,864
Research and development credits	14,903	13,069
Research and development expenditures, capitalized for tax	12,283	8,271
Fixed assets and inventory	28	151
Accruals and reserves	1,399	1,633
Interest expense carryforward	5,747	5,033
Operating lease liability	3,515	3,958
Other	1,281	1,718
Gross deferred tax assets	81,199	75,697
Deferred tax liabilities:		
Operating lease right-of-use asset	(3,014)	(3,436)
Total deferred tax liabilities	(3,014)	(3,436)
Valuation allowance	(78,185)	(72,261)
Net deferred tax assets	$ —	$ —

Beginning January 1, 2022, the Tax Cuts and Jobs Act, or the Tax Act, eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. As a result of this provision of the Tax Act, deferred tax assets related to capitalized research expenses increased by $12.3 million.

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes, as well as for tax attribute carryforwards. We regularly evaluate the

positive and negative evidence in determining the realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance and reported cumulative net losses since inception, we maintained a full valuation allowance on the net deferred tax assets as of December 31, 2024 and 2023. We intend to maintain a full valuation allowance on our deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. The valuation allowance increased by $5.9 million during the year ended December 31, 2024 primarily resulting from $5.5 million increase in gross deferred tax assets net of a $0.4 million decrease in deferred tax liabilities. The valuation allowance increased by $7.5 million during the year ended December 31, 2023 primarily resulting from $7.0 million increase in gross deferred tax assets net of a $0.5 million decrease in deferred tax liabilities.

As of December 31, 2024, the Company had net operating loss, or NOL, carryforwards of $152.5 million and $162.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal and state NOL carryforwards begin expiring in 2026 and 2029, respectively. As of December 31, 2024, the amount of federal NOL carryforwards that does not expire is $114.0 million (subject to certain utilization limitations).

As of December 31, 2024, the Company had research and development credit carryforwards of $5.4 million and $14.2 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin expiring in 2037 and the state credits carryforward indefinitely.

Utilization of the Company's NOL and tax credit carryforwards may be subject to a substantial annual limitation due to the ownership change provisions included in the Internal Revenue Code, or Section 382, and similar state provisions. An annual limitation may result in the expiration of NOL and credit carryforwards before utilization. The Company conducted Section 382 studies as of 2016, 2021, and 2024, and has determined that it experienced Section 382 ownership changes in 2016 and in 2021, and no change in 2024. The 2016 ownership change resulted in permanent limitations of its NOL and credit carryforwards. The 2021 ownership change did not result in permanent limitations of its NOL or credit carryforwards. It has been determined that $226.8 million and $150.7 million of federal and state NOL carryforwards, respectively, have been permanently limited and will expire unutilized. It has also been determined that $10.4 million of federal research and development credits have been permanently limited and will expire unutilized. The gross deferred tax assets disclosed above exclude NOL and credit carryforwards that are expected to expire due to the Section 382 limitation.

The American Rescue Plan Act of 2021 was signed into law on March 11, 2021 expanding the definition of covered employees as defined under Section 162(m). The provisions under the expanded definition of covered employees did not have a material impact on the Company's tax positions for the year ended December 31, 2023 or 2024.

California Assembly Bill 85 (AB 85) was signed into law by Governor Gavin Newsom on June 29, 2020. The legislation suspends the California NOL deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation on certain California tax credits for 2020, 2021, and 2022. The legislation disallows the use of California NOL deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1,000,000. The carryover periods for NOL deductions disallowed by this provision will be extended. Additionally, any business credit will only offset a maximum of $5,000,000 of California tax. Given the Company's taxable loss position, this legislation did not impact the tax provision for the years ended December 31, 2023 or 2024.

California Senate Bill 113 (SB 113), was signed into law by Governor Newsom on February 9, 2022. The legislation contains important California tax law changes, including reinstatement of business tax credits and net NOL deductions limited by AB 85 mentioned above. The new tax law should be accounted for under ASC 740 in the period of enactment (2022) but is not expected to have a material impact on the Company's tax provision due to its taxable loss position.

On August 16, 2022, the President signed into law H.R. 5376, or the Inflation Reduction Act of 2022. The primary tax provisions in the new law include an alternative minimum tax on certain large corporations, a tax on stock buybacks and certain energy-related tax credits, each of which become effective after December 31, 2022. The

provisions of the Inflation Reduction Act of 2022 does not have a material impact on the Company's financial statements and related disclosures.

As of December 31, 2024, the Company had unrecognized tax benefits of $2.1 million related to $5.4 million and $14.2 million of federal and state research and development tax credit carryforwards, respectively. The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate, due to the valuation allowance. It is unlikely that the amount of unrecognized tax benefits will significantly change over the next twelve months. No liability related to uncertain tax positions is recorded in the financial statements.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance	$ 1,730	$ 1,601
Increase in balance related to tax positions taken during the current year	355	136
Decrease in balance related to tax positions taken during prior years	—	(7)
Ending balance	$ 2,085	$ 1,730

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. The Company determined that no accrual for interest and penalties related to unrecognized tax benefits was required as of December 31, 2024 and December 31, 2023.

All of the Company's tax years will remain open for examination by the federal and state authorities for 3 and 4 years, respectively, from the date of utilization of its tax attributes.

10. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except for share and per share amounts):

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (27,141)	$ (32,956)
Denominator:		
Weighted-average common stock outstanding used to compute basic and diluted net loss per share	29,126,314	25,851,813
Net loss per share attributable to common stockholders, basic and diluted	$ (0.93)	$ (1.27)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	December 31,	
	2024	2023
Options to purchase common stock	2,368,208	2,588,765
Unvested restricted stock units	1,480,338	2,430,803
Shares committed under ESPP	68,138	81,102
Unvested early exercised common stock options	—	30,211
Total Shares	3,916,684	5,130,881

11. Segment Information

The Company operates as one operating and reportable segment. All of the Company's long-lived assets, comprised of property and equipment, are based in the United States. All of the Company's revenue, with the exception of $0.2 million and less than $0.1 million, was in the United States for the years ended December 31, 2024 and 2023, respectively, based on the shipping location of the external customer.

The Company's CODM is our Chief Executive Officer. Our CODM makes decisions on resource allocation, evaluates operating performance, and monitors budget versus actual results using net loss. In addition to the significant expense categories included within net loss presented on the Company's Statements of Operations and Comprehensive Loss, disaggregated amounts that comprise selling, general and administrative expenses are as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Sales and marketing expense	$ 39,669	$ 35,487
General and administrative expense	17,434	19,031
Total selling, general and administrative expense	$ 57,103	$ 54,518

Other segment items within net loss include interest income, interest expense, and other income (expense), net.

12. Subsequent Events

In February 2025, the Company completed a follow-on offering of 7,475,000 shares of the Company's common stock, including 975,000 shares from the exercise of the underwriters' option to purchase additional shares, at an offering price of $10.00 per share. The aggregate net proceeds to the Company from the follow-on offering were approximately $69.8 million after deducting underwriting discounts and commissions and estimated offering expenses. The Company used $49.5 million of the net proceeds to repurchase all of the 5,270,845 shares held by our significant stockholder, KCK Ltd., at $9.40 per share. The repurchased shares became authorized but unissued shares.

In February 2025, the Company terminated its Sales Agreement with Leerink and closed the ATM program. On the date of termination, the Company had $38.3 million remaining under the ATM program.

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as amended) as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). The rules define internal control over financial reporting as a process designed by, or under the supervision of, the Company's Chief Executive Officer and Chief Financial Officer, 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Attestation Report of the Registered Public Accounting Firm.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Arrangement

During the quarter ended December 31, 2024, none of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this report because we will file with the SEC a definitive proxy statement pursuant to Regulation 14A, or the 2025 Proxy Statement, no later than 120 days after the end of our fiscal year, and certain information included therein is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1: Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Information Regarding Executive Officers" and "Delinquent Section 16(a) Reports," if applicable, in our 2025 Proxy Statement.

Information regarding our Code of Business Conduct and Ethics, or the Code of Conduct, required by this item will be contained in our 2025 Proxy Statement under the caption "Information Regarding the Board of Directors and Corporate Governance – Code of Ethics," and is hereby incorporated by reference. If we make any substantive amendments to the Code of Conduct or grants any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. The full text of our Code of Conduct is available on our website at https://investors.neuropace.com/corporate-governance. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the section titled "Executive Compensation" and "Director Compensation" in our 2025 Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Equity Compensation Plans at December 31, 2021" and "Security Ownership of Certain Beneficial Owners and Management" in our 2025 Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Transactions with Related Persons and Indemnification" and "Information Regarding the Board of Directors and Corporate Governance–Independence of the Board of Directors" in our 2025 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

Information regarding accounting fees and services required by this item will be contained in our 2025 Proxy Statement in Proposal 2 under the captions "–Principal Accountant Fees and Services" and "–Pre-Approval Policies and Procedures" and is hereby incorporated by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

(1) FINANCIAL STATEMENTS

Our financial statements are listed in the "Index to the Financial Statements" under Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES

All schedules to the financial statements are omitted because they are not applicable, not material or the required information is shown in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(3) EXHIBITS

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this Annual Report on Form 10-K, in each case as indicated therein.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.	8-K	001-40377	3.1	April 26, 2021	
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-254663	3.4	April 14, 2021	
4.1	Form of common stock certificate of the Registrant.	S-1/A	333-254663	4.1	April 14, 2021	
4.2	Description of securities	10-K	001-40377	4.2	March 2, 2023	
10.1+	2020 Stock Plan.	S-1	333-254663	10.4	March 24, 2021	
10.2+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2020 Stock Plan.	S-1	333-254663	10.5	March 24, 2021	
10.3+	2021 Equity Incentive Plan.	S-1/A	333-254663	10.6	April 14, 2021	
10.4+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under 2021 Equity Incentive Plan.	S-1/A	333-254663	10.7	April 14, 2021	
10.5+	Forms of Restricted Stock Unit Grant Notice and Award Agreement (RSU Award) under 2021 Equity Incentive Plan					X
10.6+	2021 Employee Stock Purchase Plan.	S-1/A	333-254663	10.8	April 14, 2021	
10.7+	2023 Inducement Plan, Form of Stock Option Grant Notice, and Form of Stock Option Agreement	8-K	001-40377	10.1	July 19, 2023	
10.8+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1/A	333-254663	10.9	April 14, 2021	
10.9+	Offer Letter dated June 27, 2023, by and between NeuroPace and Joel Becker	8-K	001-40377	10.2	June 28, 2023	
10.10+	Amended and Restated Offer Letter, dated March 24, 2021, by and between the Company and Rebecca Kuhn.	S-1	333-254663	10.12	March 24, 2021	
10.11+	Amended and Restated Offer Letter, dated March 24, 2021, by and between the Company and Martha Morell, M.D.	S-1	333-254663	10.13	March 24, 2021	
10.12+	Transition and Separation Agreement, dated February 7, 2024 by and between the Company and Irina Ridley.	10-K	001-40337	10.12	March 5, 2024	

10.13	Term Loan Agreement, dated September 24, 2020, by among the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG Servicing LLC.	S-1	333-254663	10.17	March 24, 2021	
10.14	First Amendment to Term Loan Agreement, dated September 24, 2020, by among the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG Servicing LLC	10-Q	001-40337	10.1	May 12, 2022	
10.15	Second Amendment to Term Loan Agreement, dated February 28, 2023, by among the Company, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and CRG	10-Q	001-40337	10.1	May 4, 2023	
10.16**	Supply Agreement, dated November 16, 2022, by and between the Company and Micro Systems Technologies, Inc.	10-K	001-40337	10.16	March 5, 2024	
10.17**	Amendment 1 to Supply Agreement, dated November 16, 2022, by and between the Company and Micro Systems Technologies, Inc.	10-Q	001-40337	10.2	May 4, 2023	
10.18**	Supply Agreement, dated January 1, 2021, by and between the Company and Greatbatch Ltd.	S-1/A	333-254663	10.19	April 14, 2021	
10.19**	First Amendment to Supply Agreement, dated January 1, 2021, by and between the Company and Greatbatch Ltd.	10-K	001-40337	10.19	March 5, 2024	
10.20**	Second Amendment to Supply Agreement, dated January 1, 2021, by and between the Company and Greatbatch Ltd.	10-K	001-40337	10.20	March 5, 2024	
10.21+	Non-Employee Director Compensation Policy, as amended as of October 30, 2024.					X
10.22	Office Lease, dated August 24, 2011, by and between the Company and BXP Research Park LP (f/k/a BP MV Research Park LLC).	S-1/A	333-254663	10.21	April 14, 2021	
10.23	First Amendment to Office Lease, dated May 24, 2018, by and between the Company and BXP Research Park LP (f/k/a BP MV Research Park LLC).	S-1/A	333-254663	10.22	April 14, 2021	

10.24	Lease Modification Agreement, dated April 30, 2020, by and between the Company and BXP Research Park LP (f/k/a BP MV Research Park LLC).	S-1/A	333-254663	10.23	April 14, 2021	
10.25	Second Amendment to Office Lease, dated August 22, 2022, by and between the Company and BXP Research Park LP (f/k/a BP MV Research Park LLC).	10-Q	001-40337	10.2	November 8, 2022	
10.26+	Officer Severance Benefit Plan.	S-1/A	333-254663	10.24	April 14, 2021	
10.27+	Employee Cash Incentive Plan.	S-1/A	333-254663	10.25	April 14, 2021	
10.28	Amended and Restated Investors' Rights Agreement, dated August 19, 2020, by and among the Registrant and the investors listed on Exhibit A thereto.	S-1/A	333-254663	10.1	April 14, 2021	
10.29**	Exclusive Distribution Agreement, dated August 9, 2022, by and between the Company and DIXI Medical USA Corp.	10-Q	001-40337	10.3	November 8, 2022	
10.30	Sales Agreement, dated November 8, 2022, among the registrant and SVB Securities LLC	S-3	333-268243	1.2	November 8, 2022	
19.1	Insider Trading Policy					X
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.					X
24.1	Power of Attorney (included on signature page hereto).					X
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Principal Executive Officer and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
97+	Incentive Compensation Recoupment Policy.	10-K	001-40337	97	March 5, 2024	
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its SBRL tags are embedded within the Inline XBRL document.					X

101.SCH	XBRL Taxonomy Extension Schema with Embedded Linkbase Document.	X
104	Cover Page formatted as inline XBRL and contained in Exhibits 101	X

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\+ Indicates management contract or compensatory plan.

* The certifications attached as Exhibit 32.1 and 32.2 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, irrespective of any general incorporation language contained in any such filing.

** Portions of this exhibit (indicated by [*]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential.

Item 16. Form 10–K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on March 4, 2025.

NEUROPACE, INC.

By: /s/ Joel Becker
Joel Becker
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Rebecca Kuhn
Rebecca Kuhn
Chief Financial Officer and Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Joel Becker and Rebecca Kuhn, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K 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/ Joel Becker Joel Becker	Director, President and Chief Executive Officer (Principal Executive Officer)	March 4, 2025
/s/ Rebecca Kuhn Rebecca Kuhn	Chief Financial Officer and Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 4, 2025
/s/ Frank Fischer Frank Fischer	Director	March 4, 2025
/s/ Lisa Andrade Lisa Andrade	Director	March 4, 2025
/s/ Uri Geiger Uri Geiger	Director	March 4, 2025
/s/ Scott Huennekens Scott Huennekens	Director	March 4, 2025
/s/ Rakhi Kumar Rakhi Kumar	Director	March 4, 2025
/s/ Joseph S. Lacob Joseph S. Lacob	Director	March 4, 2025
/s/ Renee Ryan Renee Ryan	Director	March 4, 2025

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EXECUTIVE OFFICERS

Joel D. Becker
President, Chief Executive Officer and Director

Martha Morrell, M.D.
Chief Medical Officer

Rebecca Kuhn
Chief Financial Officer and Vice President, Finance and Administration

BOARD OF DIRECTORS

Lisa Andrade
Chief Executive Officer
M33, LLC

Joel D. Becker
President and Chief Executive Officer
NeuroPace, Inc.

Frank Fischer
Chairman of the Board and former Chief Executive Officer
NeuroPace, Inc.

Uri Geiger
Co-founder and Managing Partner
Accelmed Partners

R. Scott Huennekens
Chairman of the board of directors of Envista Holdings Corp. and Chairman of the board of directors of Hyperfine, Inc

Rakhi Kumar
Former Chief Accounting Officer
Roivant Sciences Ltd.

Joseph S. Lacob
Governor, Co-Executive Chairman, and Chief Executive Officer
Golden State Warriors

Renee Ryan
Founder and Chief Executive Officer
PinPrint, Inc

LISTING

Our common stock is listed on Nasdaq under the ticker symbols “NPCE.”

TRANSFER AGENT AND REGISTRAR

Broadridge Shareholder Services
c/o Broadridge Corporate Issuer Solutions, Inc.
1155 Long Island Avenue
Edgewood, NY 11717
www.shareholder.broadridge.com
shareholder@broadridge.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP

LEGAL COUNSEL

Cooley LLP

ANNUAL MEETING

June 6, 2025, at 10:30 a.m. Pacific time
Virtual Meeting Only:
www.virtualshareholdermeeting.com/NPCE2025

FORM 10-K

A copy of our Form 10-K filed with the Securities and Exchange Commission (SEC) will be made available to all stockholders at no charge.

The Form 10-K also can be accessed through the SEC website at www.sec.gov, or through our investor website at https://investors.neuropace.com/financial-information/sec-filings.

To receive a copy by mail please contact:

Investor Relations
c/o Office of the CFO
NeuroPace, Inc.
455 N. Bernardo Ave.
Mountain View, CA 94043